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Tony Evers, Governor
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PHARMACY EXAMINING BOARD
Room N108, 4822 Madison Yards Way, 1st Floor, Madison
Contact: Debra Sybell (608) 266-2112
January 3, 2020

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions of the Board.

AGENDA

8:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-2)

B. Approval of Minutes
1) December 17, 2019 **(3-6)**

C. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Board Members – Term Expiration Dates

D. Administrative Rules Matters – Discussion and Consideration
1) Phar 7: CR 19-145, Relating to the Practice of Pharmacy **(7-159)**
   a. Review and Respond to Clearinghouse Report and Public Hearing Comments
2) Pending and Possible Rulemaking Projects

E. Discussion and Consideration on Items Added After Preparation of Agenda
1) Administrative Rule Matters

F. Public Comments

ADJOURNMENT

NEXT MEETING: JANUARY 30, 2020

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by

the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

PHARMACY EXAMINING BOARD
MEETING MINUTES
DECEMBER 17, 2019

PRESENT: Franklin LaDien, Anthony Peterangelo *(arrived at 8:41 a.m.)*, Philip Trapskin, Shana Weiss *(joined via Skype at 8:55 a.m., excused at 4:57 p.m.)*, Michael Walsh, John Weitekamp, Cathy Winters

STAFF: Debra Sybell, Executive Director; Jameson Whitney, Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Megan Glaeser, Bureau Assistant; Kimberly Wood, Program Assistant Supervisor-Adv; and other Department staff

CALL TO ORDER

Philip Trapskin, Chairperson, called the meeting to order at 8:32 a.m. A quorum was confirmed with five (5) board members present.

ADOPTION OF AGENDA

MOTION: Cathy Winters moved, seconded by John Weitekamp, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES

MOTION: Franklin LaDien moved, seconded by Cathy Winters, to adopt the Minutes of October 23, 2019, October 28, 2019 and November 15, 2019 as published. Motion carried unanimously.

CLOSED SESSION

MOTION: Cathy Winters moved, seconded by Franklin LaDien, to convene to Closed Session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). Philip Trapskin, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Franklin LaDien-yes; Anthony Peterangelo-yes; Philip Trapskin-yes; Michael Walsh-yes; John Weitekamp-yes; and Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 1:10 p.m.

(Shana Weiss was disconnected from the meeting for this vote.)

DELIBERATION ON DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Administrative Warnings

MOTION: Franklin LaDien moved, seconded by Cathy Winters, to issue an Administrative Warning in the matter of the following cases:

1. 17 PHM 135 – G.W.H.
2. 17 PHM 153 – P.D.F.
3. 17 PHM 172 – I.A.

Motion carried unanimously.

Proposed Stipulation, Final Decisions, and Orders

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings of the following cases:

1. 16 PHM 201 – Kevin Litten, R.Ph.
2. 17 PHM 068, 19 PHM 025, 19 PHM 054 – Shawnte L. Robinson, R.Ph.
3. 18 PHM 041 – Brenda L. Wellner, R.Ph.

Motion carried unanimously.

17 PHM 135 – Walgreens #10925

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Walgreens #10925, DLSC Case Number 17 PHM 135. Motion carried. Abstained: Franklin LaDien

Case Closings

MOTION: Cathy Winters moved, seconded by John Weitekamp, to close the following DLSC Cases for the reasons outlined below:

1. 17 PHM 068 – A.H.A.: No Violation & H.P.: Prosecutorial Discretion (P2)
2. 17 PHM 153 – C.P. – No Violation
3. 18 PHM 025 – B.D.K. – No Violation
4. 18 PHM 073 – A.W.F., K.C.N., W. – No Violation
5. 19 PHM 012 – M.W. – No Violation
6. 19 PHM 061 – N.C.P., N.P. – Prosecutorial Discretion (P1)

Motion carried unanimously.

Monitoring Matters

Robert Stevens, R.Ph. – Requesting Reduction in Testing Frequency, Reduction in AA/NA Attendance Frequency, and Additional Unsupervised Practice Hours

MOTION: Cathy Winters moved, seconded by Franklin LaDien, to deny the request of Robert Stevens, R.Ph. for additional unsupervised practice hours, and to grant the request for a reduction in AA/NA attendance frequency to once per week and a reduction in the frequency of drug screens to fourteen (14) per year plus one annual hair test while he is not working as a pharmacist. Upon providing proof of employment as a pharmacist, frequency shall be increased to no less than twenty-four (24) screens per year and one (1) annual hair test. **Reason for Denial**: Insufficient time in compliance with the Board Order (1/3/2017). Motion carried unanimously.

Robin Block, R.Ph. – Requesting Full Licensure

MOTION: John Weitekamp moved, seconded by Franklin LaDien, to grant the request of Robin Block, R.Ph. for full licensure. Motion carried unanimously.

RECONVENE TO OPEN SESSION

MOTION: Franklin LaDien moved, seconded by Cathy Winters, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 2:01 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Cathy Winters moved, seconded by Franklin LaDien, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

(Be advised that any recusals or abstentions reflected in the Closed Session motions stand for the purposes of the affirmation vote.)

PUBLIC HEARING: CR 19-145,
RELATING TO THE PRACTICE OF PHARMACY

Review and Respond to Clearinghouse Report and Public Hearing Comments

MOTION: Michael Walsh moved, seconded by Cathy Winters, to accept all Clearinghouse comments for Clearinghouse Rule CR 19-145, relating to the practice of pharmacy. Motion carried unanimously.

(Shana Weiss was excused at 4:57 p.m.)

ADJOURNMENT

MOTION: Franklin LaDien moved, seconded by Anthony Peterangelo, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 6:20 p.m.

The draft included in this packet includes revisions made at the December 17, 2019 meeting.

Enclosed are the written comments (submitted as written or written copy of verbal testimony). In addition, the following people testified (without submitting a copy of their testimony):

Phar 7.08

Thad Schumacher: Information. Counseling leads to better outcomes. All licensees should use professional judgement.

Peggy Breuer: Against proposed rule. Keep requirement for all prescriptions to have consultation.

Rick Conner: Information. All pharmacies, regardless of type, should consult.

Dharmesh Ghelani: Against. Keep requirement for all prescriptions to have consultation. Remove the requirement for the sign notifying patients of right to consultation.

Cathy Winters: Against. Does not like process. Would like a new scope for consulting issue.

The written comments are arranged based upon the citation referenced in the comment. Those referencing multiple citations are placed in order of the first the citation.

The following citations to the proposed rule received comments:

7.01
7.02 [includes sub. (1) and (2); subd. (3)(b)1.; sub. (4)]
7.03 [includes pars. (1) (b) and (d)
7.04 [includes subd. (3)(d)4.]
7.05 [Includes sub. (1); pars (2)(b) (k)]
7.07 [includes sub. (2)]
7.06
7.08
7.085 [includes sub. (4)]
7.09
7.10 [includes par. (2)(c)]
7.11
7.13 [includes par.(4)(c)]
7.14 [includes par. (1)(c), subds. (3)(b)3. and 7.]
7.31
7.42 [includes sub. (6)]
7.43 [includes subd. (5)(a)3.]
7.50
7.51 [includes sub. (7)]
7.52 [includes sub. (3)]
7.55

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal and recreate ch. Phar 7 relating to the practice of pharmacy.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 450.033, 450.035, 450.062, 450.09, 450.11, and 450.12, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (2), and 450.02 (3) (a) to (e), Stats.

Explanation of agency authority:

The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession. [s. 15.08 (5) (b), Stats.]

The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05. [s. 450.02, Stats.]

The board may promulgate rules:
(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
(b) Establishing security standards for pharmacies.
(c) Relating to the manufacture, distribution and dispensing of hypodermic syringes, needles and other objects used, intended for use or designed for use in injecting a drug.
(d) Necessary for the administration and enforcement of this chapter and ch. 961.
(e) Establishing minimum standards for the practice of pharmacy.
[ss. 450.02 (3) (a) to (e), Stats.]

Related statute or rule: Phar 6 and 8

Plain language analysis:

This rule repeals and recreates the chapter delineating the practice of pharmacy.

A prescription is required to have the date it is written, name and address of the prescriber (and if delegated that person's name), the drug's name, strength, formulation and quantity, whether there are any refills authorized, name of the patient and the prescriber's signature. A standing order is required to have all the same elements as a prescription with the exception of prescriber's signature and indicate that it is pursuant to a standing order. A pharmacist may dispense pursuant to an electronic prescription, if the prescription is sent to the patient's choice of pharmacy, contains the elements of a prescription and may be signed with the prescriber's electronic signature. Verbal prescriptions may be received and reduced to writing on paper or in a computer system. Any alterations to a prescription which changes the prescriber's original intent must be documented including the pharmacist who made the alteration and the prescriber who authorized the change.

A drug utilization review must be completed prior to dispensing a prescription drug. It includes checking the prescription for the following: known allergies, rational therapy, contraindications, reasonable dose, duration of use and route of administration, reasonable directions for use, potential or actual adverse drug reactions, drug interactions with food, beverages, other drugs or medical conditions, therapeutic duplication, reasonable utilization and optimum therapeutic outcomes and potential for abuse or misuse. If there is a concern with any of these items, the pharmacist will take steps to resolve the matter.

A prescription can be transferred either orally between two pharmacists or between two pharmacies by fax machine or electronically. New or refill prescriptions for non-controlled substances can be transferred by indicating the prescription is void at the original pharmacy and indicating the prescription is a transfer at the receiving pharmacy. Unless a real time shared computer is used between the pharmacies, the receiving pharmacy will record the name and address of the patient, name and address of the prescribing practitioner, name, strength, form and quantity of the drug product or device, date of the original prescription, the original prescription order number, original number of refills authorized, dates of previous dispensing, number of valid refills or quantity remaining, original pharmacy name and address and the names of the transferring and receiving pharmacists. Refill prescriptions for controlled substances can be transferred by the same procedures as a non-controlled with the addition of recording the drug enforcement administration (DEA) registration numbers of the originating pharmacy and prescriber.

All prescription drugs and devices shall have a label. The label will identify the patient, symptom or purpose (if indicated on prescription), name and strength of drug, date the drug should not be used after, the name, address and telephone number of the pharmacy, prescriber name, date prescription filled, prescription number, quantity, number of refills or quantity remaining, and written or graphic product descriptions. A label may include the symptom or purpose if requested by the patient, both generic and brand names unless the prescriber requests the brand name be omitted, and any other cautions or provisions. A label is not required on complimentary drug or device samples dispensed in original packaging by a prescriber.

A pharmacist can repackage drugs into different containers for stocking purposes. When repackaging drugs into other containers, the pharmacist must ensure the process is done under

conditions which will not compromise the integrity of the drug, select containers which mitigate adulteration from light, temperature or humidity, and label the new container(s) with drug name, strength and form, pharmacy control or manufacturer lot number, national drug code (NDC) or if NDC is not available, the manufacturer or distributor name, and the beyond use date or expiration date. Records must include the drug name, strength and form, the quantity in each container and number of containers the drug was repackaged into, the NDC number (or if not available manufacturer or distributor), manufacturer lot number, the original container's expiration date and the beyond use date for the new containers, the name of the pharmacist or delegate that repackaged the drug, the name of the pharmacist that verified the accuracy of the repackaging and the date the repackaging was done.

All prescription drugs and devices must have a final check prior to dispensing. A final check includes checking that label requirements are met, it is the correct drug product or device, and a drug utilization review was completed. The check can be done by one or multiple pharmacists, with the prescription record reflecting which pharmacist was responsible for each part of the final check. If the label and product verification was done by automated technology or delegate check delegate, the prescription record will reflect the name of the pharmacist supervising the delegation.

A pharmacist must consult the patient or patient's agent for every new prescription which has not been dispensed previously to the patient or any change in the patient's therapy. Patient consultation includes the name and description of the drug, form, dose, route of administration and duration for drug therapy, intended use of the drug and expected action, special directions and precautions, common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid and action if they occur, techniques for self-monitoring drug therapy, proper storage and disposal and action to be taken in the event of a missed dose. A pharmacist may omit or vary the content of the consultation if it is in the best interest of the patient. The information must be transmitted orally unless it is the pharmacist's judgment it is not in the best interest of the patient. In addition, the information contained in the consultation must be given to the patient or patient's agent in writing and the patient or patient's agent advised by what method the pharmacist may be contacted for consultation. Consultation is available upon patient request and a pharmacist shall use professional judgment in determining whether to do a consultation on a prescription refill. A consultation is not required when a health care provider is administering the medication or if a patient or patient's agent refuses consultation. Every pharmacy shall post a sign stating a patient's right to consultation and information on how to file a complaint for failure to consult and a copy of the sign shall accompany all delivered prescriptions by common carrier or delivery service.

Delivery of prescription drugs by common carrier or delivery services shall ensure environmental controls are in place to prevent drug adulteration. The delivery method provides for verification of receipt of all controlled substances. The patient must be provided with a method to report any irregularities in the delivery including timeliness, condition of the drug and failure to receive the correct drug or device. Any drug compromised by delivery shall be replaced at no additional cost to the patient by next day delivery or the pharmacist will contact the prescriber to arrange for a 7 day supply of the prescription drug product to be dispensed by a pharmacy of the patient's choice.

A pharmacy shall get prescription drugs from a drug wholesaler licensed by the board or U.S. Food and Drug Administration or from another licensed pharmacy or practitioner located in the United States. A pharmacy must have a system for identifying any drugs or devices subject to a recall and to take appropriate action as required in a recall notice. A drug or device can't be dispensed after its expiration or beyond use date. All outdated drugs or devices must be removed from dispensing stock and quarantined until properly disposed.

The only health care items that may be returned to a pharmacy are health care items dispensed in error, defective, adulterated or misbranded, when in the pharmacist's professional judgment substantial harm could result to the public or patient if they were to remain in the possession of the patient, patient's family or others, or a health item is prepackaged for consumer use without a prescription when returned in compliance with state or federal laws. Only returned health items that are prepackaged for consumer use may be sold, resold or dispensed. It is not considered a return if the health care item is returned to the pharmacy for purposes of packaging, relabeling and returned to the same patient. This rule does not prohibit participation in a drug repository program in accordance with ch. DHS 148.

Pharmacy records are to be kept for a minimum of five years. A computerized system may be used if it is capable of producing a printout of the data contained in it and there is another procedure during periods of time the computer is not working. Prescription records are to be kept for 5 years after the date of the last refill. A paper prescription for non-controlled substances can be scanned and stored electronically (and at that point becomes an electronic prescription). A medication profile record system must contain the patient's name, address, date of birth, name of drug product or device dispensed, strength and form of the drug product or device dispensed, quantity dispensed and remaining, number of refills prescribed, directions for use, prescription order number, original date of issue, date of dispensing and the prescriber's name. A pharmacist will be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy. Medication profile records are to be kept for 5 years following the date of the last dispensing.

Any delegation by a physician to a pharmacist shall be documented by the pharmacist. The delegated act may not begin until it is documented. The documentation shall be maintained for a minimum of 5 years after the last delegated act under the delegation. A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has completed a course of study and training in administration techniques. A person who has successfully completed their second year and is enrolled in a school of pharmacy or a pharmacist licensed in another state who has applied for a Wisconsin pharmacist license may not administer a drug product or device unless they successfully complete a course of study and training in administration technique and administers the drug product or device only under the direct supervision of a pharmacist who has successfully completed the course of study.
The course of study must be from a course provider approved by the Accreditation Council for Pharmacy Education or the Board. The Board will evaluate programs using criteria substantially equivalent to the criteria used by the Accreditation Council or Pharmacy Education. After the pharmacist administers a prescribed drug product or device, the pharmacist or the pharmacist's

agent shall notify the prescribing practitioner or enter the information in a patient record system the pharmacist shares with the prescribing practitioner.

Delegate-check-delegate allows a person delegated by a supervising pharmacist to check the product verification of a product prepared by another person delegated by the pharmacist. In order for a person to be delegated product verification, the individual must meet all of the following: be 18 years of age; completed an accredited technician training program or has a minimum of 500 hours of experience in product selection labeling and packaging; completed a didactic and practical training curriculum; and completed a validation process.
The didactic and practical training curriculum must include elements of a package label; medication and pharmacy abbreviations needed to match ordered medication with dispensed medication; common dispensing medication errors and concepts; eligible medications; policies and procedures on reporting of medication errors; overview of the pharmacy's medication use process and a practical training designed to assess the competency of the individual. The validation process requires a check of 500 product verifications over at least 5 days with an accuracy rate of at least 99.8%. A product is eligible in institutional pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In an institutional pharmacy the medication is required to be administered by a health care provider or a person authorized to administer drugs at the institution. Product verifications can be done by delegates in community pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In a community pharmacy the medication is required to include a description of the medication on the prescription label that allows for a patient to check the accuracy of the medication. Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, documentation of supervising and managing pharmacist responsibilities and dates of supervision responsibilities.

A pharmacy may use a central shared services pharmacy acting as its agent. The central shared services pharmacy must be owned by the same owner as the originating pharmacy or have a written contact with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy to be in compliance with state and federal law. The central shared services pharmacy must keep a record of all originating pharmacies it serves including name, address and DEA number. The originating and central shared services pharmacies shall maintain a written protocol outlining each pharmacy's assumption of responsibility for compliance with state and federal law. If the central shared services pharmacy and originating pharmacy share a computer system, the central shared services pharmacy may perform drug utilization review. The prescription label will have the name and address of the pharmacy which did the product verification. The date the prescription was dispensed will be the date the pharmacy filled the prescription order.

A prescription can be delivered to a secure delivery system. The system must be designed in a manner which only the patient or patient's agent is able to open the door or locker containing only the patient's prescription and designed in a manner which does not disclose protected health

information. It also has to maintain appropriate environmental controls to prevent drug adulteration. Using a delivery system does not create an exemption to the controlled substances photo identification requirement. The dispensing pharmacy is to maintain a log of all prescriptions delivered to the delivery system and inventory it at least weekly so that unclaimed prescriptions can be reviewed by a pharmacist. The managing pharmacist shall develop written policies and procedures.

Automated direct-to-patient dispensing systems (more generally described as vending machines) may be used in health care facilities, office or clinic of a practitioner, a county jail, rehabilitation facility, state prison, or county house of correction or a juvenile correctional facility, juvenile detention facility, residential care center, and a secured residential care center for children and youth. The automated direct-to-patient dispensing system shall be associated with a pharmacy (a prescriber may not dispense utilizing an automated direct-to-patient dispensing system, however, a prescriber may submit a prescription for dispensing by such a system). Stocking, inventory, and monitoring the machine shall be limited to a pharmacist or pharmacist delegate. Labeling and recordkeeping requirements are to be met. If the associated pharmacy is open, the pharmacist shall do drug utilization review and consultation. If the pharmacy is closed, the prescriber is responsible for the drug utilization review and consulting.

Remote dispensing may be done at health care facilities, office or clinic of a practitioner, a county jail, rehabilitation facility, state prison, or county house of correction or a juvenile correctional facility, juvenile detention facility, residential care center, and a secured residential care center for children and youth. A sign shall be posted indicating prescriptions may be filled at the location and the supervising pharmacy. Remote dispensing can't occur if the supervising pharmacy is closed. No prescribed drug or device may be dispensed in the absence of a patient and pharmacist's delegate to communicate with a pharmacist. The prescription label shall contain the name and address of the supervising pharmacy. The managing pharmacist shall have written policies and procedures, implement on-going quality assurance program, visit the remote dispensing location at least monthly to confirm delivery status of all drugs and to ensure compliance with federal and state laws and retain documentation of the visits for a minimum of 5 years. A pharmacist delegate who is remote dispensing must be 18 years of age or older, a high school graduate or equivalent and competed 1500 hours of work as a pharmacist delegate within 3 years prior to remote dispensing or completed an accredited technician training program.

Institutional pharmacies are pharmacies serving institutional facilities. Chart orders shall contain patient's name, patient's medical record number or date of birth, date of issuance, name, strength and form of the drug product or device prescribed, directions for use, practitioner's signature, and if done by a practitioner's delegate, the name of the delegate. All drug products and devices dispensed for administration by a health care provider at the institutional facility shall have a label that includes the drug name, strength and form, beyond use date or expiration date, NDC and lot number and any special storage conditions. The managing pharmacist shall make arrangements for access of drugs by health care staff when a pharmacist is not available to do the dispensing. In the absence of a pharmacist, drugs shall be stored in a manner that only authorized personnel may obtain access and is secure enough to deny access to unauthorized persons. Policies and procedures must be in place to mitigate and prevent theft and diversion. A health item can be returned to the institutional pharmacy if it has not left control of the health

care facility staff authorized to have access to prescription drug products. A returned health item may be dispensed at the institutional facility if the health item was never in the possession and control of the patient, it is in a tamper-evident package, it was not commingled with a different health item, is in the original container and the pharmacist determines the contents are not adulterated or misbranded.

Automated technology can be utilized for the product verification of a prescription if the machine is located within the pharmacy, utilizes barcodes or other machine-readable technology and the automated technology is validated for accuracy. Product verifications can be done by automated technology if it is contained in a final package from a manufacturer or if a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, strength, form, control or lot number and beyond use date.
The medication is required to be administered by a health care provider or a person authorized to administer drugs within an institution. Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, names of supervising pharmacist, managing and supervising pharmacist responsibilities, manufacturer's recommended maintenance and quality assurance measures, dates of all software upgrades, and documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

A person practicing pharmacy who has completed their second year of pharmacy school or is a pharmacist from another state applying for license in Wisconsin, can perform duties under direct supervision.

An unlicensed person performing tasks delegated to the person by a pharmacist is working under general supervision. A pharmacist must be available to the unlicensed person for consultation either in person or contact by telecommunication means. An unlicensed person may not provide the final verification for accuracy, validity, or completeness of a filled prescription or order unless the person is validated for delegate-check-delegate. An unlicensed person may not complete the drug utilization review, administer any prescribed drug products, devices or vaccines or provide patient specific counseling or consultation (general education is allowed). The managing pharmacist shall provide training to or verify competency of and unlicensed person in performing a delegated act. The managing pharmacist shall determine what acts may be delegated in the pharmacy. The managing pharmacist has a responsibility to notify all pharmacist practicing in the pharmacy of what acts may be delegated to specific unlicensed persons. A pharmacist may delegate to an unlicensed person any delegated act approved by the managing pharmacist.

Summary of, and comparison with, existing or proposed federal regulation:

Generally, the practice of pharmacy is under state jurisdiction.
There are federal regulations related to controlled substances and drug supply chain.
21 CFR 1306.25 governs the transfer of controlled substances prescriptions for refill purposes.
This proposed rule mirrors the federal requirements.

Title II of the Drug Quality and Security Act requires all health care providers who dispense or administer prescription drugs to patients to purchase their prescription drug products only from authorized trading partners licensed by or registered with the state or federal government.

Comparison with rules in adjacent states:

Illinois: Illinois has elements required to be on a prescription and labels. Transfers for the purpose of original fill or refill shall include name, address and original prescription number, and all prescription data. A prescription for a Schedule III-IV controlled substance must follow federal law. A drug being removed from the original manufacturer container and placed in a dispensing container for other than immediate dispensing to a patient must contain a label indicating the name and strength of the drug, manufacturer or distributor name, beyond use date, and lot number. Illinois requires consultation for a prescription to a new patient, new medication to existing patient and medication that changes dose, strength, route or directions. An offer to consult is required on all other prescriptions. Consult is not required if a patient refuses consult or if a health care provider is administering the drug. There are designated required elements to be included in consultation. If oral counseling is not practicable, then alternative forms of patient information are provided and shall advise the patient that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free or collect telephone service. Every licensed pharmacy must post a sign with patient's rights to a consultation and information on how to file a complaint for failure to consult. Pharmacies without a physical location directly serving patients must include a copy of the sign with any dispensed prescriptions. A mail order pharmacy is required to provide a toll-free telephone service available not less than 6 days per week for a minimum of 40 hours per week. Once a drug is removed from the premises by a patient or the patient's agent, that drug shall not be accepted for return or exchange by a pharmacy or pharmacist. Drugs can be returned for destruction; the wrong medication was dispensed or drug recall. Pharmacy and prescription records are to be maintained for 5 years. Pharmacies providing centralized prescription filling shall share a common electronic file to allow access to sufficient information necessary to fill or refill a prescription order. Appropriate records shall be maintained to identify a responsible pharmacist in the dispensing process and to track the prescription drug order during each step in the process. A delivery system must be secured against a wall or floor, provide a method to identify the patient and deliver the prescription only to that patient or the patient's agent. The delivery system must have adequate security systems to prevent unauthorized access, maintain patient confidentiality and record the time and date the patient removed the prescription from the delivery system. A remote dispensing site is under the supervision of a pharmacy. All records must be maintained at the home pharmacy. Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy. A pharmacist at the home pharmacy must verify each prescription before it leaves the remote site. Counseling must be done by a pharmacist via video link and audio link before the drug or device is released. A pharmacist must make monthly inspections of the remote site. There shall be a working computer link, video link and audio link working at all times between the remote site and the home pharmacy unless a pharmacist is present at the remote site. The sign must clearly identify it as a remote dispensing site. Remote consulting sites can't have any prescription inventory-only filled prescriptions by the home pharmacy. Institutional labels for administration shall include drug name, strength, beyond use date and reference code to identify source and lot number. An after-hour cabinet

shall contain a minimal supply of the most frequently required medication and shall only be used in the absence of a pharmacist. Only personnel specifically authorized by the institution may obtain access and it is sufficiently secure to deny access to unauthorized persons. In an institutional health care facility where a licensed healthcare professional administers the drug, a drug may be returned if the drug is not contaminated, deteriorated or beyond the use date, returns are properly documented and obtaining payment twice for the same drug is prohibited. Illinois does not allow for delegation to unlicensed persons. Illinois certifies technicians.

Iowa: In Iowa, the original prescription shall be retained in the original format. Each prescription shall have specified elements. Dispensing documentation shall include the date of fill; the name, strength, NDC of the drug; and the initials of the pharmacist, pharmacist-intern, or technician in an approved tech-check-tech program. The pharmacy shall ensure that the prescription drug or medication order has been issued for a legitimate medical purpose by a prescriber. The pharmacist shall do a prospective drug use review to promote therapeutic appropriateness and rational drug therapy. If there are any problems, the pharmacist shall take appropriate steps to resolve. When transferring a prescription, both the transferring and receiving pharmacies shall maintain records of the prescription drug order information. Non-controlled substances prescriptions are permissible to be transferred as long as the number of transfers does not exceed the number of authorized refills and the prescription is still valid. Transfer of Schedule III – IV prescriptions are permissible on a one-time basis except as provided by federal law. The prescription label shall include prescription number, name, telephone number and address of the pharmacy, name of the prescriber, date dispensed, directions for use and unless directed by the prescriber, the name, strength and quantity of the drug dispensed. Iowa requires a consultation for new prescriptions and change in drug therapy. Consultation is not required when other licensed health care professionals are authorized to administer drugs or if the patient refuses consultation. There are discretionary elements to the consultation. An offer to counsel shall not fulfill the requirements of the rule. If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may use alternative forms of patient information. "Not practicable" refers to the patient variables and does not include pharmacy variables. Nonresident pharmacies shall ensure that Iowa patients receive appropriate counseling pursuant to the Iowa rule. Prescriptions may be delivered by common carrier or delivery service to the patient at the office or home of the prescriber, at the residence of the patient or caregiver, at the hospital or medical care facility, an outpatient medical care facility or place of employment. Prescriptions may be delivered to the place of employment only if the pharmacy has the patient's written authorization, the prescription is delivered directly to or received directly from the patient or agent and the pharmacy ensures the security of confidential information. Pharmacies shipping or delivering drugs shall ensure accountability, safe delivery, and compliance with temperature requirements. There shall be a patient record system. Records shall be stored for 2 years. Iowa allows automated technology to conduct the product verification if the system utilizes barcode scanning technology and the product is prestocked and no manipulation of drug or package other than affixing a patient label is taking place. If the product is going to require further manipulation than a pharmacist is required to do the product verification prior to dispensing to a patient. Iowa allows technician-check-technician. The technician must have active Iowa registration, hold national technician certification, have experience as a technician and be trained in technician-check-technician (including medication errors). There shall be a supervising pharmacist. The pharmacy is

required to have policies and procedures in place and maintain records. The drug utilization review must be performed by a pharmacist. The medication checked by a technician must be checked by a licensed health care practitioner prior to administration. When utilizing a central fill pharmacy, the originating pharmacy shall be responsible for all dispensing functions. A central fill pharmacy that shares a common central processing unit with the originating pharmacy may perform prospective drug use review. The label on the prescription shall indicate it was filled at a central fill pharmacy and have the name, address, and telephone number of the originating pharmacy. A hospital may implement the InstyMeds dispensing system in the hospital emergency department. Stocking, inventory and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns. It should be located in a secure location. The stock shall be limited to acute care drugs for a 72-hour supply except antimicrobials may be dispensed in a quantity to provide the full course of therapy. The prescriber shall provide the patient with consultation. The hospital pharmacist shall review the printout of drugs provided utilizing the InstyMeds dispensing system within 24 hours (or the first day the pharmacy is open) to identify any dispensing errors, to determine dosage appropriateness, and to complete a retrospective drug use review of any antimicrobials dispensed in a quantity greater than a 72-hour supply. Telepharmacy is allowed in Iowa. There shall be a written agreement between the managing pharmacy and telepharmacy site. In the event that a verifying pharmacist is not available or that the audiovisual communication connection between the telepharmacy site and the managing pharmacy is not available, the telepharmacy site shall close. The site shall inform the public it is a telepharmacy site. The telepharmacy site shall be secure. Patient counseling is required utilizing the audiovisual technology employed between the two sites. The label shall include the name, telephone number and address of the telepharmacy site and the name and telephone number of the managing pharmacy. A pharmacist shall monthly inspect the telepharmacy site. A technician working in a telepharmacy site shall have completed a minimum of 2,000 hours and completed training. In an institutional pharmacy, supplies for drugs for use in medical emergencies shall be immediately available pursuant to policies and procedures. All drug storage areas within the facility shall be routinely inspected to ensure that no outdated or unusable items are available for administration and all stock items are properly labeled and stored. Iowa does not allow for delegation to unlicensed persons. Iowa registers technicians.

Michigan: In Michigan, a prescription shall be legible and include the name of the patient, prescriber's name and address, drug name and strength, the quantity prescribed, directions for use, and number of refills authorized. The label shall include mandatory elements. A consultation is required for each prescription for a drug not previously prescribed for the patient or by request of the patient or agent for any prescription. Consultation is not required if the patient refuses or for prescriptions administered to a patient while the patient is in a medical institution. The elements of the consultation are to encourage intended, positive patient outcomes, necessary and appropriate information regarding safe and effective medication use at the time a prescription is dispensed. The consultation shall be communicated orally and in person, except when the patient or caregiver is not at the pharmacy or when a specific communication barrier prohibits oral communication. In either situation, providing printed material designed to help the patient use the medication safely and effectively satisfies the requirement. Prescription records shall be maintained for 5 years. Prescription drugs or devices which have been dispensed and have left the control of the pharmacist shall not be returned

except for pharmacies operated by the department of corrections or county jail, or a pharmacy that participates in the program for the utilization of unused prescription drugs. A pharmacy engaging in centralized prescription processing shall be responsible for each function of the prescription's processing performed by that pharmacy. A delivering pharmacist shall be responsible for complying with patient counseling. The prescription label for a prescription that was filled by a centralized processing center shall identify each pharmacy that was involved in preparing and delivering a prescription. Both pharmacies shall maintain records. An automated device may be used only in the following locations: pharmacy, hospital, county medical care facility, hospice, nursing home, other skilled nursing facility or office of a dispensing prescriber. The pharmacist or pharmacy personnel shall be responsible for the stocking of the automated device unless located in a dispensing prescriber's office (then it is the responsibility of the dispensing prescriber). A pharmacist shall review the prescription or medication order before removal of any medication from the system unless it being used as an after-hours cabinet or in place of an emergency kit. Michigan does not allow for delegation to unlicensed persons. Michigan credentials technicians.

Minnesota: In Minnesota, a pharmacist shall examine the patient's profile record and conduct a prospective drug review. Upon recognizing any drug-related problems, the pharmacist shall take appropriate steps to avoid or resolve the problem. A pharmacy may transfer prescription drug order information for the purpose of refilling a prescription if the information is communicated directly by a licensed pharmacist or registered intern to another licensed pharmacist or registered intern. A pharmacy may transfer prescription drug order information for the purpose of initial filing only for non-controlled substance. There are specific elements to a label. Pharmacies may prepackage and label drugs in convenient quantities for subsequent complete labeling and dispensing. Each prepackaged container shall bear a label providing the name of drug, strength, name of the manufacturer or distributor of the finished dosage form of the drug, a beyond use date, internal control number or date and a physical description including any identification code that may appear on tablets and capsules or a bar code based on the NDC. A consultation is required for new prescriptions. Consultation is not required for inpatients where other licensed health care professionals are authorized to administer the drugs or if the patient has expressed a desire not to receive a consultation. There are mandatory elements to the consultation; however, the pharmacist may vary or omit if in the pharmacist's professional judgment, it is in the best interest of the patient. The pharmacist shall document variations from the required consultation elements. The consultation discussion shall be in person and may be supplemented with written material. When a prescription for which counseling is required is being mailed or delivered to the patient by common carrier or delivery services, the consultation must still be provided but may be accomplished by providing the written information and the availability of the pharmacist to answer questions through the provision of a toll-free phone number. Pharmacies are prohibited from accepting returns of drugs or medical devices except from a hospital items which were dispensed for hospital inpatient use only. Drugs from nursing home and assisted living facilities can be returned and redispensed if the pharmacist can assure proper storage conditions for the drugs, the facility as 24-hour on-site licensed nursing coverage 7-days a week, the drugs are returned to the same pharmacy which dispensed the drugs, and the integrity of the packaging remains intact. A patient profile record system must be maintained in all pharmacies. Pharmacy records shall be kept not less than 2 years. A pharmacy may perform or outsource centralized prescription drug order filling or centralized prescription drug order processing services. The

parties must have the same owner or a written contract outlining the services to be provided. There shall be an agreement to how the parties will comply with federal and state laws. Both pharmacies are to maintain records. The pharmacy that delivers the completed prescription drug order to the patient is responsible for certifying the completed prescription drug order and is responsible for counseling the patient. Minnesota does not allow for delegation to unlicensed persons. Minnesota registers technicians.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board did a comprehensive review of the practice of pharmacy in order to update the rules to current standards and practices. In addition, the Pharmacy Examining Board reviewed the National Association of Boards of Pharmacy's model rules, the rules of the surrounding states as well as other states and considered stakeholder input.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule was posted for economic comments for 14 days. The Pharmacy Examining Board invited those who submitted economic comments to a board meeting to discuss economic concerns.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on December 17, 2019 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter 7 is repealed and recreated to read:

Chapter Phar 7
PHARMACY PRACTICE

Subchapter I — General

7.01 Definitions. In this chapter:
(1) "Managing pharmacist" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, and who is personally in full and actual charge of the pharmacy and personnel.
(2) "NDC" means national drug code.
(3) "Repackaging for stock" means transferring a non-sterile drug product from the stock container in which it was distributed by the original manufacturer and placing it into a different stock container as a source for subsequent prescription dispensing without further manipulation of the drug.
(4) "Standing order" means an order transmitted electronically or in writing by a practitioner for a drug or device for use by a pharmacy for multiple patients or for one or more groups of patients.

7.02 Prescription (1) REQUIREMENTS. A prescription drug order shall include all of the following:

(a) Date of issue.
(b) First and last name and address of the practitioner.
(c) Prescriptions ordered by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name and address of the practitioner.
(d) Name, strength, and quantity of the drug product or device.
(e) Directions for use of the drug product or device.
(f) Refills, if any.
(g) Symptom or purpose for which the drug is being prescribed if the patient indicates in writing to the practitioner that the patient wants the symptom or purpose for the prescription to be disclosed on the label.
(h) Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2)(a)1., 448.035 (2) and 448.037 (2) (a) 1., Stats.
(i) If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.
(j) If prescription is issued under s. 255.07 (2), the name and address of the authorized entity or individual.
(k) Practitioner's written signature, or electronic or digital signature.

(2) STANDING ORDER. (a) A prescription pursuant to a standing order shall include all of the following:

1. Date of issue.
2. First and last name and address of the practitioner.

3. Prescriptions ordered by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name and address of the practitioner.
4. Name, strength, form and quantity of the drug product or device.
5. Directions for use of the drug product or device.
6. Refills, if any.
7. Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2)(a)1., 448.035 (2) and 448.037 (2) (a) 1., Stats.
8. If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.
9. If prescription is issued under s. 255.07 (2), the name and address of the authorized entity or individual.
10. Indicate the prescription is pursuant to a standing order.

(b) A copy of the standing order shall be retained under s. Phar 7.11 (1).

(3) ELECTRONIC PRESCRIPTION. (a) Except as provided in s. 89.068 (1) (c) 4., Stats., and as otherwise prohibited by law, prescription orders may be accepted and dispensed if they have been transmitted electronically from a practitioner or his or her designated agent to a pharmacy via computer modem or other similar electronic device. Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

(b) A pharmacist may dispense a prescription pursuant to a prescription order transmitted electronically, if the pharmacist assures the prescription order meets all of the following:

1. Was sent only to the pharmacy of the patient's choice and only at the option of the patient, with no intervening person or third-party having access to the prescription order other than to forward it to the pharmacy.
2. Contains all other information that is required in a prescription order.

(c) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided with a prescription order electronically transmitted via computer modem or other similar electronic device.

(4) VERBAL PRESCRIPTION. Verbal prescription orders may be received at a pharmacy via a direct conversation, telephone answering device or voice mail. The verbal prescription shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

(5) ALTERATIONS. Any alterations that modify the original intent of a prescription shall be documented including the identification of the pharmacist responsible for the alteration and the practitioner or practitioner's delegate who authorized the alteration.

7.03 Drug utilization review. (1) A pharmacist shall complete a drug utilization review by reviewing the patient record prior to dispensing each prescription drug order for all of the following:

(a) Known allergies.
(b) Rational therapy.
(c) Contraindications.
(d) Reasonable dose, duration of use, and route of administration, considering the age, and other patient factors.
(e) Reasonable directions for use.

(f) Potential or actual adverse drug reactions.
(g) Drug interactions with food, beverages, other drugs or medical conditions.
(h) Therapeutic duplication.
(i) Reasonable utilization and optimum therapeutic outcomes.
(j) Potential abuse or misuse.

(2) Upon recognizing a concern with any of the items in sub. (1) (a) to (j), the pharmacist shall take steps to mitigate or resolve the problem.

7.04 Transferring prescription order information. (1) GENERAL REQUIREMENTS. (a) A transfer of prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing of non-controlled substances and refills of controlled substances, may occur if all of the following conditions are satisfied:

1. The transfer of prescription order information is communicated in one of the following ways:
   a. Verbal communication between two pharmacists.
   b. Electronically or by facsimile machine between the two pharmacies.
2. A transfer of prescription information verbally shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

(b) A pharmacist shall transfer a prescription upon patient request pursuant to this section.

(2) NON-CONTROLLED SUBSTANCES. The transfer of prescription order information for non-controlled substances for the purposes of original or refill dispensing is permissible pursuant to the following requirements:

(a) The prescription record of the transferred prescription shall include the following information:
1. The word “VOID" is written on the face of the invalidated prescription order or recorded in a similar manner to “VOID" on a prescription order in a computer system meeting the requirements of s. Phar 7.11 (2) (a).
2. The name and address of the pharmacy to which it was transferred, the date and the first and last name of the pharmacist transferring the information are recorded on the invalidated prescription order or in a computer system meeting the requirements s. Phar 7.11 (2) (a).

(b) Unless a computer system meeting the requirements in sub. (4) is used, the transferred prescription order information shall include the following:
1. The word “TRANSFER" on the face of the transferred prescription order or recorded in a similar manner in a computer system.
2. The first and last name and address of the patient, the first and last name and address of the prescribing practitioner.
3. Name, strength, form and quantity of the drug product or device prescribed and the directions for use.
4. The date of issuance of the original prescription order, the original prescription order number, the original number of refills authorized on the original prescription order and the date of original dispensing if the prescription order has previously been dispensed.

5. The number of valid refills or total quantity remaining and the date of the last refill.

6. The pharmacy's name and address from which the prescription order information was transferred.

7. The first and last name of the pharmacist transferring and receiving the prescription order information.

(3) CONTROLLED SUBSTANCES. The transfer of original prescription information for a controlled substance listed in Schedule III – IV shall meet the following requirements:

(a) The transfer of prescription order information is permissible only on a one-time basis. Pharmacies electronically sharing a computer system meeting the requirements of sub. (4) may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(b) The transfer shall be communicated directly between 2 licensed pharmacists.

(c) The transferring pharmacist shall do all of the following:

1. Write the word "VOID" on the face of the invalidated prescription. For electronic prescriptions, information that the prescription has been transferred shall be added to the prescription record.

2. Record on the reverse of the invalidated prescription or in the electronic prescription record all of the following:

a. Name, address and DEA registration number of the pharmacy to which it was transferred.

b. The first and last name of the pharmacist receiving the prescription order.

3. Record the date of the transfer.

4. Record the first and last name of the pharmacist transferring the information.

(d) For paper prescriptions and prescriptions received verbally and reduced to writing by the pharmacist, the pharmacist receiving the transferred prescription information shall write the word "TRANSFER" on the face of the transferred prescription and reduce to writing all information required to be on prescription, including all of the following:

1. Date of issuance of the original prescription order.

2. Original number of refills authorized on the original prescription order.

3. Date of original dispensing.

4. Number of valid refills remaining and the date and location of previous refills.

5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.

8. First and last name of the pharmacist making the transfer.

9. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

(e) For electronic prescriptions being transferred electronically, the transferring pharmacist shall provide the receiving pharmacist with the original electronic prescription data and all of the following:

1. The date of the original dispensing.

2. The number of refills remaining and the dates and locations of previous refills.

3. The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.

4. The first and last name of the pharmacist transferring the prescription.

5. The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.

(4) USE OF SHARED COMPUTER SYSTEM. A shared computer system used for transferring prescription order information shall, in addition to meeting the requirements of s. Phar 7.11 (2) (a), contain a shared real time electronic file database with complete prescription record filled and dispensed.

Phar 7.05 Label requirements. (1) This section does not apply to institutional pharmacies as defined in s. Phar 7.50 (2).

(2) All prescribed drugs or devices shall have a label attached to the container disclosing all of the following:

(a) Identification of the patient by one of the following:

1. Except as provided in subds. 2. to 5., the first and last name of the patient.
2. For an antimicrobial drug dispensed under s. 450.11 (1g), Stats., the first and last name of the patient, if known, or the words, "expedited partner therapy" or the letters "EPT".
3. For an opioid antagonist when delivered under s. 450.11 (1i), Stats., the first and last name of the person to whom the opioid antagonist is delivered.
4. For an epinephrine auto-injector prescribed under s. 118.2925 (3) or 255.07 (2), Stats., the name of the school, authorized entity, or other person specified under s. 255.07 (3), Stats.
5. If the patient is an animal, the last name of the owner, name of the animal and animal species.

(b) Symptom or purpose for which the drug is being prescribed if the prescription order specifies the symptom or purpose.

(c) Name and strength of the prescribed drug product or device dispensed, unless the prescribing practitioner requests omission of the name and strength of the drug product or device.

(d) The date for which the medication shall not be used after.

(e) Pharmacy name, address and telephone.

(f) Prescriber name.

(g) Date the prescription was filled.

(h) Prescription order number.

(i) Quantity.

(j) Number of refills or quantity remaining.

(k) Directions for use of the prescribed drug or device as contained in the prescription order.

(3) A label for prescribed drugs or devices may include the following:

(a) Symptom or purpose for which the drug is being prescribed if requested by the patient.

(b) Both the generic name of the drug product equivalent and the brand name specified in the prescription order may be listed on the label if the brand name is listed on the prescription and the drug product equivalent is dispensed, unless the prescribing practitioner requests that the brand name be omitted from the label.

(c) Written or graphic product descriptions.

(c) Any cautions or other provisions.

(4) Subsection (2) does not apply to complimentary samples of drug products or devices dispensed in original packaging by a practitioner to his or her patients.

Phar 7.06 Repackaging for stock. A pharmacy repackaging for stock any non-sterile drugs shall do all of the following:

(1) The repackaging for stock process is conducted under conditions that ensure the integrity of the drug.

(2) Products repackaged for stock shall include a beyond use date that ensures the integrity of the drug.

(3) The repackaged container shall be selected to mitigate adulteration from light, temperature and humidity.

(4) The repackaged for stock drugs are labeled physically or electronically with all the following components:

(a) Drug name, strength and form.

(b) Pharmacy control or manufacturer lot number.

(c) NDC number or the name of the manufacturer or distributor of the drug product.

(d) Beyond use date.

(5) Records of all repackaging for stock operations are maintained and include all the following:

(a) Name, strength, form, quantity per container, and quantity of containers.

(b) NDC number or the name of the manufacturer or distributor of the drug product.

(c) Manufacturer lot number.

(d) Original container's expiration date and the beyond-use date for the new containers.

(e) First and last name of the pharmacist or delegate that repackaged the drug and the first and last name of the pharmacist that verified the accuracy of the repackaging.

(f) Date of repackaging.

Phar 7.07 Final check. (1) A final check of accuracy and correctness is required for any prescription drug product or device dispensed and shall include all of the following:

(a) Verifying label is correct and meets labeling requirements.

(b) Verifying the drug product or device is correct.

(c) Completion of the drug utilization review.

(2) For all prescription drug product or device dispensing, the prescription record shall identify the pharmacist responsible for each part of the final check. If sub. (1) (a) or (b) is completed by delegate check delegate under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the delegate performing the check.

Phar 7.08 Patient consultation. (1) A pharmacist shall give the patient or patient's agent consultation relative to the prescription for any new drug product or device which has not been dispensed previously to the patient or any change in the patient's therapy. Patient consultation shall meet all of the following requirements:

(a) Contain all of the following information, unless in the pharmacist's professional judgment it serves the best interest of the patient to omit or vary the content of the consultation:

1. Name and description of the drug.
2. Form, dose, route of administration and duration for drug therapy.

3. Intended use of the drug and expected action.
4. Special directions and precautions for preparation, administration and use by the patient.
5. Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
6. Techniques for self-monitoring drug therapy.
7. Proper storage and appropriate disposal method of unwanted or unused medication.
8. Action to be taken in the event of a missed dose.

(b) Be communicated verbally unless in the pharmacist's professional judgment it is not in the best interest of the patient or patient's agent or not practicable.

(c) Provide written documentation of the information in par. (a) 1. to 8.

(d) Advise the patient or patient's agent the method which the pharmacist may be contacted for consultation.

(2) The consultation requirement is not satisfied by only offering to provide consultation.

(3) Every licensed pharmacy dispensing directly to patients at a physical location must conspicuously post a sign approved by the board stating a patient's rights to consultation and information on how to file a complaint to the Board for failure to consult. A copy of the sign must be included in any delivery by common carrier or delivery service.

(4) Consultation is required upon patient request.

(5) A pharmacist shall utilize professional judgement in determining whether to give the patient or patient's agent appropriate consultation relative to the prescription for any refill.

(6) Notwithstanding sub. (1), a consultation is not required when a health care provider is administering the medication or if a patient or patient's agent refuses consultation.

Phar 7.085 Delivery by common carrier or delivery services. Utilization of common carrier or delivery services to deliver a prescription from the pharmacy which fills the prescription to the patient or patient's agent shall ensure all of the following:

(1) The delivery method is appropriate to prevent drug adulteration.

(2) The delivery method provides for verification of receipt of all controlled substances.

(3) The patient or patient's agent is provided a method by which the patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the prescription drug product or device, including all of the following:

(a) Timeliness of delivery.

(b) Condition of the prescription drug upon delivery.

(c) Failure to receive the proper prescription drug product or device.

(4) Any prescription drug product or device which is compromised by delivery shall be replaced by the pharmacy. The pharmacy shall replace at no additional cost to the patient the prescription drug product or device by next-day delivery or the pharmacist shall contact the patient's practitioner to arrange for a prescription for a minimum 7 day supply of the prescription drug product to be dispensed to the patient by a pharmacy of the patient's choice.

Phar 7.09 Procurement, recall and out-of-date drugs and devices.

(1) Procurement of prescription drugs and devices shall be from a drug wholesaler licensed by the board or U.S. food and drug administration to distribute to pharmacies or from another licensed pharmacy or licensed practitioner located in the United States.
(2) A pharmacy shall have a system for identifying any drugs or devices subjected to a product recall and for taking appropriate actions as required by the recall notice.
(3) Any drug or device may not be dispensed after the drug's or device's expiration date or beyond use date. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed.

7.10 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug product, or items of personal hygiene.

(b) "Original container" means the container in which a health item was sold, distributed, or dispensed.

(c) "Tamper-evident package" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.

(2) No health item after taken from a pharmacy where sold, distributed or dispensed, may be returned to that pharmacy, except for any of the following:

(a) Where the health item was dispensed in error, was defective, adulterated, or misbranded.

(b) When in the professional judgment of the pharmacist substantial harm could result to the public or patient if it were to remain in the possession of the patient, patient's family or agent, or other person.

(c) A health item that is prepackaged for consumer use without a prescription when returned in compliance with all applicable state and federal laws.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

(3) A health item returned to a pharmacy pursuant to sub. (2) (a) and (b), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. A returned health item shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.
(4) It is not a return of a health care item if a patient or agent of a patient delivers a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device is for the same patient's use.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

(5) It is not a return of a health care item if a patient or agent of a patient delivers a previously dispensed drug or device to a pharmacy for the purpose of destruction at the pharmacy or other disposal by an authorized person or entity.
(6) This section does not prohibit participation in a drug repository program in accordance with ch. DHS 148.

Phar 7.11 Pharmacy records. (1) GENERAL. Pharmacy records shall be maintained for a minimum period of five years unless otherwise specified in state or federal law.

(2) PRESCRIPTION RECORDS. (a) A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of prescription order information for the purposes of original or refill dispensing if the system is:

1. Capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining.

2. Equipped with an auxiliary procedure which, during periods of down-time, shall be used for documentation of prescription dispensing. The auxiliary procedure shall ensure that prescription refills are authorized by the original prescription order, that the maximum number of prescription refills has not been exceeded and that all of the appropriate data are retained for on-line entry as soon as the computer system is again available for use.

(b) A record of all prescriptions dispensed shall be maintained for a minimum period of 5 years after the date of the last refill.

(c) All systems used for maintaining a record of any prescription dispensing shall contain all items required in the medical profile record system.

(d) A paper prescription for non-controlled substances may be scanned and stored electronically in the computer system under par. (a). For purposes of this chapter, the prescription becomes an electronic prescription.

(3) MEDICATION PROFILE RECORD SYSTEM. (a) An individual medication profile record system shall be maintained in all pharmacies for humans and non-humans for whom prescriptions, original or refill, are dispensed. The system shall be capable of permitting the retrieval of information.

(b) The following minimum information shall be retrievable:

1. Patient's first and last name, or if not human, name of pet, species and last name of owner.
2. Address of the patient.
3. Birth date of the patient or if not human birthdate of the owner.
4. Name of the drug product or device dispensed.
5. Strength of the drug product or device dispensed.
6. Form of the drug product or device dispensed.
7. Quantity of the drug product or device prescribed, dispensed and remaining.
8. Number of refills prescribed.
9. Directions for use.
10. Prescription order number.
11. Original date of issue.
12. Dates of dispensing.
13. Prescriber's first and last name.

(c) The pharmacist shall be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy as communicated by the patient or agent of the patient. If none, this should be indicated.

(d) Medication profile records shall be maintained for a minimum period of 5 years following the date of the last dispensing.

Phar 7.12 Delegation by a physician. The pharmacist shall document the delegation by a physician under 450.033, Stats. The delegated act may not be started prior to the documentation.

The documentation shall be maintained for a minimum of five years after the last delegated act under that delegation.

Phar 7.13 Administration of drug products and devices other than vaccines. (1) In this section, "course of study" means one or more classes, workshops, seminars, or continuing education programs.

(2) A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats. After the pharmacist administers a prescribed drug product or device, the pharmacist, a person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., or the pharmacist's agent shall notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner.

(3) A pharmacist may not administer by injection a prescribed drug product or device unless the pharmacist has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board.

(4) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g), Stats., may not administer a prescribed drug product or device unless the person satisfies all of the following:

(a) Successfully completes a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board.

(b) Administers the prescribed drug product or device only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council of Pharmacy Education or the board.

(c) After administering the prescribed drug product or device, notifies the prescribing practitioner or enters the information in a patient record system shared by the prescribing practitioner.

(5) The board may approve courses of study which meet criteria substantially equivalent to criteria used by the Accreditation Council for Pharmacy Education.

(6) A course of study and training in administration technique shall include all of the following topics:

(a) Safe injection practices to prevent infections.

(b) Anatomy.

(c) Proper injection techniques.

(d) The five rights of administration including right patient, right drug, right dose, right route, and right time.

(e) Patient reassessment after administration including signs and symptoms of adverse drug reactions.

(f) Best practices in documentation of the medication administration.

(7) This section does not apply to the administration of vaccines.

Note: To administer a vaccine a pharmacist must meet the requirements in s. 450.035, Stats.

Phar 7.14 Delegate-check-delegate. (1) DEFINITIONS. In this section:

(a) "Delegate" means a person to whom the pharmacist has delegated the task of product verification.

(b) "Delegate-check-delegate" means the process in which one delegate conducts the task of product verification of technical dispensing functions completed by an

unlicensed individual. A delegate may not conduct product verification as part of the final check of their own product preparation.

(c) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(d) "Supervising pharmacist" means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a delegate and ensuring for direct supervision of the delegate.

(2) DELEGATE QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:

(a) Is at least 18 years old.

(b) Completed an accredited technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(c) Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:

1. Elements of correct product including all of the following:
    a. Drug name.
    b. Strength.
    c. Formulation.
    d. Expiration date.
    e. Beyond use date.
2. Common dispensing medication errors and concepts including all of the following:
    a. Wrong medication.
    b. Wrong strength.
    c. Wrong formulation.
    d. Extra or insufficient quantity.
    e. Omitted medications if utilizing unit dose or compliance packaging.
    f. Expired medication.
    g. Look-alike or sound-alike errors.
    h. High-alert medications.
3. Eligible medications for delegate-check-delegate.
4. Organizational policies and procedures on reporting of medication errors.
5. Overview of the medication use process including all of the following:
    a. Procurement.
    b. Ordering.
    c. Dispensing.
    d. Administration.
    e. Monitoring.
6. A practical training designed to assess the competency of the delegate prior to starting the validation process. The practical training shall include simulation of at least two occurrences of each of the following:
    a. Wrong drug.
    b. Wrong strength.
    c. Wrong formulation.
    d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

1. The delegate being validated shall make a product verification on the work of a pharmacist or unlicensed person for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.
2. A pharmacist shall audit 100% of the product verifications made by the delegate during the validation process.

(e) Notwithstanding, pars. (a) to (d), a delegate who completed the Pharmacy Examining Board's pilot program validation process between October 1, 2016 and September 30, 2019 meets the delegation qualifications unless the delegate fails to meet the quality assurance standards under sub. (4).

(3) ELIGIBLE PRODUCT. (a) *Institutional pharmacies.* The delegate may do the product verification in an institutional pharmacy if all of the following requirements are met:

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.
2. A drug utilization review performed by a pharmacist prior to dispensing.
3. The drug product will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The delegate may do the product verification in a community pharmacy if all of the following requirements are met:

1. The source drug product or device is in an original package from a manufacturer or a licensed pharmacist has ensured that the source package is labeled with the correct name, strength, form, control or lot number, and beyond use or expiration date.
2. A drug utilization review performed by a pharmacist prior to dispensing.
3. The drug product or device is in the original packaging from a manufacturer, the drug product or device includes a description of the drug product or device on the prescription label that allows for a non-pharmacist to check the accuracy of the medication after it is delivered.

(4) QUALITY ASSURANCE. (a) A minimum of 5% of each delegate's product verifications shall be audited by a licensed pharmacist. The accuracy of each delegate shall be tracked individually.

(b) A record of each delegate-check-delegate audit shall include all of the following:

1. Name of the product verification delegate.
2. Total number of product verifications performed.
3. Number of product verifications audited by the pharmacist.
4. Percentage of product verifications audited by pharmacist.
5. Percentage of accuracy.
6. Number of product verification errors identified.
7. Type of error under sub. (2) (c) 3.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each delegate's previous 12 months accuracy and correctness of delegate-check-delegate product verifications including a review of the quality assurance log.

(d) A delegate shall be revalidated if the delegate fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed delegate-check-delegate product verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate which shall be made available to the board upon request.

(6) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each delegate that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising delegate-check-delegate pharmacist, indicating the name of the supervising delegate-check-delegate pharmacist, and the dates the supervision responsibilities begin and end.
3. Quality assurance audits and quarterly assessments.

(b) Records shall be made available to the board upon request.

Subchapter II — Central Shared Services

7.30 Definitions. In this subchapter:

(1) "Central shared services pharmacy" means a pharmacy licensed in this state acting as an agent of an originating pharmacy.

(2) "Labeling pharmacy" means the central shared services pharmacy or originating pharmacy which is responsible for product verification under s. Phar 7.07 (1) (a) and (b).

(3) "Originating pharmacy" means a pharmacy licensed in this state that uses a central shared services pharmacy.

7.31 Requirements. An originating pharmacy may use a central shared services pharmacy only pursuant to the following requirements:

(1) The central shared services pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract.

(2) The central shared services pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number that it provides services to.

(3) The central shared services pharmacy and originating pharmacy maintain a written protocol delineating each pharmacy's assumption of responsibility for compliance with state and federal law.

(4) Unless the central shared services pharmacy shares a computer system with the originating pharmacy meeting the requirements of s. Phar 7.04 (4) and contains the medication profile record under s. Phar 7.11 (3), it may not perform drug utilization review under s. Phar 7.03 to satisfy the final check requirement under s. Phar 7.07 (1) (c).

(5) The prescription label attached to the container shall contain the name and address of the labeling pharmacy. The date on which the prescription was dispensed for purposes of s. 450.11 (4) (a) 2., Stats., shall be the date on which the labeling pharmacy filled the prescription order.

(6) The originating pharmacy or central shared services pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.
(7) In addition to meeting the other recordkeeping requirements required by state and federal law, the central shared services pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for the final check under s. Phar 7.07 (1).

Subchapter III — Delivery Systems and Remote Dispensing

Phar 7.40 Definition. In this subchapter:
(1) "Delivery system" means a structure, controlled by a pharmacy licensed in this state, that a prescription is placed in for patient pick-up.
(2) "Supervising pharmacy" means a licensed pharmacy that oversees the operations and administration of remote dispensing.

Phar 7.41 Delivery system (1) Prescription shall be stored in a secure delivery system immediately upon delivery to the location of the delivery system. Only the patient or patient's agent shall be able to open the door or locker containing only the patient's prescription.
(2) The delivery system shall be designed in a manner which does not disclose protected health information.
(3) The delivery system shall maintain appropriate environmental controls, including temperature and humidity, to prevent drug adulteration.
(4) The use of a delivery system does not create an exemption to s. 450.11 (1b), Stats.
(5) A log shall be maintained by the dispensing pharmacy of all prescriptions delivered to the delivery system.
(6) The delivery system shall be inventoried at least weekly and a list of unclaimed prescriptions shall be reviewed by a pharmacist.
(7) The managing pharmacist shall establish written policies and procedures for all of the following:
(a) Stocking of the delivery system.
(b) Determining access to the delivery system.
(c) Detection and mitigation of diversion and theft.

Phar 7.42 Automated direct-to-patient dispensing system. (1) A pharmacy may utilize an automated direct-to-patient dispensing system in a secure and professionally appropriate environment in any of the locations under s. 450.062 (1) to (4), Stats.
(2) An automated direct-to-patient dispensing system shall be associated with a pharmacy. A prescriber may not dispense utilizing an automated direct-to-patient dispensing system. A prescriber may submit a prescription for dispensing by an automated direct-to-patient dispensing system.
(3) Individuals with access to the automated direct-to-patient dispensing system for the purpose of stocking, inventory, and monitoring shall be limited to a pharmacist or a pharmacist delegate.
(4) The automated direct-to-patient dispensing system shall label the prescription in compliance with s. Phar 7.05.
(5) The automated direct-to-patient dispensing system shall maintain prescription records in compliance with s. Phar 7.11 (1).

(6) If the associated pharmacy is open, the pharmacist shall do a drug utilization review under s. Phar 7.03 and consulting requirements in s. Phar 7.08. If the associated pharmacy is not open, then the prescriber is responsible for the drug utilization review and consulting.
(7) The managing pharmacist is responsible for maintaining records of the automated direct-to-patient dispensing system.
(8) The managing pharmacist shall establish written policies and procedures for automated direct-to-patient dispensing system for all of the following:

(a) Stocking, including identifying the responsible pharmacist.
(b) Determining access.
(c) Detection and mitigation of diversion and theft.

(9) The use of a automated direct to patient dispensing system does not create an exemption to s. 450.11 (1b), Stats.

Phar 7.43 Remote dispensing. (1) LOCATION**.** A pharmacist or a person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i) may dispense at any of the locations under s. 450.062 (1) to (4), Stats.
(2) TITLE**.** No person may use or display the title "pharmacy", "drugstore," "apothecary," or any other title, symbol or insignia having the same or similar meanings in connection with remote dispensing.
(3) REQUIREMENTS. (a) A remote dispensing location shall display a sign, easily viewable by customers, that states all of the following:

1. Prescriptions may be filled at this location.
2. This remote dispensing location is being supervised by a pharmacist located at all of the following:
    a. Name of pharmacy.
    b. Address of pharmacy.
    c. Telephone of pharmacy.
3. The pharmacist is available for consultation.

(b) Remote dispensing may not occur if the supervising pharmacy is closed.
(c) A prescribed drug or device may not be dispensed in the absence of the ability of a patient and pharmacist's delegate to communicate with a pharmacist.
(d) Remote dispensing locations shall have a centrally monitored alarm. For all after hour entries, the personnel entering the location shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for a minimum of 5 years.

(4) DISPENSING REQUIREMENTS. Remote dispensing shall comply with all of the following:

(a) Visually inspecting all prescription orders, labels and dispensed product.
(b) Labeling requirements under s. Phar 7.05. The prescription label shall contain the name and address of the supervising pharmacy as the licensed facility from which the prescribed drug or device was dispensed.
(c) Final check under s. Phar 7.07.
(d) Federal law if dispensing controlled substances.

(5) RESPONSIBILITIES OF MANAGING PHARMACIST. (a) The managing pharmacist of the supervising pharmacy shall do all of the following:

1. Have written policies and procedures for system operation, safety, security, accuracy and access.

2. Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.

3. Visit the remote dispensing location at least monthly to confirm delivery status of all drugs, to ensure written policies and procedures are being followed, and to ensure that remote dispensing personnel comply with all federal and state laws regulating the practice of pharmacy.

4. Retain documentation of the visits at the remote dispensing location for a minimum of 5 years.

(b) The managing pharmacist at the supervising pharmacy is responsible for all remote dispensing connected to the supervising pharmacy.

(6) DELEGATE REQUIREMENTS. A person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i), Stats., shall meet the following requirements to remote dispense:

(a) Be 18 years of age or older.

(b) Be a high school graduate or have equivalent education.

(c) Have completed 1500 hours of work as a pharmacist delegate within the 3 years prior to engaging in remote dispensing or completed an accredited pharmacy technician training program.

Subchapter IV — Institutional Pharmacies

Phar 7.50 Definitions. In this subchapter:

(1) "Chart order" means an order entered on the chart or a medical record of an inpatient or resident of an institutional facility by a practitioner or practitioner's delegate for a drug product or device

(2) "Institutional facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; a hospice facility under s. 50.90 (1) (c), Stats.; a county jail; and a correctional facility operated under the authority of the department of corrections.

(3) "Institutional pharmacy" means a pharmacy that provides pharmacy services to an institutional facility. This definition is not for purposes under s. 450.09 (1) (a), Stats.

Phar 7.51 Chart orders. A chart order shall contain all of the following:

(1) First and last name of the patient.

(2) Patient's medical record number or date of birth.

(3) Date of issuance.

(4) Name, strength, and form of the drug product or device prescribed.

(5) Directions for use.

(6) Practitioner's written signature, or electronic or digital signature.

(7) Chart orders written by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name of the practitioner.

Phar 7.52 Labels. All prescribed drug products and devices dispensed for administration by a health care provider at the institutional facility shall have a label attached to the container disclosing all of the following:
(1) Drug name, strength and form.
(2) Beyond use date or expiration date.
(3) NDC and lot number, if applicable.
(4) Special storage conditions, if required.

Phar 7.53 Security and access. (1) Arrangements shall be made in advance by the managing pharmacist for access of drugs by the health care staff of the institutional facility when dispensing by a pharmacist is not available.
(2) In the absence of a pharmacist, drugs shall be stored in a manner in which only authorized personnel may obtain access and is sufficiently secure to deny access to unauthorized persons.
(3) The managing pharmacist shall develop policies and procedures in place to mitigate and prevent theft and diversion.

7.54 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug product, or items of personal hygiene.

(b) "Original container" means the container in which a health item was sold, distributed, or dispensed.

(c) "Tamper-evident package" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that tampering has occurred.

(2) A health item which has been sold, distributed or dispensed, may be returned to the institutional pharmacy under Phar 7.10 (2) or if the health item has not left the control of the health care facility staff authorized to have access to prescription drug products.
(3) A health item returned to an institutional pharmacy, may be sold, distributed, or dispensed to the institutional facility if all of the following apply:

(a) The health item was never in the possession and control of the patient.

(b) The health item was sold, distributed or dispensed in a tamper-evident package and, for a drug product, includes the beyond use date or expiration date and manufacturer's lot number.

(c) The health item is not commingled with a different health item.

(d) The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

Phar 7.55 Automated technology product verification (1) DEFINITIONS. In this section:

(a) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(b) "Supervising pharmacist" means the pharmacist licensed in this state who is responsible for the operations and outcomes of the product verification done by an automated technology.

(2) AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS. Product verification may be done only by an automated technology which meets all of the following:

(a) Located within a licensed pharmacy.

(b) Utilizing barcodes or another machine-readable technology to complete the product verification.

(c) Validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

(d) Revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy and correctness of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations.

(3) ELIGIBLE PRODUCT. The automated technology may do the product verification if the product meets all of the following:

(a) Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date.

(b) Has a drug utilization review performed by a pharmacist prior to delivery.

(c) Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(4) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated technology product verification which shall be made available to the board upon request.

(5) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.

3. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.

4. Documentation of the dates of all software upgrades.

5. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

(b) Records shall be made available to the board upon request.

Subchapter V — Unlicensed Persons

7.60 Definitions.

(1) "Direct supervision" means immediate availability to continually coordinate, direct and inspect in real time the practice of another.

(2) "General supervision" means to continually coordinate, direct and inspect the practice of another.

7.61 Persons who have completed their second year of pharmacy school or pharmacists from another state applying for licensure. A person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats. is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board.

7.62 Unlicensed persons. (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats.
(2) A pharmacist shall provide general supervision of unlicensed personnel. A pharmacist shall be available to the unlicensed person for consultation either in person or contact by telecommunication means.
(3) An unlicensed person may not do any of the following:

(a) Provide the final check on the accuracy and correctness of drug product or device dispensing under s. Phar 7.07 (1) (a) or (b), unless the person is validated for delegate-check-delegate under s. Phar 7.14.
(b) Complete the drug utilization review under Phar 7.03.
(c) Administer any prescribed drug products, devices or vaccines under s. 450.035, Stats.
(d) Provide patient specific counseling or consultation.

(4) The prohibitions in sub. (3), do not apply to a person completing an internship for purposes of meeting the internship requirement under s. 450.03 (2) (b).
(5) A managing pharmacist shall provide training to or verify competency of unlicensed person prior to the unlicensed person performing a delegated act.
(6) The managing pharmacist shall determine which acts may be delegated in a pharmacy. The managing pharmacist has a duty to notify all pharmacists practicing in that pharmacy which acts may be delegated to specific unlicensed persons. This record shall be provided to the board upon request.
(7) A pharmacist may delegate to an unlicensed person any delegated act approved by the managing pharmacist.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

PSW
Pharmacy Society of Wisconsin

DATE: December 17, 2019
TO: Dr. Philip Trapskin, Chairman
Members, Pharmacy Examining Board (PEB)
FROM: Danielle Womack, Vice President of Public Affairs
Pharmacy Society of Wisconsin
SUBJECT: Phar 7: Practice of Pharmacy

On behalf of the Pharmacy Society of Wisconsin's more than 4,000 members, I would like to thank you for the opportunity to share our thoughts on Phar 7, relating to pharmacy practice, and for accepting stakeholder input throughout the entire rulemaking process.

The Pharmacy Society of Wisconsin is dedicated to advancing the practice of pharmacy with the ultimate purpose of enhancing patients' lives. Therefore, we recognize and appreciate the Pharmacy Examining Board's work in updating regulations on pharmacy practice to address contemporary pharmacy practice models.

The PEB has been very open to stakeholder feedback throughout the Phar 7 rewrite process and PSW appreciates their willingness to engage in dialogue with affected parties. Upon reviewing the preliminary rule draft, we respectfully suggest some changes based upon feedback from our membership. These changes will bring more clarity to the chapter for pharmacies while ensuring that the practice of pharmacy is completed safely and effectively for optimum patient safety. Below are the changes that PSW respectfully and specifically requests.

- Phar 7.01(1): The definitions of "managing pharmacist" in Phar 7.01(1) and Phar 1.02(6) do not match, which has led to confusion as to the requirements of the "managing pharmacist." We request that these definitions are made to match.
- Phar 7.02(1)(4): Concerns have been raised about the requirement that the prescription order include the drug "form." This is not a statutory requirement (statute requires only name and quantity) and often prescribers do not include form on prescription orders, particularly hard copy prescriptions. PSW is concerned that requiring "form" on the prescription order would either lead to audit or complaint risks for pharmacies, or could cause a delay in care while pharmacists work to get a rule-compliant prescription order. We request that "form" is removed.
- Phar 7.02(3)(b)(1): It is impossible for the pharmacist to know if a prescription order was sent to the location of the patient's choice; this is the responsibility of the prescriber. We request the language be modified to state that a pharmacist shall transfer a prescription upon patient request (pursuant to transfer rules).
- Phar 7.02(4): We recommend using the term "verbal prescription" throughout, rather than alternating between "verbal prescription" and "oral prescription." Additionally, this section implies that verbal prescriptions may only be transmitted via telephone answering device or voice mail. We request that the PEB clarify that prescriptions may be transmitted via direct conversation over the phone.
- Phar 7.03(1)(b): We have concerns about interpreting the intent of "rational therapy" and how this requirement may be understood in complaint or audit circumstances. We request that this component of the required DUR be eliminated.

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- Phar 7.03(1)(d): We request that patient gender is not included in this requirement.
- Phar 7.05(1): While recognizing that this section does not apply to institutional pharmacies, we would request that clinic-administered medications in an ambulatory, outpatient setting are also exempt from these requirements.
- Phar 7.05(2)(k): While we support including written or graphic product descriptions on prescription labels, many pharmacy software system vendors are not capable of printing this information on the label. Additionally, questions have been raised about how this requirement would be implemented for compounded medications. Therefore, we recommend removing this as a requirement and instead including "written or graphic product description" under the optional label components, Phar 7.05(3).
- Phar 7.06: We request that repackaging in an automated dispensing cabinet is exempt from these requirements.
- Phar 7.07(2): The requirement for the supervising pharmacist to be identified is problematic as most pharmacy software vendors do not allow for this information to be recorded and the supervising pharmacist is already documented in the policies and procedures required by the delegate-check-delegate rules.
- Phar 7.085: Current Phar 7.01 includes language clarifying that a pharmacy may deliver a prescription to the location of the patient's choice. We strongly support including specific language allowing for delivery to any location of the patient's choosing.
- Phar 7.14(1)(c): Checking the accuracy and correctness of expiration and beyond use date was not required to be a documented component of "product verification" during the Community Tech-Check-Tech pilot. We request that this component of the definition be removed.
- Phar 7.14(3)(b)(3): While we support including product descriptions on prescription labels and understand the need for this description in delegate-check-delegate situations, many pharmacy software systems are not capable of printing this information on the label. Therefore, we recommend modifying this requirement to allow the description to either be on the label or accompanying paperwork, or to allow for the pharmacist to utilize show-and-tell in lieu of the printed description, as allowed by the Community Tech-Check-Tech pilot program.
- Phar 7.14(4)(b)(7): This section incorrectly refers to the location of error types. The PEB has previously discussed this incorrect reference at the public hearing on the final delegate-check-delegate administrative rules. We request that the reference be updated to state *"Type of error under sub. (2)(c)(2)(a) through (c) and (e)."*
- Phar 7.42(6): Some health systems have reported that their workflow has the prescriber always completing the DUR and consultation, regardless of whether the associated pharmacy is open or not. We request flexibility in allowing the pharmacist or the prescriber to provide the DUR and consultation, regardless of whether or not the pharmacy is open when the prescription is dispensed in order to maintain critical access to medications in facilities that may have limited pharmacy hours.
- Phar 7.43(5)(a)(3): We request allowing the managing pharmacist to delegate visiting the remote dispensing locations monthly to another licensed pharmacist.
- Phar 7.51(7): We request that the language is modified to state that only delegates without independent prescriptive authority are required to document both the first and last name of the delegate and the first and last name of the practitioner. We request that the language be changed to state *"Chart orders written by a practitioner's delegate without independent prescribing authority shall include the first and last name of the delegate and the first and last name of the practitioner."*
- Phar 7.52(3): We request removal of this line, as the interpretation in complaint cases of "if applicable" is unclear. Additionally, we are concerned that many software systems do not allow for lot number to be printed on a label.

Over the past few months, PSW has received a countless amount of member outreach on the proposed changes to the counseling requirements in Phar 7.08. Our members hold a spectrum of thoughts regarding the proposed changes and the feedback we have received has transcended practice site. In other words, independent pharmacies have expressed both support and opposition; health system pharmacies have expressed both support and opposition; the same can be said for many other pharmacy practice sites. There are clearly strong viewpoints about both intended and unintended consequences that pharmacists believe will result from proposed changes.

We have received comments and have led our Board of Directors and various advisory boards in discussion around the following aspects of the proposed changes to pharmacist patient counseling:

- Removing the requirement for patient counseling on refill prescriptions
- Differences in counseling requirements and counseling quality based on prescription dispensing pharmacy
- Patient counseling on mailed and delivered prescriptions and the workflow evolutions or patient care situations that constitute delivery of prescriptions to a location of a patient's choice
- Data available to support the pharmacist's role in patient counseling
- Patient choice in prescription filling location and in receiving counseling from a pharmacist
- Whether any changes to the current counseling requirements are warranted at all
- The process by which the proposed changes have been developed and have further evolved

After careful discussion with the PSW Board of Directors, given the broad spectrum of views our members hold and the clear lack of professional consensus on this topic, PSW does not have a position as to whether counseling should or should not be required on mailed and delivered prescriptions or whether the counseling regulation should be changed at all. PSW recognizes that many of our members, including PEB members, are disappointed that we have not taken a position on the proposed changes to the counseling requirement. We would like to clarify that this lack of position comes from a clear and widespread lack of consensus among our membership. Due to this broad professional lack of consensus, we ask that the PEB consider a separate scope statement regarding counseling so as to not inhibit the countless other positive changes in Phar 7 and to allow deeper discussions of the various counseling requirement models and their related benefits and consequences. PSW is concerned about the quantity of comments and concerns raised in the development of Phar 7.08 as proposed. The lack of professional consensus suggests there may be a role for PSW to support further discussion and that this portion of the rule as proposed today should be the subject of further dialogue.

PSW does have concerns about the overly prescriptive nature of the proposed Phar 7.08. Specifically, Phar 7.08(1), which lists eight components that must be included in all patient consultation is very prescriptive; while Phar 7.08(2)(a) allows the pharmacist to utilize professional judgement in omitting or altering this information, the concern has been raised that pharmacists would need to document every omission or alteration in case of a complaint. This practice would be overly and unnecessarily burdensome on pharmacies to track and document every patient consultation that occurs. PSW believes the elements of a pharmacist-patient interaction should not be listed in rule.

Additionally, Phar 7.08(2)(c) requires pharmacies to supply specific written information to each patient. While we do not oppose the provision of written information, we have concerns that some of the requirements listed in the proposed rule cannot be met by many pharmacy drug information vendors. Specifically, the requirement to provide written documentation of "duration" of drug therapy (which may or may not be known to the pharmacist or prescriber if the patient is on a chronic medication) and "techniques for self-monitoring drug therapy" may be difficult for pharmacies to meet. PSW recommends the elimination of these elements from the list of required written materials.

Finally, questions have been raised about the definition of "administer" and "health care provider" in Phar 7.08(7). While "administer" is defined in both Wis. Stat. §450.01(1) and Wis. Stat. §961.01(1r), the definitions are different. In Wis. Stat. §450.01(1), the definition does not include the patient inhaling, injecting, or ingesting a drug product in the presence of a practitioner; Wis. Stat. §961.01(1r), which applies to controlled substance administration, does include "in the presence of a practitioner." Therefore, questions have arisen about Phar 7.08(7) and whether consultation must occur if patient ingests, injects, or inhales a drug product in the presence of a practitioner. Additionally, there is no definition of "health care provider" in Phar 1, Phar 7, Wis. Stat. §450 or Wis. Stat. §961, making it impossible for pharmacists to know whether the individual administering the product meets the definition. Many pharmacies that service long-term care facilities, in particular, have questioned whether this definition includes only licensed providers, or if delegates of a licensed provider (e.g. a medication passer). We encourage the PEB to clarify the definition of "administer" to include the inhalation, injection, or ingestion of a drug product in the presence of a health care provider and to define "health care provider" to include both licensed providers and their delegates.

To reiterate, our goal, like that of the PEB, is to advance the practice of pharmacy while ensuring patient safety and we appreciate the PEB's diligence and work in rewriting Phar 7. Thank you again for allowing me to testify on behalf of more than 4,000 Pharmacy Society of Wisconsin members.

SSM Statement on Proposed Changes to Phar 7 Summary

Rule Change Recommendations

General Statement: The below rule changes will have a significant financial impact that would increase pharmacist and technician resources needed to carry out current business operations. In addition, some of these changes will increase cost of goods and additional operating expenses that pharmacies will be required to burden. In order to limit the detrimental financial impact on pharmacy operations at SSM Health and other pharmacies across the state we are recommending the below changes.

1. Section 7.02 (Plain Language Paragraph 1)
    a. 3(b): The proposed rule states the prescription must be sent to the "patient's choice" . The Pharmacy staff will not know if a prescription was sent to the patient's choice, that responsibility is owned by the ordering provider. By receiving the prescription they are assumed to be the pharmacy of choice. We would recommend this language on patient's choice be omitted.
2. Section 7.04 (Plain Language Paragraph 3)
    a. The proposed rule states when transferring prescriptions, the receiving pharmacy has to record all dates of previous dispenses. We recommend this to be changed to require documentation only of the last refill dispensed.
3. Section 7.05 (Plain Language Paragraph 7)
    a. 5: The proposed rule states that the pharmacy can be contacted by "toll-free telephone service." We recommend this be changed to remove the "toll-free" as many pharmacies only have a regular phone number and do not have a toll-free line.
4. Section 7.085 (Plain Language Paragraph 8)
    a. 4: The proposed rule states the pharmacy must replace the product at no cost by the next-day. We very strongly recommend this be omitted. Pharmacies are not able to control if a patient is not able to receive delivery or delivery service fails to deliver. In addition Pharmacies cannot guarantee physician will sign a 7 day order or that there is plausible method for the patient to receive by the next day.
5. Section 7.11
    a. 3 (c):The proposed rule state that pharmacy must record all chronic conditions. Pharmacies may not have accurate record of diagnosis to validate condition. We recommend this language be omitted.
6. Section 7.42
    a. 6: The proposed rules states if the associated pharmacy is open, the pharmacist shall do a drug utilization review under s. Phar 7.03 and consulting requirements in s. Phar 7.08. If "associated pharmacy" means the hospital pharmacy, we recommend that this statement is removed and that the drug utilization review and consulting is always the responsibility of the prescriber. Even if the hospital pharmacy is open when the automated dispensing system is being utilized, there is not an efficient way to notify the hospital pharmacist that they would need to perform the DUR and perform the consultation. This could lead to delays in care and also additional resources for a hospital pharmacy to be able to address the additional review and consultation requirements.
7. Section 7.43 (Plain Language Paragraph 17)
    a. 5: The proposed rules states the pharmacy manager must perform these duties. We would recommend that a different pharmacist could be delegated to these duties. The rules also states the manager must conduct biweekly visit. A biweekly visit is unreasonable and does not add additional safety or value. We would strongly recommend monthly pharmacist visits and quarterly manager visits.

SSM Statement on Proposed Changes to Phar 7 Summary

Rule Change Recommendations

8. Section 7.52
    a. The proposed rule states that a LOT# number should be on the label for dispenses at an institutional pharmacy. We recommend this language be omitted, since there is not enough clarity on what "when applicable" means, and many software systems do not have the ability to include this material. There is no added value to having this material as long as the other items in the section are included on the container. .
9. Section 7.54
    a. 1(c) The proposed rules states the health items is not commingled with a different health item. We recommend that this statement is removed. Medications are often commingled upon delivery to the patient care areas in cart boxes or in nurse drawers. If this means that hospitals are unable to re-use these medications even though they are still in their intact unit dose packaging, this would lead to a significant increase in unnecessary pharmaceutical waste of usable medications. This would be costly and wasteful. It would mean for every discharged patient all of the unadministered medications would be thrown away in pharmaceutical waste instead of going back down to pharmacy to be redistributed.

Need Additional Clarification on the Following Sections:

1. Section 7.01 "Managing Pharmacist" definition in Chapter 7 and Chapter 1 do not match. We would recommend that definitions should match.
2. Section 7.10 Does section 2(c) allow the health item to be resold? If so, please provide examples of health items that could be resold.

To: Sharon Henes
Administrative Rules Coordinator

I would like to address several items in the proposed Rule changes for Chapter Phar 7.
The rule changes should include diagnosis, cannot indicate on a new prescription fill all refills as before, previous refills patient consultation on refills, ask a question on a refill and if multiple refills pick one refill to ask a question, business only decision, compliance on refills, use of the word technician, use of the state registry for vaccines, symptoms or purpose.

Under 7.02

Add diagnosis on prescription but does not need to be on the label if the provider indicates do not put on the label. (This should also be included on the standing order.) The reason for this is the Pharmacist then can make a determination if the drug prescribed is appropriate for the intended use.

Add a Pharmacist cannot receive a prescription orally or in writing that indicates refill all prescriptions as before. (The reason for this is how does the Pharmacists know which refills are still current vs the provider eliminated some refills.

Under 7.03

Add is the patient compliant on refills.

Under 7.04 (3) (d,4)

Date and location of previous refills. Why is this necessary since it is plural and you can only transfer once

Under 7.05 (2) (b)

Symptom or purpose should be mandatory unless the provider indicates not to be put on label.

Under 7.08

Add patient consultation is mandatory for refills. Must ask a question on a refill or if multiple refills pick one of the refills.

(The reason for this is the importance of refills in knowing that the patient understands its use. Example: What is your A1C numbers, or what are your blood pressure readings etc.)

Add is the patient compliant on refills and if not ask why and determine if is appropriate for the provider be informed.

Under 7.085 (4)

Drop the phrase "the pharmacy shall replace at no additional cost etc".

(The reason for this is this should be a business decision not a law)

Under 7.13 (c)

State registry for vaccines is required.

Under 7.14

Why do you have to add a new word (delegate) when the word should be technician? The word technician is a universal word and it enhances the importance of a technician.

Submitted by:

Kenneth R. Schaefer
Retired Pharmacist

149330 Mountain Lane
Wausau, Wisconsin 54401

Phone: 715-848-8748

Henes, Sharon - DSPS

From: Dawn Wypiszynski <dwypiszynski@mortonltc.com>
Sent: Tuesday, December 17, 2019 9:52 AM
To: DSPS Admin Rules
Cc: Dawn Wypiszynski
Subject: FW: Phar 7 Public Hearing

Sent from my U.S.Cellular© Smartphone

-------- Original message --------
From: Dawn Wypiszynski <dwypiszynski@mortonltc.com>
Date: 12/12/19 5:32 PM (GMT-06:00)
To: Steve Morton <smorton@mortonltc.com>
Cc: Kate Springborn <kspringborn@mortonltc.com>, Dawn Wypiszynski <dwypiszynski@mortonltc.com>
Subject: Phar 7 Public Hearing

Here's a summary of the comments I'd like to make at the WI Phar 7 Public Hearing on Tuesday.

1) Phar 7.02 (2) Standing Order- Current LTC practice does not include obtaining address of practitioner on the standing order. Requiring this information would delay patient care in time spent by the pharmacist and the practitioner in obtaining the practitioner address and adding that information to the standing orders.

2) 7.05 (1) Label Requirements- Requesting clarification for labeling requirements for institutional pharmacies. 'This sections does not apply to institutional pharmacies as defined in s. Pharm 7.50 (2)'. 7.50 (2) refers to institutional facility, not institutional pharmacy. Labeling requirements in Phar 7.52 do not include current standard labeling requirements such as patient name and directions for use.

3) Phar 7.08 (4) Patient Consultation. Requesting clarification for definition of a 'physical location' to determine if an institutional pharmacy is required to post signage regarding a patient's rights to consultation.

    a. Pharm 7.08 (7) states that 'a consultation is not required when a health care provider is administering the medication' so typical institutional pharmacies would not be required to provide consultation.

4) Phar 7.51 Chart Orders- Requesting clarification to determine if a pharmacist can add or change information on chart orders as is currently allowed for prescription orders.

5) I would like to request consideration for adequate time to implement Phar 7 requirements once approved. This chapter is completely rewritten in parts and will require more time to implement than other legislative changes.

I would like clarification about the DUR requirement as in 7.03 and 7.07 (1) (c). Request to change to each new order dispensing. LTC pharmacy in our practice includes profile reviews with status change, discharge from hospital, monthly for SNF, and annual for CBRF patients.

Thank you!

Dawn Wypiszynski, PharmD

Pharmacy Director

Morton LTC

Neenah, WI

Wisconsin Pharmacy Examining Board

Phar 7 Public Comment

Submitted on behalf of the signatures of support

7.03 Drug utilization review.

7.03 (1)(d) Reasonable dose, duration of use, and route of administration, considering the age, gender, and other patient factors.

As a community pharmacist, I care for patients that identify as non-binary, refusing to provide a gender reference, but if only for the payment of their insurance. I care for trans-gender people that are in various stages of the transformative processes. In these instances, gender becomes more about assumptions, than real information.

I would recommend to the Board to strike the word gender from this rule. It is the only time in the chapter that it is used. This rule applies to a cis-gender normative society where the designations of M and F, represent Male and Female. As our society grows more accepting of a gender fluid population, the letters we assign to designate male/female become ambiguous.

It is impossible for a pharmacist to truly know a patient's gender to a level that would be pharmaceutically relevant. Gaining the level of intimate knowledge needed to make a pharmaceutical care decision relevant, may take years of trust building, or may never be achievable in some practice settings.

Since gender is not easily observable, I would ask that it be removed from the requirements of Drug Utilization Review. The remaining items on the list is sufficient to keep people safe and foster positive outcomes.

I feel it is important to address this now, since the next review of these rules may not happen for several decades. If the Board would like more information on this topic, I would be happy to provide it.

Thad Schumacher PharmD

Fitchburg Family Pharmacy

Pronouns: he/him/his

Timestamp	Full Name	City, State	Personal Information (Check all that apply)	Name of school/pharmacy/organization, if relevant
11/14/2019 6:58:20	Thad Schumacher	Madison	Wisconsinite, Pharmacist, I know an impacted (trans/nonbinary) person	Fitchburg Family Pharmacy
11/14/2019 12:25:17	Maddie Schumacher	Fitchburg	Wisconsinite, I am an impacted (trans/nonbinary) person, I know an impacted (trans/nonbinary) person	Fitchburg Family Pharmacy
11/17/2019 6:51:02	Sydney Ertz	Madison, WI	Pharmacy Student, I know an impacted (trans/nonbinary) person	University of Wisconsin Madison School of Pharmacy
11/17/2019 7:02:10	Michelle Farrell	Boscobel	Wisconsinite, Pharmacist, I know an impacted (trans/nonbinary) person	Boscobel Pharmacy
11/18/2019 5:43:39	Cara Geho	Madison	Wisconsinite, I am an impacted (trans/nonbinary) person, I know an impacted (trans/nonbinary) person	
11/18/2019 6:12:00	DeAnna Goldade	Johnson Creek	Wisconsinite, I know an impacted (trans/nonbinary) person	
11/18/2019 6:22:17	Scott Sullivan	Prairie du sac	Wisconsinite, I know an impacted (trans/nonbinary) person	
11/18/2019 6:28:28	Greg Hasheider	Fitchburg	Wisconsinite, I know an impacted (trans/nonbinary) person	Walgreens
11/18/2019 6:46:16	Alan C Robinson	Madison	Wisconsinite, I know an impacted (trans/nonbinary) person	Wisconsin NORML
11/18/2019 6:52:35	McNeil Lunenburg	Janesville	Wisconsinite	None
11/18/2019 6:56:53	Nichole L Miller	Cottage Grove	Wisconsinite, I know an impacted (trans/nonbinary) person	
11/18/2019 8:47:42	Donna Lynn Decker	Baraboo	Wisconsinite	
11/18/2019 9:14:33	Angela Kippert	Sun Prairie	Wisconsinite, I know an impacted (trans/nonbinary) person	
11/18/2019 14:01:54	Colin Murray	Madison	Wisconsinite	
11/19/2019 7:50:39	Matt Huppert	Verona, WI	Wisconsinite, Pharmacist, I know an impacted (trans/nonbinary) person	
11/19/2019 12:18:15	Sophie Migacz	St. Paul	I know an impacted (trans/nonbinary) person	
11/19/2019 15:29:35	Sophie wolbert	Madison	Wisconsinite, I know an impacted (trans/nonbinary) person	
11/19/2019 15:47:28	Cassandra Habel	Madison, WI	I know an impacted (trans/nonbinary) person	
11/19/2019 18:59:41	Lindsey Hazlett	Mount Horeb	Wisconsinite, I know an impacted (trans/nonbinary) person	
11/19/2019 23:24:52	Frances Lucia Bartolutti	Madison	Wisconsinite, I know an impacted (trans/nonbinary) person	
11/20/2019 0:58:54	Taylor Watterson	Madison, WI	Pharmacist, I know an impacted (trans/nonbinary) person	Fitchburg Family Pharmacy
11/20/2019 4:45:03	Susan Kleppin	Madison	Wisconsinite, Pharmacist	
11/20/2019 16:57:02	Debra Anderson	Fitchburg, WI	Wisconsinite	
11/20/2019 16:58:15	Mariana Garcia Ornelas	Madison, Wisconsin	I know an impacted (trans/nonbinary) person	Fitchurg Family Pharmacy
11/20/2019 17:13:51	Jamie Hill	Fitchburg	Wisconsinite	Fitchburg Family Pharmacy
11/20/2019 22:40:47	Evan Robert schumacher	Madison, WI	Wisconsinite, I know an impacted (trans/nonbinary) person	Fitchburg Family Pharmacy
11/21/2019 19:18:54	Jennifer Grice	Town of Union, WI	Wisconsinite, Pharmacist, I know an impacted (trans/nonbinary) person	
11/22/2019 17:25:08	Kierstin Huelsemann	Fitchburg, WI	Wisconsinite, I know an impacted (trans/nonbinary) person	N/A
11/24/2019 23:01:40	WENDI KENT	Madison	Wisconsinite, I know an impacted (trans/nonbinary) person	
11/28/2019 16:44:09	Michael Kern	Interlochen, Mi	I am an impacted (trans/nonbinary) person, I know an impacted (trans/nonbinary) person	
12/3/2019 16:53:29	Cara Geho	Madison	Wisconsinite, I am an impacted (trans/nonbinary) person, I know an impacted (trans/nonbinary) person	
12/5/2019 4:55:51	Scott Sullivan	Prairie du Sac	Wisconsinite	
12/5/2019 14:04:26	Daniel Funk	Madison, WI	Wisconsinite, Pharmacy Student	University of Wisconsin School of Pharmacy
12/5/2019 19:34:53	Madeline Gallo	Kenosha, WI	Wisconsinite, Pharmacy Student	UW-Madison School of Pharmacy
12/9/2019 7:55:54	Alexis Biehl	Madison, WI	Wisconsinite, Pharmacy Student, I know an impacted (trans/nonbinary) person	University of Wisconsin - School of Pharmacy
12/10/2019 12:31:09	Marc Ertz	Holmen, WI	Wisconsinite, Pharmacist, I know an impacted (trans/nonbinary) person	University of Wisconsin, Madison
12/10/2019 18:39:11	Madeline Moran	Madison, WI	Wisconsinite	University of Wisconsin- Madison
12/10/2019 19:43:49	Alicia Dixon	Baltimore, MD	I know an impacted (trans/nonbinary) person	University of Wisconsin- Madison
12/11/2019 8:19:13	Gretchen Kunze	La Crosse, WI	Pharmacist, I know an impacted (trans/nonbinary) person	Cass St Pharmacy GHS
12/11/2019 10:55:01	Rebecca Nindorf	Holmen, WI	Wisconsinite, Pharmacist, I know an impacted (trans/nonbinary) person	Dr.
12/12/2019 11:56:08	Erika Brown	Holmen, WI	Pharmacist	Gundersen Health System Pharmacy
12/13/2019 11:54:53	Kenji Hamamoto	LaCrosse, Wi	Wisconsinite, Pharmacist	
12/13/2019 15:48:49	Trisha Stroyny	Holmen, WI	Wisconsinite, Pharmacist	Gundersen Clinic Pharmacy

CVSHealth

John Long, RPh, MBA | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 614-572-9008

Via Electronic Mail

December 16, 2019

Ms. Sharon Henes
Administrative Rules Coordinator
Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way
Madison, WI 53708-8366

Re: Comments Proposed Language Chapter Phar 7 - Pharmacy Practice

Dear Ms. Henes::

I am writing to you in my capacity as Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide care with diverse access points to patients in the state of Wisconsin through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments to the Pharmacy Examining Board (Board) pertaining to Chapter Phar 7 – Pharmacy Practice. All requested changes are signified in red and underlined below.

A. Drug Utilization Review

CVS Health believes that Drug Utilization Review (DUR) that is conducted with each new new drug product or device accomplishes the same outcome as performing DUR "prior to dispensing each prescription drug order"; the patient's profile has not changed since the last new drug product or device was dispensed, so performing DUR when refilling a drug product or device is duplicative, clinically irrelevant, diverts the pharmacist's attention from other impactful patient centered activities, and may cause distracting DUR fatigue. In comparison, the Board has appropriately not required patient counseling prior to dispensing refilled drug product or devices, and we suggest the DUR requirements mirror Phar 7.08 (2) "*A pharmacist shall give the patient or patient's agent consultation reletaive to the prescription for any new drug product or device which has not been dispensed previously to the patient or any change in the patient's therapy.*"

7.03 Drug utilization review. (1) A pharmacist shall complete a drug utilization review by reviewing the patient record prior to dispensing ~~each prescription drug order~~ any new drug product or device which has not been previously dispensed to the patient or any change in the patient's therapy for all of the following:
(a) Known allergies.
(b) Rational therapy.
(c) Contraindications.
(d) Reasonable dose, duration of use, and route of administration, considering the age, gender, and other patient factors.
(e) Reasonable directions for use.
(f) Potential or actual adverse drug reactions.
(g) Drug interactions with food, beverages, other drugs or medical conditions.

(h) Therapeutic duplication.
(i) Reasonable utilization and optimum therapeutic outcomes.
(j) Potential abuse or misuse.
(2) Upon recognizing a concern with any of the items in sub. (1) (a) to (j), the pharmacist shall take steps to mitigate or resolve the problem.

B. Delegation

Community pharmacists provide high quality, accessible patient care services, including medication management, immunizations, preventive screenings, and chronic care management. Despite a growing need for increased access to patient care services, community pharmacists spend only 21% of their professional time performing patient care services that are not associated with dispensing prescriptions.[1] To further enhance and optimize patient care services delivered at community pharmacies, leveraging and expanding current roles of pharmacy delegates should be considered in community pharmacies. Increasing the scope of pharmacy delegates practice to include administrative and supportive tasks for pharmacist-provided patient care services will allow pharmacists to more effectively and efficiently provide for patients' medication-related needs.[2] Most importantly, some states have a patient safety track record of success with expanded pharmacy delegate roles that spans over four decades.[3] Paramount and centric to all Board rules, including pharmacy delegate roles and responsibilities, is patient safety. The national landscape reveals an overwhelming safety track record of success and shift towards pharmacy delegates transferring prescription order information, including 16 states that currently allow for this expanded duty and more that are actively engaging in such rule promulgation. As discussed during the rules review meetings over the last several weeks, the Board desires to expand the allowance for transferring prescription order information to pharmacist delegates. This increase in delegate duties will allow for pharmacists to provide added clinical duties throughout the workday. Please see the requested edits below.

7.04 Transferring prescription order information.
(1) GENERAL REQUIREMENTS
(a) The transfer of prescription order information is communicated in one of the following ways:
1. Oral communication between two pharmacists <u>or delegates.</u>
(b) A transfer of prescription information orally shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist <u>or delegate</u> responsible for the accuracy of the prescription information.
(2) NON-CONTROLLED SUBSTANCES
(a) The prescription record of the transferred prescription shall include the following information
2. The name and address of the pharmacy to which it was transferred, the date and the first and last name of the pharmacist <u>or delegate</u> transferring the information are recorded on the invalidated prescription order or in a computer system meeting the requirements s. Phar 7.11 (2) (a).
(b) Unless a computer system meeting the requirements in sub. (4) is used, the transferred prescription order information shall include the following:
7. The first and last name of the pharmacist <u>or delegate</u> transferring and receiving the prescription order information.

C. Labeling

The Institute for Safe Medication Practices published recommended industry guidelines for medication labels for community and mail order pharmacies on December 30, 2014[4] in which they explained that the prescription label for dispensed medication exists for the benefit of the patient. Pharmacy records are best suited to answer a Board's inquiry as to what pharmacy labeled in a central shared services arrangement, as different business models may

render any of the pharmacies involved in the arrangement to be best suited to serve the patient's need after dispensing. As currently drafted Phar 7.30(5) and 7.31(2) do allow for the central shared services pharmacy's name and address to appear on the label, but only allow the originating pharmacy's name and address to appear on the label, if the originating pharmacy is responsible for product verification. CVS Health believes that the label should reflect the pharmacy best suited to serve the patient's needs, which is not necessarily the pharmacy that filled or verified the prescription, and offers the following edits for the Board's consideration.

7.31 Requirements. An originating pharmacy may use a central shared services pharmacy only pursuant to the following requirements:
(5) The prescription label attached to the container shall contain the name and address of the pharmacy best suited to serve the patient's needs. The date on which the prescription was dispensed for purposes of s. 450.11
(4) (a) 2., Stats., shall be the date on which the ~~labeling~~ pharmacy filled the prescription order.

7.30 Definitions. In this subchapter:
(1) "Central shared services pharmacy" means a pharmacy licensed in this state acting as an agent of an originating pharmacy.
~~(2) "Labeling pharmacy" means the central shared services pharmacy or originating pharmacy which is responsible for product verification under s. Phar 7.07 (1) (a) and (b).~~
(~~3~~2) "Originating pharmacy" means a pharmacy licensed in this state that uses a central shared services pharmacy

D. Institutional Pharmacies

In 2017 the National Association of Boards of Pharmacy (NABP) convened a task force of board of pharmacy representatives and long term care experts. Subsequently, NABP published the Report of the Task Force on Long-Term-Care Pharmacy Rules[5] and revised their Model State Pharmacy Act and Model Rules[6]. These publications updated the definition of "chart order", which include the components necessary for validity. These experts concluded that a patient's medical record number or birth date was not a necessary component of a valid chart order, and that requiring such data elements would create delays in therapy for these fragile institutionalized patients, while prescribers were contacted. Additionally to avoid delays in therapy, the Task Force Report details allowances for verbal chart orders and for chart orders signed by the prescriber's designee. In the best interests of our patients and in harmony with NABP, CVS Health respectfully requests the following changes:

Phar 7.51 Chart orders. A chart order shall contain all of the following:
(1) First and last name of the patient.
~~(2) Patient's medical record number or date of birth.~~
(2) Date of issuance.
(3) Name, strength, and form of the drug product or device prescribed.
(4) Directions for use~~.~~, and
(5) If written, the ~~P~~practitioner's written signature, or electronic or digital signature~~.~~ , or
(6) ~~Chart orders written by~~ The signature of a delegate of the practitioner ~~shall include~~, the first and last name of the delegate, and the first and last name of the practitioner.

The Task Force also discussed the need for chart order validity in a variety of different facilities, as the demographics of institutionalized patients is rapidly changing. Skilled nursing facilities are looking more and more like hospitals of years past; assisted living facilities are looking more and more like skilled nursing facilities of years past, and group homes are looking more and more like assisted living facilities of years past. The proposed definition of institutional facility recognizes this trend, by including facilities such as community-based

residential facilities. In the theme of the NABP Task Force Report and for consistency, CVS Health respectfully requests the following changes:

Phar 7.50 Definitions. In this subchapter
(2) "Institutional facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community-based residential facility, residential care apartment complexes, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 48.625, 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; a hospice facility under s. 50.90 (1) (c), Stats.; a county jail; and a correctional facility operated under the authority of the department of corrections.

E. Automation

CVS Health mail order pharmacies are highly automated and operate a six sigma level of accuracy. As a reminder, six sigma is a continuous quality improvement process often used in manufacturing to reach a goal of 3.4 defects (in this case prescription errors) per million, which is a 99.99966% accuracy rate. Our two pharmacies operate with a better accuracy rate than this standard (i.e. less than 3 defects or errors per million prescriptions filled). CVS Health respectfully requests that Phar 7.55's automated technology product verification allowances be extended to potential future Wisconsin based pharmacies that are not limited to product administered within institutional facilities.

Phar 7.55 Automated technology product verification
(3) ELIGIBLE PRODUCT. The automated technology may do the product verification if the product meets all of the following:
(a) Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date.
(b) Has a drug utilization review performed by a pharmacist prior to delivery, if required.
~~(c) Will be administered by an individual authorized to administer medications at the institution where the medication is administered.~~

We appreciate the opportunity to submit comments to the Pharmacy Examining Board for review. As you consider our comments, please contact me directly at 614-572-9008 if you have any questions.

Best regards,

John Long, RPh, MBA
Director, Pharmacy Regulatory Affairs CVS Health

cc: Debra Sybell
Jameson R. Whitney Esq.

Phar 7 Review by Kate Schaafsma

Section	Comments
7.03.2	**Comment**: We support the intent of requiring a DUR and an effort to collect pertinent clarifications as noted in 7.03.2. Acknowledging that pharmacists are sometimes restricted to information, we recommend the slight adjustment to part 2, adding the comment, "a good faith effort". **Recommendation**: Revise 7.03.2 by adding, "a good faith effort to mitigate or resolve the problem.
7.05.4	**Comments**: The intent of 7.05.4 is unclear as to whether it is limiting medication dispensing from physician offices or supporting distribution of samples. We agree with the intent of supporting sample medication distribution, but believe labeling should as align with requirements for other medications. **Recommendation**: Revise 7.05.4 by removing the exclusion of samples from labeling requirements with the exception of not requiring the need for items such as prescription order number, # of refills, etc.
7.06	**Comments**: Repackaging labels often are limited based on space. **Recommendation**: We support the intent of including NDC and recommend allowing a pharmacy control number in place of NDC.
7.08	**Comments**: We agree that a patient should be provided medication counseling prior to a prescription medication being dispensed to a patient each time. We support the continued use of professional judgement on the elements included in the medication counseling. **Recommendation**: Maintain additional guidance on the elements of medication counseling outside the statue of the law. Revise 7.08 to state, " (1) Patient consultation shall **be provided on each medication dispense."** Strike a-h, (2), and (6)
7.085.2	**Comments**: Verification of receipt should occur for all legend and controlled medications. **Recommendation**: Revise statement by removing, "controlled substances"
7.085.4	Comment: We agree with the intent of ensuring the patient has adequate supply of medication regardless of transaction method; however, the statement as it currently reads is too prescriptive to the detriment of the practice, patient, and pharmacist. Recommendation: Replace with "Pharmacy is responsible to ensure patient maintains access to the drug product or device."
7.09	Comment: The intent of 7.09.1 is unclear whether the statement is limiting medication distribution to wholesaler. Many products are currently distributed by licensed entities outside of wholesalers. Recommendation: Recommend to replace the word "wholesaler" with "entity". Suggested wording: "Procurement of prescription drugs and devices shall be from an ~~drug wholesaler~~ **entity** licensed by the board or U.S. food and drug administration to distribute..."
7.11.3.b	Recommendation: Change birthdate of pet to birthdate of pet not owner
7.52	Comment: It is unclear what "if applicable" means and what it refer to. We support the intent to identify the source of the reapackaged medication and support flexibility to use the NDC or a pharmacy control number. .

	Recommendation: Update to reflect NDC or pharmacy control number and remove, if applicable. support intent, recommend to include NDC or pharmacy control number and remove or clarify intent of "if applicable"

School of Pharmacy
UNIVERSITY OF WISCONSIN-MADISON

To the Pharmacy Examining Board:

Thank you for providing this opportunity for stakeholders impacted by the Phar 7 changes to provide their unique perspectives. The Board's proposed changes will bring Wisconsin pharmacy practice in line with current pharmacy standards and practice, including the heavily endorsed Pharmacists' Patient Care Process. (Joint Commission of Pharmacy Practitioners, 2014) This process is grounded in patient-centered care, in which the needs and values of the patient are prioritized above all else.

The International Pharmaceutical Federation standards of pharmacy practice set expectations that pharmacists should "ensure that health management, disease prevention and healthy lifestyle behaviors are incorporated into the patient assessment and care process." Pharmacist-led counseling is one method that ensures patients optimally benefit from drug therapy through individualized care plans, coordinated care, and improved knowledge of both medications and disease. (Okumura et al., 2014)

Pharmacist-led patient counseling is a valuable component of improving health across the state, especially in priority areas of chronic disease prevention and management, communicable disease prevention and control, mental health, reproductive and sexual health, and tobacco use and exposure - all critical elements in the Healthiest Wisconsin plan. (Wisconsin Department of Health Services, 2018) Pharmacist counseling has been demonstrated to reduce morbidity and mortality related to drug therapy in several studies, in addition to reducing costs of drug therapy. (Okumura et al., 2014)

Written information regarding safe and effective medication use alone is insufficient for many patients, as evidenced by a recently published study in which 72% of patients enrolled in mail order prescription delivery indicated the information sheets were never or rarely useful. (Desai et al., 2018) Although the majority of patients (68%) were aware of a phone number to access a pharmacist, 81% of patients never called. Over half of these patients (53%) indicated that more frequent conversations with a pharmacist could help them manage their conditions better. These findings are consistent with older studies which also found that when patients, who received only written medication information through mail order delivery, needed more information about their medications, they often asked no one. (Birtcher and Shepard, 1992)

The proposed changes in consultation requirements will result in new consultation requirements for mail order pharmacies. There is a substantial number of studies in the literature that compare medication use outcomes, such as medication adherence, between mail order and non-mail order retail pharmacies. A conclusion of several of the studies is that patients who

receive their medications from mail order pharmacies experience better medication use outcomes, such as adherence and better disease control, compared to patients who receive their medications from non-mail order retail pharmacies. An additional conclusion from the studies could be that there should be no concerns regarding the current lack of counseling requirement for prescriptions delivered via mail order.

However, it is important to note that the quality of evidence generated by a majority of these studies is very poor. (Fernandez et al., 2016) A strong majority of the studies suffer from selection bias or differences in characteristics of patients who use mail order or retail pharmacies in the analyses. The concern with selection bias is that patients who use mail order pharmacies tend to have characteristics such as higher income level, higher education level, higher health literacy, lower disease severity, better prior adherence behavior, etc. that are positively associated with being more adherent with medications or having better disease control. One is left wondering if the positive effect of mail order pharmacy on adherence is due to mail order pharmacy or to the characteristics of the patients who use mail order pharmacy. Further, simply controlling for these characteristics in a statistical analysis does not completely deal with the selection bias problem.

The best evidence would come from randomized controlled trials comparing the outcomes for patients randomly assigned to mail order pharmacies and randomly assigned to retail pharmacies. No such trials exist. The next best evidence would come from observational studies that use a statistical procedure to account for the non-random assignment of mail order pharmacy to patients (i.e. dealing with the selection bias issue). Two statistical procedures that are commonly used in observational studies are propensity score matching and estimation via instrumental variables.

There are at least five observational studies (Khandelwal et al., 2011; Schmittdiel et al., 2011; Duru et al., 2010; Zhang et al., 2011; Schwab et al., 2019) in the literature that compare medication use outcomes for patients using mail order pharmacy versus those using retail pharmacies that use either a propensity score matching approach or estimation via instrumental variables. The conclusions from the studies are equivocal. Some studies show positive benefits from using mail order pharmacy and some show no difference. When positive benefits are reported, they tend to be small differences, but small differences can be very important when applied to a population level. Additionally, there is very little information about why patients who use mail order pharmacies have better outcomes. No published information could be found that reports, for example, the proportion of mail order patients that request and or use written or oral information provided by mail order pharmacies.

It is important to note however, that these studies differ in the definition of mail order pharmacy they use to select patients who will be included in the mail order pharmacy group. Additionally, they differ in the patient populations that are studied and the geographic regions of the country in which the populations live. Also, no study has accounted for the variability in mandatory consultation requirements across states that could impact medication outcomes for patients using retail pharmacies. For example, no study has examined medication use outcomes for

patients using mail order pharmacy and retail pharmacy including only patients from Wisconsin. This is significant considering the mandatory counseling requirements for retail pharmacies in Wisconsin. In summary, although some good quality evidence suggests mail order pharmacies result in better medication use outcomes, some good quality evidence does not support better outcomes from mail order pharmacy. Also, good quality evidence is needed examining medication outcomes for mail order pharmacy and retail pharmacy using only patients living in Wisconsin.

Minorities, patients with limited health literacy, and patients with low income and education are not adequately represented in studies that show increased adherence with use of mail order pharmacies. (Ma and Wang, 2018) These vulnerable populations are at risk for confusion/misunderstanding of medication instructions leading to adverse events, and would benefit from consistent face to face interactions with a pharmacist for tailored counseling. In 2019, Governor Evers established executive order #17 which created a Health Equity Council charged with the development of a plan to reduce and eliminate health disparities based on race, economic status, and education level by 2030 (The State of Wisconsin Executive Department, 2019). This call to action is in response to the UW Population Health Institute's 2016 Wisconsin Report Card which shows an overall health disparities grade of a "D" for the State of Wisconsin. (University of Wisconsin-Madison Population Health Institute, 2016)

Although the rule as currently written requires counseling only with new and renewal prescriptions, patients can benefit from counseling at every refill. As Kimberlin et al. (2011) identified in her national observation study, states with strong consultation regulation such as Wisconsin had the highest frequency of oral consultation with medication. The strength of states' counseling regulation and opportunities for a pharmacist to directly hand the medication to the patient predicted whether patients received oral counseling with medication and risk information and appropriate questions. Per personal communication with the author, Wisconsin pharmacists performed the highest in this study (data collected in 2008).

Respectfully,

Betty Chewning, PhD, Professor
Mara Kieser, MS, Professor (CHS) and Assistant Dean, Experiential Education
Beth Martin, PhD, Professor (CHS) and Chair, Pharmacy Practice Division
David Mott, PhD, Professor and Chair, Social and Administrative Sciences Division
Kate Rotzenberg, Associate Faculty Associate
Olayinka Shiyanbola, PhD, Associate Professor

Citations

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Women's International Pharmacy
Custom Compounded Prescriptions for Men and Women

December 17, 2019

Sharon Henes, Administrative Rules Coordinator
Division of Policy Development
Department of Safety and Professional Services
4822 Madison Yards Way, 2nd Floor
PO Box 8366
Madison, WI 53708

RE: Proposed changes to Phar 7 patient consultation law

Dear Ms. Henes,

Women's International Pharmacy is a compounding pharmacy with a focus on bioidentical hormones for women and men. We are a local Madison business, founded in 1985 by a pharmacist with the passion to find unique, patient specific solutions to medical issues not typically addressed by traditional medicine.

Today our goals are the same as when we started: to use the highest quality ingredients to compound unique medications at reasonable prices and to support our patients with excellent customer service.

As a pharmacy with a unique area of practice, our medications are prescribed by practitioners and used by patients throughout the country. Women's International Pharmacy is a retail compounding pharmacy. We are not a mail order pharmacy. However, based on the demand for our compounded medications, Women's International Pharmacy is licensed in and ships to, all 50 U.S. states, the District of Columbia, Puerto Rico and Guam.

Women's International Pharmacy has the following concerns about the proposed changes to Wisconsin consultation law:

- Phar 7.08 (1) states "consultation shall include all of the following," but Phar 7.08 (2)(a) says "pharmacist may use professional judgment." Which is correct? 1 and

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2 are overlapping and confusing. **Recommend:** Remove Phar 7.08 (1)

- Consultation inclusion requirements are too specific in Phar 7.08 (1) and (2). This will not happen in practice. **Recommend:** Replace "shall" with "can" and add (i) other topics deemed necessary by the pharmacist.

- Requirement to provide **oral** consultation will provide an access issue for patients who receive their medications via common carrier. Written materials and a written offer to counsel are appropriate for medications delivered by common carrier. Patients are then able to contact a pharmacist at a time that works best for them. **Recommend:** 1. Retain current requirements (Phar 7.01 (1)(e)) OR 2. Add "or" between Phar 7.08 (2)(b) and (c)(d) OR 3. Substitute "is not practicable" for "is not in the best interest of the patient or patient's agent" in Phar 7.08 (2)(b).

- Oral consultation is not required prior to dispense. Once the medication is dispensed, what happens when the pharmacist is unable to reach the patient? According to the rule, oral consultation is required and an attempt does not satisfy this requirement. Pharmacists will find themselves trying to contact patients into infinity. This is unreasonable and not a good use of pharmacist time. **Recommend:** 1. Retain current requirements (Phar 7.01 (1)(e)) OR 2. Add "or" between Phar 7.08 (2)(b) and (c)(d) OR 3. Substitute "is not practicable" for "is not in the best interest of the patient or patient's agent" in Phar 7.08 (2)(b).

- The current consultation requirements are sufficient. The Board has discussed and concluded in previous meetings that they have not seen documented complaints leading to harm caused by not requiring oral consultation for medications delivered via common carrier. **Recommendation:** 1. Retain current requirements (Phar 7.01 (1)(e)) OR 2. Add "or" between Phar 7.08 (2)(b) and (c)(d) OR 3. Substitute "is not practicable" for "is not in the best interest of the patient or patient's agent" in Phar 7.08 (2)(b).

- Other states do not require oral consultation for medications delivered by common carrier. If the lack of oral consultation for these medications was causing patient harm, these states would change this rule. However, they have not. **Recommendation:** 1. Retain current requirements (Phar 7.01 (1)(e)) OR 2. Add "or" between Phar 7.08 (2)(b) and (c)(d) OR 3. Substitute "is not practicable" for "is not in the best interest of the patient or patient's agent" in Phar 7.08 (2)(b).

- Specifying oral consultation limits the use and progress of technology. Some pharmacies may use a secure website where patients can ask questions and receive consultation via text. Undoubtedly, there are other innovations in the pipeline that will be hindered by the language of this rule. **Recommendation:** 1. Retain current requirements (Phar 7.01 (1)(e)) OR 2. Add "or" between Phar 7.08 (2)(b) and (c) (d) OR 3. Substitute "is not practicable" for "is not in the best interest of the patient or patient's agent" in Phar 7.08 (2)(b).

- **Economic impact analysis for Women's International Pharmacy**: Based on prescription volume and a 10 minute consultation per prescription, Women's International Pharmacy would have to hire 5 additional pharmacists to complete consultations for all new and changed prescriptions. Based on an average pharmacist's salary in WI ($104,990), this would incur an additional $524,950 per year in payroll costs. **Recommendation:** 1. Retain current requirements (Phar 7.01 (1)(e)) OR 2. Add "or" between Phar 7.08 (2)(b) and (c)(d) OR 3. Substitute "is not practicable" for "is not in the best interest of the patient or patient's agent" in Phar 7.08 (2)(b).

We hope you will take into consideration our concerns and recommendations in drafting the final version of Phar 7. Should the current version stand, Women's International Pharmacy would find it necessary to either curtail our services or pass the additional costs on to our patients, neither of which would be good for our patients or for our business.

Sincerely,

Gina Besteman, R.Ph.
Director of Compounding and Dispensing

Michelle Violi, Pharm.D.
Dispensing Pharmacists Manager

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December 17, 2019

Testimony to the Wisconsin Pharmacy Examining Board
Opposition to Proposed Repeal and Rewrite of Phar 7 as Drafted
George Kowalski, RPh, Vice President Retail Pharmacy

Chair Trapskin, members of the Board – thank you for the opportunity to testify today. I am George Kowalski, Vice President of Retail Pharmacy for Advocate Aurora Health. I am here today to voice our opposition to the rewrite of Phar 7 as it is currently drafted. We understand that there is some urgency to move this draft forward because of procedural deadlines, but we respectfully ask that the proposal be modified before doing so.

For background, Advocate Aurora is among the largest not-for-profit health systems in the United States and the leading employer in the Midwest. We employ more than 70,000 people throughout Wisconsin and northern Illinois, and we see nearly 3 million unique patients per year. In Wisconsin, our service area covers the eastern part of the state, where we have 71 pharmacy sites including traditional pharmacies, remote dispensaries, a central fill, a mail order pharmacy and a specialty pharmacy, 150+ clinics and 16 hospitals.

My testimony on Phar 7 today follows the written comment and economic impact estimate we submitted for the Board's consideration over the past two months. In the time since we and others provided that feedback, some of the problematic provisions initially under consideration – like the proposed changes to remote dispensing managing pharmacists – have been removed. We sincerely appreciate that the Board was responsive and alleviated those concerns. Thank you for addressing those important issues.

However, the proposed rewrite of the patient consultation requirements in section 7.08, which would require oral consultation in mail order pharmacy, remains extremely problematic. Simply put, it appears to us to be a solution in search of a problem and would likely have an adverse effect on patient care and the practice of pharmacy in our state.

Our current mail order operations are highly sophisticated. We fill between four and five thousand packaged prescriptions daily. Our pharmacists have access to real time medical information through our integrated health records, make clinical interventions where warranted, provide consultations per their professional judgement and are held to strict standards to ensure that our patients have the medications they need when they need them. We work diligently to achieve an optimal balance of safety and outcomes. We can demonstrate that our patients have significantly better adherence than traditional retail settings and have fewer dispensing errors as well.

Yet, unfortunately, the proposed rule before us today appears to ignore these successes in favor of a "one size fits all" mandate. This blanket requirement for oral consultation may look good at first glance, but as we and others pointed out in our written comments, it would almost immediately lead to delays in therapy and risk harm to our patients.

In response to this critique, the state's economic impact analysis claims that the "proposed rule does not indicate *when* the consultation needs to occur." The implication of this statement is that a pharmacist could fulfill the proposed requirement by consulting the patient sometime after dispensing the treatment. But in that case, there is little value to a consultation. Why would any patient want to be informed of a drug's expected action, directions or precautions, *after* they may have already taken the medication?

Further, the Board's economic impact analysis also seems to argue that the change to Phar 7.08 will not have a substantial impact because pharmacies already provide consults on mail order when it is in the best interest of the patient. But, if the Board understands this is already happening when necessary (and it is), then there is no need to implement a broad mandate that will decrease efficiency and increase cost. The current regulatory requirements work precisely because we allow for pharmacists to use professional judgment. The proposed rules are clearly moving toward something stricter, although there is seemingly no rational justification such a change. If the Board has data that indicates otherwise, I respectfully ask that this information be shared so that we can all have a clear understanding of the need to implement stricter rules.

We at Advocate Aurora would be happy to work with the PEB, DSPS, and other stakeholders if there is interest in finding solutions to these issues. My team has as one of our rules of engagement that we always "Assume positive intent". However, this proposal as it is currently written, although well intended, would do more harm than good. Therefore, I ask that you revise the draft to continue allowing mail order pharmacies to provide safe, efficient and convenient service to our patients by trusting our pharmacists' professional judgment.

With that, I'd be happy to answer any questions. Thank you for your time and consideration.

SERVE YOU Rx
SERVE-YOU-RX.com
10201 West Innovation Drive Suite 600 Milwaukee WI 53226

December 13, 2019

Sharon Henes, Administrative Rules Coordinator
Division of Policy Development
Department of Safety and Professional Services
PO Box 8366
Madison, WI 53708-8935
Via email: DSPSAdminRules@wisconsin.gov

Re: Public Comment Submission on Phar 7

Members of the Board, Chairperson Trapskin,

Serve You Rx is a mail-order pharmacy based in Milwaukee that has served patients in Wisconsin and across the nation since 1992. Thank you for allowing us to submit comments regarding the proposed Phar 7 language. Though we have submitted similar comments before, we want to ensure that our message is clear, and our concerns are included in the proposed rule's report to the chief clerk of each house of the legislature.

Serve You Rx is deeply concerned about the language used in Phar 7.08 and how it was drafted. Firstly, the language on counseling will interrupt and delay patient care for mail-order patients. Under the proposed language, a pharmacist is required to provide oral consultations for new prescriptions, unless she deems that it is not in the best interest of the patient to be communicated orally. "[B]est interests of the patient" is not defined, forcing the pharmacist to determine what is required in the mail order setting. In an attempt to ensure that her interpretation does not differ from the Board's interpretation, the mail order pharmacist is left in a position to make phone calls for many if not all new prescriptions.

This requirement is replete with problems and will delay care. Patients may not answer their phones, particularly as many individuals do not answer 1-800 calls. Leaving HIPAA-compliant voicemails will not give patients enough information to know how important calling back will be. And, forcing pharmacists to determine in their professional judgment how long to hold a prescription until oral consultation is delivered will impede the patient's receipt of their prescription and delay care for an untold number of patients.

This problem is compounded because the Board has confirmed that it cannot provide position statements or guidance on the rules that it publishes. Leaving vagaries in the rule such as "in the best interest of the patient" will only lead to difficult implementation of the rule and contentious disciplinary hearings in the future. Reasonable pharmacists can disagree on the best way to serve mail-order patients. The conversation around the construction of this rule is a perfect example of that. Even the statement that the rule does not dictate that the consultation occur prior to dispensing leaves the mail order pharmacist in the predicament of determining whether it is best to provide the prescription and hope that later phone calls might result in oral communication with the patient.

This proposed language is out of step with the requirements of our neighboring states as well as the remaining 45 states in the country. Illinois and Iowa use language stating that when a pharmacist determines that oral counseling is not practicable, the pharmacist may issue an alternative form of patient consultation. Michigan states that oral counseling should be used unless the patient is not physically at the pharmacy. Minnesota states that consultation for prescriptions mailed or delivered by common carrier or delivery service may be accomplished by providing written information to the patient. The exact regulatory language is included in Appendix A to this statement.

The proposed Phar 7.08 language is unique. It does not state that written consultation may take the place of oral consultation. It does not provide a straightforward exception for cases where the patient is not physically at the pharmacy. And it does not provide an exception for pharmacists who determine oral consultation is not practicable. The proposed Phar 7.08 language provides an exception for when the pharmacist believes it is not in the patient's best interest for consultation to be communicated orally. While this may seem similar to the Illinois and Iowa language, it forces the pharmacist into an entirely different decision making process. Determining whether oral consultation is not practicable and whether oral consultation is in the patient's best interest are not the same thing. This Board has not yet explained why it is using a different approach than our neighboring states as required at Wis. Stat. 227.137(a).

Furthermore, the Board has not examined what implementation and compliance with the proposed Phar 7.08 language will cost businesses. In the previous Board meeting, the Pharmaceutical Care Management Association submitted a comment that proposed Phar 7.08 would cost some of its member companies close to $30 million over a two-year time period. This Board, stating that the proposed language does not change current practices in Wisconsin, disregarded that number. If the proposed language does not change current practices, there is no reason to change the language. For Serve You Rx alone, orally consulting patients for new prescriptions or changes in therapy would cost no less than $2.5 million in the first year, with much of those costs repeating in following years. This includes implementation and compliance costs that are reasonably expected to be incurred due to multiple calls to reach patients by phone. It will require increased pharmacist staff, increased technician staff, and additional pharmacy management equipment.

The costs of the proposed rulemaking logically extend beyond Serve You Rx. Increased cost will be experienced by most mail and delivery facilities, both those in Wisconsin and those providing services to Wisconsin. This includes the growing segment of retail pharmacies offering the convenience of prescription delivery. Based on industry comment at the last meeting, the calculation far exceeds the $20 million threshold that our Legislature established whereby the rulemaking must go through additional steps to fully consider the effects of implementation and compliance. It is concerning that the Board dismissed the costs that numerous businesses identified to the Board. It is equally concerning that the Board did so in order to rush a rule through the process, knowing it was against a deadline.

SERVE YOU Rx
SERVE-YOU-RX.com
10201 West Innovation Drive Suite 600 Milwaukee WI 53226

The current language at Phar 7.01(1)(e) provides instructions for pharmacies delivering prescriptions to a location of the patient's choice. This language has worked for the last 15 years and there is no reason to amend it. The only modern modification to this rule was in 2013, allowing pharmacies to deliver to any location of the patient's choice instead of just their residence. When this Board amended Phar 7.01(1)(e) at that time it did not see a reason to change the language regarding consultation and in fact stated that the rule is beneficial to patients and pharmacies without negatively impacting public safety. Serve You Rx complies with this language and has safely provided patients in Wisconsin with their prescriptions for over 25 years, including access 24/7 to a pharmacist.

No one is arguing that patient consultation should be skipped or has no value. But the language proposed at Phar 7.08 creates a new standard that no other state currently adheres to. Mail-order pharmacies face a different set of circumstances than community pharmacies. They have been able to provide patients with their prescriptions efficiently, timely, and safely under the current rules in Wisconsin and throughout the rest of the country. There is no reason for Wisconsin to upend current practices and create a burden that would stand in the way of modern practices. Serve You Rx urges you one more time to amend the proposed language at Phar 7.08 so that it is in line with the rest of the country. Thank you for your time.

Best regards,

Cindy Ten Pas
Director of Compliance
Serve You Rx

Appendix A

Illinois:
"If, in the pharmacist's professional judgment, oral counseling is not practicable for the patient or patient's agent, the pharmacist shall use alternative forms of patient information." Ill. Admin. Code tit. 68, pt. 1330.700(b)

Iowa:
"If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may select and use alternative forms of patient information which shall include information for the patient or patient's caregiver to contact the pharmacist for further consultation. ... 'Not practicable' refers to patient variables including, but not limited to, the absence of the patient or patient's caregiver...." Iowa Admin. Code r. 657-6.14(4)

Michigan:
"The information shall be communicated orally and in person, except when the patient or patient's caregiver is not at the pharmacy or when a specific communication barrier prohibits oral communication. In either situation, providing printed material designed to help the patient use the medication safely and effectively satisfies the requirements of this subrule." Mich. Admin. Code r. 338.490(4)(a)

Minnesota:
"When a new filled prescription or a refilled prescription for which counseling is required is being mailed or delivered to the patient by common carrier or delivery services, the consultation must still be provided but may be accomplished by providing written information to the patient regarding the medication being dispensed and the availability of the pharmacist to answer questions, and through the provision of a toll-free phone number for long distance calls." Minn. R. 6800.0910(2)(B)

HOMETOWN PHARMACY

Pharmacy Examining Board

Dear Members of the Pharmacy Examining Board:

We thank you for receiving and considering comments on the proposed changes to Phar 7 and ensuring proper procedures are in place for patients and taxpayers.

We strongly believe it is critical for patient safety **that each patient receive their original and renewal prescription fill in person.** The patient consultation components, outlined in proposed Phar 7.08, reiterate the importance of patients being consulted on their medication, and especially the importance of the first fill patient-pharmacist interaction:

> ***Proposed* Phar 7.08 Patient consultation.** (1) Patient consultation shall include all of the following:
>
> (a) Name and description of the drug.
> (b) Form, dose, route of administration and duration for drug therapy.
> (c) Intended use of the drug and expected action.
> (d) Special directions and precautions for preparation, administration and use by the patient.
> (e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
> (f) Techniques for self-monitoring drug therapy.
> (g) Proper storage and appropriate disposal method of unwanted or unused medication.
> (h) Action to be taken in the event of a missed dose.

Wisconsin for many years felt this initial consultation was so important that it mandated on every fill.

> **Phar 7.01 Minimum procedures for compounding and dispensing. (1)** Except as provided in sub. (4), a pharmacist or pharmacist–intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist or pharmacist–intern as directed and supervised by a pharmacist shall:
>
> ...
>
> (e) Give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a location of the patient's choice if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a location of the patient's choice, is not satisfied by only offering to provide consultation.

Any exemption to Phar 7 which allows patients to get their original fill by mail order, where no consultation exists, simply puts patient's safety and health at risk. We are very concerned about a

process in which a patient would receive a new prescription and not receive the important patient consultation information contained in proposed Phar 7.08 (1) (a), (b), (c), (d), (e), (f) and (g) all on their own. And we question the situation in which professional judgment would deem that a patient should not receive consultation on new medications they are receiving.

One of the most critical times for a patient is when they are released from a care facility. That transition of care, especially starting their proper prescription protocols, is very important for their health and recovery. Studies have shown that proper adherence to prescription protocols, reduces readmission and improves patient outcomes. Without a consultation, how can someone "professionally judge" whether a patient is taking an over the counter (OTC) product or who has a diet consisting of something that could negatively interact with a medication? Removing this critical and basic consulting component is not in the best interest of patients nor taxpayers.

Under the current regulatory scheme, we already field calls from our community members who, with no choice, are forced into mail order. They feel abandoned. In fact, weekly there are many instances where our former patients, who have been forced into mail order, still call us and ask our pharmacists to explain their medications and the potential side effects.

The Pharmacy Examining Board (PEB) plays a critical role to help protect patients. And we believe the consultation component requirements outlined in proposed **"Phar 7.08 Patient consultation"** are critical for protecting patients. We have serious concerns that those requirements can be avoided if a patient is required to, or chooses to, receive their medication via mail order. We urge the PEB to ensure every patient is protected and receives a consultation.

Sincerely,

Dan Strause, President
Hometown Pharmacies of Wisconsin

Abbi Linde, PharmD

Owner Beaver Dam Hometown Pharmacy

Hometown Pharmacy Director of Clinical Services

920.356.1500 alinde@hometownpharmacywi.com

Dear Members of the Pharmacy Examining Board:

Thank you for receiving and considering comments on the proposed changes to Phar 7 and ensuring proper procedures are in place for patients.

The role of the Pharmacy Examining Board (PEB) is to define the active practice of pharmacy and establish minimum standards for the practice of pharmacy. There has been much discussion about how the new proposed rules will affect pharmacies both in state and out of state, but the "practice of pharmacy" is actually intended to provide a minimum level of practice such that patients are able to receive and utilize medications appropriately and safely. In other words, the role of the PEB is to ensure patient safety. How can we as healthcare professionals ensure patient safety without consultation? Why do only some Wisconsin patients deserve that? As only 12% of adults have proficient health literacy, (Kutner, 2003) I have particular concern for patients with complex medication regimens and low health literacy that are forced to receive their medications without consultation due to insurance and PBM requirements. I personally believe they all equally deserve that consultation and that it is the responsibility of the board to ensure that all pharmacists serving Wisconsin patients meet that requirement.

In our pharmacy, we are not anxious to decrease the amount of time we are talking with our patients. In fact, as part of our medication synchronization we are implementing a pre-fill call to our patients to ensure adherence and coordinate any changes or problems. To repeat, we want to talk to our patients MORE, not LESS because this is what is best for the patient. The feedback we have received has been overwhelmingly positive that more contact with pharmacy staff is appreciated and beneficial to the patient with regards to adherence, patient satisfaction, and presumably clinical outcomes and healthcare costs overall.

The Pharmacy Examining Board's primary and critical role is to establish a minimum requirement of practice to help protect the public. I have serious concerns that those requirements can be avoided if a patient is required or chooses to receive their medication via mail order. I urge the PEB to hold all pharmacies and pharmacists to the same standard.

Sincerely,

Abbigail Linde, PharmD

Reference List

Kutner M, Greenberg E, Jin Y, Paulsen C. The Health Literacy of America's Adults: Results from the 2003 NationalAssessment of Adult Literacy [Internet]. U.S. Department of Education. Washington, DC: National Center for Education Statistics. 2006 Sep 6 [cited 2013 Feb 27]; NCES 2006–483. Available from: http://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2006483

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Wednesday, October 30, 2019 12:48 PM
To: Henes, Sharon - DSPS
Subject: FW: Proposed Rule Change Phar 7.08 Patient Counseling.

From: Mike Zagelow <mzagelow@hometownpharmacywi.com>
Sent: Wednesday, October 30, 2019 12:13 PM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: Proposed Rule Change Phar 7.08 Patient Counseling.

Dear Executive Director Sybell,
I am writing to express my support for the proposed rule change regarding patient consultation requirements in wisconsin and to specifically express the need for this rule to be consistent across all pharmacy dispensing models including mail order.

Along with my partners (Hometown Pharmacy) I own an independent pharmacy that has been at the center of pharmacy patient care on the same corner in Fort Atkinson since 1876.

I would like to share the example of my patient Sandy (name changed to protect her privacy) as an example and would be glad to share or have someone read this example at a future meeting.

Sandy works at a local factory here in Fort Atkinson. Sandy and her husband have been coming to our pharmacy for nearly 50 years. They both have complicated medical histories and, as the pharmacist/owners before me, I always take the time to answer Sandy's questions, review many of the counseling points in Phar. 7.08 and when busy, also call to follow up after hours to ensure Sandy and her husband are well educated and cared for.

Last week Sandy called me in tears because at meeting at her factory they informed everyone that for 2020 they would be implementing mandatory mail order and that patients would be required to get prescriptions filled at their PBM's mail order facility for prescriptions to be covered. Sandy is concerned and has talked to her HR department and legislators who have told her there is nothing they can do to help her.

My belief is that the best way to optimize patient care would be for patients to always be able to go to the pharmacy of their choice to empower patients to hold pharmacies accountable to offering the best patient care.

Minus that solution, requiring all pharmacies (including mail order) to meet minimum consultation standards will be the best alternative to ensure that if, PBM's are going to make the money grab of forcing patients to their own mail order pharmacies, patients like Sandy and her husband will be as protected and as well cared for as possible in that pharmacy model.

Thank you for your leadership on this issue and persistence in the face of what undoubtedly will be a strong push by mail order asking to continue compromising patient care by lowering standards for them.

Mike Zagelow, RPh.

Proposed Rule Change
Phar 7.08 Patient Counseling. (1) Patient counseling shall include at least one of the following: (a) Name and description

of the drug. (b) Dosage form, dose, route of administration and duration for drug therapy. (c) Intended use of the drug and expected action. (d) Special directions and precautions for preparation, administration and use by the patient. 9 (e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur. (f) Techniques for self-monitoring drug therapy. (g) Proper storage and appropriate disposal method of unwanted or unused medication. (i) Action to be taken in the event of a missed dose. (j) Assessment of the drug's effectiveness in meeting the patient's treatment goals and..

Mike Zagelow R.Ph
Fort Atkinson Hometown Pharmacy, 102 S. Main Street, Fort Atkinson, WI 53538 Phone: (920)563-6245 Fax: (920)563-2792
Janesville Hometown Pharmacy and Real Estate, 21 S. Jackson Street, Janesville, WI 53548 Phone: (608)752-7869
Cell: (608) 289-1132 mzagelow@hometownpharmacywi.com Direct Fax: (855) 778-6440

HAYAT
PHARMACY

12/16/2019

Dimmy Sokhal, PharmD

Hayat Pharmacy

414-465-8406

Thank you Chairman Trapskin to allow me share my comments about Phar 7 update with the Pharmacy Examining Board. I wanted to write regarding the counseling rule, specifically 7.08(2).

I believe that all pharmacists dispensing the medication should be responsible, we have had several instances where the patients are confused on how to take the medications even after taking it for several years. It is very valuable to consult patients on refills as it helps gather information about ongoing adverse effects and barriers to compliance.

We are referred several patients by caregivers, prescribers and community health workers to assist with the patients who get their medications delivered by mail order. These patients are often lost and confused about their medications and call their local community pharmacists to get the answers. I believe healthcare rules and regulations should be same across the board irrespective of what kind of pharmacy dispenses the medications as the risk of drug therapy problems is similar for the patients.

I would strongly support that all the prescriptions are consulted regardless if they are new or refills by the pharmacy that dispensed the prescription.

I want to thank the pharmacy examining board for their time.

Dimmy Sokhal, PharmD

Walgreens

Tomson George, R.Ph.
Director, Pharmacy Affairs
Walgreen Co.
200 Wilmot Rd. MS#2273
Deerfield, IL 60015
p: 847-315-2103
tomson.george@walgreens.com

December 16, 2019

Submitted via eMail
DSPSAdminRules@wisconsin.gov

Wisconsin Pharmacy Examining Board
4822 Madison Yards Way
Madison, WI 53708

To Whom It May Concern:

On behalf of our two-hundred fifty (250) pharmacies which provide care to patients living in the State of Wisconsin, Walgreens appreciates the opportunity to provide comments on the proposed revision to Phar 7 – 7.08 regarding patient consultation.

Proposed Phar 7.08 – Patient Consultation
Walgreens appreciates the efforts made by the Rules Committee and the Board in focusing on the proper support for patients who are not familiar with their medications.

When reviewing the proposed rules, we understand that the Board was determined to ensure that every patient should experience the same access to drug information, regardless of the practice setting of the dispensing pharmacy. However, we think it is important to note that in many cases, the patient's experience is ultimately tied to the practice setting, and applying the exact same standard in every sense is not practical, nor necessary. For example, a differentiation in practice standards between the community and institutional practice settings is very common.

The proposed rules seem to offer an opportunity for the pharmacist to engage with patients in a manner that supports the patient's best interest, while also providing written materials, and advising the patient or patient's agent that the pharmacist may be contacted for consultation. While the proposed rule does provide patients with the appropriate access to drug information, we believe the current language may produce confusion in some practice settings, and possibly delay therapy. We respectfully offer the suggested edit indicated below, which rephrases 7.08 (2) (b) in a manner that is easier to follow:

- *(b) Be communicated orally to the patient or patient's agent when, using the pharmacist's professional judgement, ~~unless in the pharmacist's professional judgment~~ it is ~~not~~ in the best interest of the patient ~~or patient's agent~~ to be communicated orally.*

In addition, we observed some redundancy between paragraphs (1) and (2), and we recommend striking paragraph (1) altogether to consolidate and reduce potential confusion.

Walgreens thanks the Board for considering our comments on this rulemaking. Please do not hesitate to contact me with any questions or for further assistance

Sincerely,

Tomson George R.Ph.

Henes, Sharon - DSPS

From: Daniel Funk <djfunk@uwalumni.com>
Sent: Tuesday, December 10, 2019 8:00 AM
To: DSPS Admin Rules
Cc: NOAH ANDREW KAITZ; SYDNEY CLAIRE ERTZ; emiesbauer@wisc.edu; petersonwebe@wisc.edu; Samantha Lewiston
Subject: Comments on Phar 7

Hello,

My name is Dan Funk, and I am the policy liaison for the Wisconsin Society of Pharmacy Students, the student organization that confers membership to the Pharmacy Society of Wisconsin, American Pharmacists Association, and American Society of Health-System Pharmacists at the University of Wisconsin-Madison School of Pharmacy. I recently met with a small group of members of our organization's policy committee to discuss the revisions of Phar 7 related to pharmacist consultations. We are in general agreement with most of the changes that have been proposed, but did find a few areas that we believe could be revised. I have included some of the comments that we discussed during this meeting below for your consideration.

1. Some members of our committee have concerns about the wording in 7.08 (2)(a) and (6) regarding a pharmacist's use of "professional judgement" to decide whether to omit information from consults and whether to consult patients for refill prescriptions respectively. We agree with the idea that consultations should not be required for all refill prescriptions, but some members feel that the language may give pharmacies a license not to consult on any refill prescriptions or to omit important information during consultations. Ideally, pharmacists should provide consultation for refill prescriptions that they believe will provide the most value to the patient or help to avoid any safety issues, and our concern is that pharmacists may not be held accountable for neglecting to provide consultations in such cases. I do not have any specific suggestions to revise the wording, but would be interested in exploring possible changes to ensure pharmacist accountability and patient safety.

2. Unless addressed elsewhere in the proposal, we are curious as to why the language about pharmacy intern involvement was removed from 7.08.

3. Our committee was also concerned with the proposed idea that no consultation should be offered for administered medications. Obviously items required for a traditional consultation such as what to do when a dose is missed and instructions for administration are not applicable to pharmacist-administered medications, but pharmacists should be required at a minimum to present the patient with the name of the medication, what it is used for, and potential side effects they may encounter prior to administering the medication. Perhaps it would be more appropriate to provide an abbreviated list of required counseling points for pharmacist-administered medications rather than excluding any consultation requirement.

Finally, another student reached out to me regarding a petition to change the wording in a different section, 7.03 (1)(d), to exclude gender from the list of patient factors to consider when pharmacists perform a DUR. While differences in a patient's sex are sometimes clinically relevant to medications, a patient's apparent gender is often not helpful in making clinical decisions. Considering a patient's apparent gender while performing a DUR could lead to medication errors or mistakes that indicate poor cultural competency. I have included a link below to the petition, which includes the petition's author Thad Schumacher's argument for this revision.

https://forms.gle/Bpv8MWnGzBF3GNF39

Thank you very much for considering the Wisconsin Society of Pharmacy Students' comments on the proposed Phar 7 revisions. I am unable to attend the public hearing on December 17th, but please do not hesitate to follow up with me with any questions or points of clarification.

Best,

Daniel J Funk, DPH-2
B.S. Biochemistry, University of Wisconsin-Madison
Doctor of Pharmacy Candidate 2022
University of Wisconsin-Madison School of Pharmacy
Wisconsin Society of Pharmacy Students- Policy Liaison
Tel: (262) 220-9077

December 9, 2019

Dear esteemed members of the Wisconsin Pharmacy Examining Board,

I would like to take the opportunity to comment on the Phar7 revisions as it pertains to patient consultation:

As a pharmacist who specializes in the delivery of MTM Services across the nation, I see firsthand how important consultation is to patient safety. I am continuously shocked by the lack of patient communication which includes instructions one would consider basic knowledge. This lack of communication has led to errors, safety concerns, increased healthcare costs, and more. Just the other day, a pharmacist on my team consulted a low-health literacy middle-age gentleman in another state (which does not require consultation) who was taking:

- 4 different beta-blockers
- Multiple prescriptions of furosemide, totaling 300mg/day
- 3 different statins totaling 240mg/day
- 2 different prescriptions of hydralazine
- 3 different prescriptions for isosorbide dinitrate
- And 2 high risk medications: zolpidem and cyclobenzaprine

All of these medications were from three different physicians. As my pharmacist coordinated care with his prescribers and circled back with the patient to educate him on what to take and what NOT to take, he told her he felt like he was "slipping away." He was confident he was going to die from his medications, which were prescribed in good faith. I was grateful for the care our pharmacist was able to provide to this man and for the timing of her intervention.

I know you are also practicing pharmacists and have seen stories like this in your careers. I thought I would showcase this one that is recently near and dear to my heart as a good example of how consultation may have caught these issues. **Therefore, I support wording which ensures every patient or their agent is counseled on new or changed prescription therapy at a minimum.**

Now, in reading the proposed rule – I do have some specific feedback as it relates to the wording:

- "A pharmacist must consult the patient or patient's agent for every new prescription which has not been dispensed previously to the patient or any change in the patient's therapy. "
    - This sentence is confusing. I recommend it be restated for clarity.
- "A consultation is not required when a health care provider is administering the medication or if a patient or patient's agent refuses consultation."
    - I recommend this language possibly be strengthened. I have witnessed first-hand technicians asking patients if they want to be counseled and patients not understanding what that means. I have worked in states where the clerk simply says "sign here" (with no other explanation) and it is a form stating the patient refuses consultation.
    - I'm not sure this was the intent of the board and would recommend this language be revisited.

Thank you for your time today. I appreciate the opportunity to share my thoughts. Please reach out if you would like clarity on anything I have written.

Cordially,

Erika Horstmann Pharm.D.

Erika Horstmann, Pharm.D.
MTM Operations Manager, Patient Engagement Team
OutcomesMTM®, a Cardinal Health Company
Phone: 608-443-9658
Email: erika.horstmann@cardinalhealth.com

My comments above are my own personal remarks and not the remarks of my employer.

November 29, 2019

Sharon Henes, Administrative Rules Coordinator
Division of Policy Development
Department of Safety and Professional Services
PO Box 8366
Madison, WI 53708-8935
VIA EMAIL: DSPSAdminRules@wisconsin.gov

RE: Comments on Proposed Oral Counseling Rule

Dear Ms. Henes:

Enclara Pharmacia respectfully submits the following comments to the Wisconsin Pharmacy Examining Board (the "Board") on the Board's proposed oral counseling rule.

Enclara Pharmacia is the largest provider of pharmacy services to hospices in the country, including to 1,676 patients in Wisconsin in 2019. We have mail service pharmacies in Memphis, Tennessee (WI License Number 185-043) and Sharon Hill, Pennsylvania (WI License Number 210-043), as well as a pharmacy call center in Philadelphia, Pennsylvania (WI License Number 564-43).

Enclara Pharmacia dispenses medications to patients at home and in health care facilities. Hospice staff, primarily nurses, directly manage the care for these patients, including their medication therapy. An interdisciplinary team, which includes input from a pharmacist, manages the patient's care while the patient is on hospice. This team meets frequently to review the patient's care. In addition, throughout the patient's enrollment, hospice staff are consulting with the patient and family on the course of treatment. As such, mandatory oral patient counseling prior to dispensing medications to hospice patients would be unnecessary and create needless delays in care.

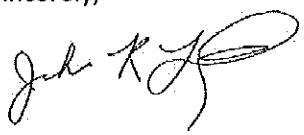
Enclara Pharmacia believes requiring verbal counseling prior to dispense would not be in the best interest of patients on hospice. Our patients often lose their ability and/or capacity to communicate verbally which would make a phone call an ineffective form of counseling. As mentioned above, hospice nurses visit the patient regularly to manage their clinical needs, order medications and update the patient and family on treatment.

In addition, the time to reach a hospice patient by phone, if possible, is unknown and variable. Requiring oral counseling prior to dispense will delay the delivery of urgently needed medications and may cause undue suffering for the patient. Providing written counseling materials with a toll- free phone number allows the hospice patient to call and speak to a pharmacist if able, however we find hospice patients rarely contact the pharmacy for counseling. Once again, the routine hospice nurse visits ensure patients receive both medications and information timely, and pharmacists provide input to the interdisciplinary care team while the patient is on service, ensuring the team has the most up-to-date information on medication therapy.

Given the unique challenges and needs of our patients and the potential harm this rule could cause, Enclara Pharmacia urges the Wisconsin Pharmacy Examining Board to exempt patients enrolled in hospice from the oral counseling requirement.

Thank you for you for the opportunity to comment. Please contact me at jloxterman@enclarapharmacia.com or 215.282.1737 if you have any questions.

Sincerely,



John R. Loxterman
SVP, Chief Ethics and Compliance Officer

Henes, Sharon - DSPS

From: Audley, Terry <terry.audley@froedtert.com>
Sent: Friday, November 22, 2019 11:24 AM
To: DSPS Admin Rules
Subject: Phar 7 Comments
Attachments: Phar 7 with feedback.pdf

Thank you for the opportunity to review and provide comments on revisions to Phar 7.

In general I have found a lack of consistency regarding the requirement to provide consultation and the ability of a pharmacist to use professional judgement to NOT provide consultation.

I agree with the elements of a consultation and believe consultation needs to be offered for initial fill and all refills and allow the patient or agent of the patient to refuse consultation.

I also note the omission of pharmacy students in the document and advocate for adding pharmacist student in any area citing pharmacist interns as well as in line 2.

Ms. Terry Audley, RPh, FASHP
Pharmacy Clinical Manager
PGY1 Residency Program Director
Phone: 262-257-3077
email: terry.audley@froedtert.com

Froedtert & the Medical College of WI
Community Memorial Hospital
W180 N8085 Town Hall Road
Menomonee Falls, WI 53051
froedterthealth.org | communitymemorial.com

Handwritten notes are from Terry Audley's document which contained note comments.

PROPOSED REQUIREMENTS

Phar 7.08 Patient consultation.

(1) Patient consultation shall include all of the following:

(a) Name and description of the drug.

(b) Form, dose, route of administration and duration for drug therapy.

(c) Intended use of the drug and expected action.

(d) Special directions and precautions for preparation, administration and use by the patient.

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(f) Techniques for self-monitoring drug therapy.

(g) Proper storage and appropriate disposal method of unwanted or unused medication.

(h) Action to be taken in the event of a missed dose.

Pharmacy intern and pharmacy student under the direction of the pharmacist should be included here

(2) A pharmacist shall give the patient or patient's agent consultation relative to the prescription for any new drug product or device which has not been dispensed previously to the patient or any change in the patient's therapy. Patient consultation shall meet all of the following requirements:

(a) Contain all of the following information, unless in the pharmacist's professional judgment it serves the best interest of the patient to omit or vary the content of the consultation:

I would exclude this, it allows variation and a subjective call

1. Name and description of the drug.
2. Form, dose, route of administration and duration for drug therapy.
3. Intended use of the drug and expected action.
4. Special directions and precautions for preparation, administration and use by the patient.
5. Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
6. Techniques for self-monitoring drug therapy.
7. Proper storage and appropriate disposal method of unwanted or unused medication.
8. Action to be taken in the event of a missed dose.

same issue as above, too much subjectivity allowed

(b) Be communicated orally unless in the pharmacist's professional judgment it is not in the best interest of the patient or patient's agent to be communicated orally.

(c) Provide written documentation of the information in par. (a) 1. to 8. (d) Advise the patient or patient's agent that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free telephone service.

yet below it can be refused 7), this is not consistent and should be removed

(3) The consultation requirement is not satisfied by only offering to provide consultation.

(4) Every licensed pharmacy directly serving patients at a physical location must conspicuously post a sign approved by the board stating a patient's rights to consultation and information on how to file a complaint to the Board for failure to consult. A copy of the sign must be included in any delivery by common carrier or delivery service.

(5) Consultation is required upon patient request.

(6) A pharmacist shall utilize professional judgement in determining whether to give the patient or patient's agent appropriate consultation relative to the prescription for any refill.

(7) Notwithstanding sub. (2), a consultation is not required when a health care provider is administering the medication or if a patient or patient's agent refuses consultation.

again a lack of consistency related to requirement or defer based upon professional judgment, it needs to be all or none. A verbal offer to consult which is refused should be acceptable as noted in C7).

CURRENT REQUIREMENTS

Phar 7.01 Minimum procedures for compounding and dispensing. or pharmacist student under the direction of the Pharmacist

(1) Except as provided in sub. (4), a pharmacist or pharmacist–intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist or pharmacist–intern as directed and supervised by a pharmacist shall:

(e) Give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a location of the patient's choice if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a location of the patient's choice, is not satisfied by only offering to provide consultation.

November 15, 2019

Pharmacy Examining Board
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708

Dear Pharmacy Examining Board:

I understand you are soliciting input to the proposal to repeal and recreate Chapter 7.08 regarding pharmacist consultation with the patient or patient's agent. My teaching and research for the past 30 years has been in the University of Wisconsin School of Pharmacy on pharmacist-patient consultation. My goal has been to promote the safety and well-being of patients through preparing pharmacists to assess patient needs and use their professional judgment to provide appropriate consultation for all new and refill prescriptions. I believe that repealing and recreating Chapter 7.08 as proposed would reduce quality of care and jeopardize the safety of patients.

I'd like to use opioid medications as one example of how the reduced responsibility to counsel at each visit undercuts the important contributions a pharmacist should make to patient safety. Forty-six deaths occur in the US every day due to prescription opioid overdose. The pharmacist is the last person a patient sees when they are picking up a prescription and has the responsibility to assess opioid drug effectiveness and any potential adverse effects related to the prescription. For example, this includes ensuring the patient is prepared to monitor possible dependency symptoms and understands the value of naloxone if needed. Over the past year my PhD graduate student Tanvee Thakur has interviewed (1) caregivers of children prescribed opioids, (2) pharmacists dispensing the opioids, and (3) prescribers of the opioids. This research will be published shortly in the *Journal of Opioid Management*. You may be as surprised as we were to learn that almost all of the children's parents reported no one told them the medication for their child was an opioid. They all wanted this information. Parents also reported assuming that children are in unbearable pain when they cry and then opting to use an opioid medication at those times. They would have liked to know about overuse risk to help assess the situation better. Patients/caregivers expect all healthcare professionals, especially pharmacists to counsel on opioid risks and safety. Equally important, in this study the prescribers believed pharmacists were giving this information to their patients and depended on it.

The proposed language for Chapter 7.08 as I understand it only requires pharmacist consultation for an initial prescription and a new renewal. This could be as little as once or twice a year for most medications. That is not enough. There is an ongoing need for pharmacists to assess a patient's experience and symptoms at a first refill and all subsequent visits as well to assess and judge what appropriate consultation is needed to protect the safety of patients. It doesn't take much imagination to identify potential adverse events such as dependency and other risks associated with inappropriate use of opioids, particularly when an earlier pharmacist and physician may never have explained them to a patient. While exercising their judgment, different pharmacists at different times consult more completely. Others do not consult at all other than ask, "Any Questions?". Our beautiful safety net for patients in Wisconsin is that we have a promise or contract to assess and offer appropriate consultation as judged by the individual pharmacist *each and every time* that medication is dispensed. If one pharmacist hasn't assessed, judged and covered the needed information, another pharmacist will do so at

the next visit. The proposed ruling pulls that safety net out and lets the patient (perhaps a child) suffer.

I am just one leg of the 3-legged stool that keeps Wisconsin patients safe, with regulation and licensing being the mandatory other two legs of that stool. Just as you depend on me to do my job as an educator and researcher, I depend on you to do yours....to keep our pharmacists protecting the safety of our patients as best they can. By changing the regulations as proposed, this action would remove that third leg of the pharmacy stool to safeguard Wisconsin citizens, with consultation as little as one or twice a year on most medications.

I used an example of opioids but I could have just as easily have cited the research on adults 65 and older, half of whom have at least three comorbidities for which they take multiple medications. As the number of medications in a regimen increases so does the risk of adverse drug events. Fully 25% of patients 65 and older have experienced an adverse drug event in the past 6 months. A high percent of hospitalizations is due to patients not using their medications effectively. Pharmacists are the front line personnel to reduce these preventable hospitalizations.

A state's health profession regulations say a lot about how it values and views a profession. Equally important, regulations influence the behavior of a health profession. An FDA funded study documented that pharmacist counseling practices varied significantly according to the intensity of a state's pharmacist counseling regulation, with frequency of any information provision climbing from 40% to 94% as states' counseling regulations increased in intensity. Wisconsin was one of the two states with the highest counseling rates. Higher regulation intensity also increased the likelihood that risk information was given and that pharmacists assessed patients' understanding. We are better on these measures than most states and that is one reason our state stood out on this national survey for its pharmacy consultation delivery. Not surprisingly, Wisconsin has pharmacists practicing from other states. It is important to know that not all pharmacists are trained as intensively as Wisconsin students with respect to consultation as Dr. Carole Kimberlin found in her national study. Given this variation, state regulation becomes a key protection.

There are tremendous business influences that undercut the protections of both the profession and patients. The regulatory environment's role could not be more important. It is with this in mind that I urge you to protect the citizens of Wisconsin and also the profession by not repealing and recreating Chapter 7.08 as proposed. There is no way pharmacists can become as efficient as robots. But there is no way the robots can become the compassionate consultants for patients that patients need and want as evidenced by our opioid studies and others.

Sincerely,

Betty Chewning

Betty Chewning, Ph.D., Professor

Fellow, American Pharmacist Association,
Fellow, Academy of Communication in Healthcare

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Thursday, November 14, 2019 2:15 PM
To: Henes, Sharon - DSPS
Subject: FW: PEB Phar 7 Rewrite

From: Adonnas Johnson <ajohnson@hometownpharmacywi.com>
Sent: Thursday, November 14, 2019 2:14 PM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: PEB Phar 7 Rewrite

Pharmacy Examining Board

Dear Members of the Pharmacy Examining Board:

I would like to thank you for receiving and considering comments on the proposed changes to Pharm 7.

I believe that one of the Pharmacy Examining Boards main roles is to regulate pharmacy to increase patient safety. Patient safety is one of my primary focus as a community pharmacist. I believe very strongly that one of the ways we can cut down on medication errors and increase patient safety is to provide counseling to patients not just on the first fill but on each subsequent encounter with patients. Health care is becoming increasingly complex for patients and health care providers are continually under pressure to speed up the rate at which they see patients. Patients are given extensive amounts of information in a time frame of about 15 to 20 minutes at their doctor or health care providers office. My role as a pharmacist is to help them understand some of the information they were given by their doctor or health care practitioner. I also teach them the proper way to take their medication, make sure there are no drug or over-the-counter medication interactions, explain possible side effects, answer any questions they may have about their medication, and help develop the patients understanding of the importance of their medication in their health care goals. Often times after a doctors appointment, the patients are overwhelmed and the extra interaction with a pharmacist can mean the difference between a patient taking a medication properly or a patient having a serious medication error. These interactions are very important, as I can't even tell you the amount of times we have caught errors when counseling a patient. These are errors in how a patient understands how to take their medication, errors in how the prescription was sent to us, drug interactions that the provider was not aware of because the patient forgot to tell them they were on a medication, and even errors in how we filled the medication. If we had not had that vital counseling interaction with a patient, these errors could have had a negative impact on the patient. I also use refill counseling to reinforce and help expand patient knowledge base about their disease states, ways to achieve their health goals through lifestyle modification, and assessing their ability to safely administer their medication.

I would really like the Pharmacy Examining Board to consider the importance of counseling in all pharmacy settings including mail order pharmacies. It is my professional responsibility to make sure that patients are safely taking their medications and it is my belief that it is your responsibility to set regulations that make all pharmacies follow those same set of standards.

Thank you for your time.

Sincerely,

Adonnas Johnson

Adonnas Johnson PharmD
Lodi Hometown Pharmacy
801 N Main St. Suite A
Lodi, WI 53555
(608)592-0662

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Thursday, November 14, 2019 11:37 AM
To: Henes, Sharon - DSPS
Subject: FW: Pharmacy consultation regulations

From: Brian Olson <bolson@hometownpharmacywi.com>
Sent: Thursday, November 14, 2019 10:14 AM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: Pharmacy consultation regulations

Pharmacy Examining Board

Dear Members of the Pharmacy Examining Board:
We thank you for receiving and considering comments on the proposed changes to Pharm 7. The Pharmacy Examining Board, in our opinion, is the governing body to ensure proper procedures are in place for patients and taxpayers.
We strongly believe it is critical for patient safety that each patient receive their first prescription fill in person. Every member of the Pharmacy Examining Board understands that the first fill is a key patient interaction point to inform them of:

1) What they are ingesting,
2) How often to ingest
3) How to ingest in regards to empty or full stomach
4) When to ingest
5) Potential side effects
6) Interactions with other medications or foods or supplements
7) Warning signs to be aware of if the body chemistry is negatively impacted
8) Instructions that may be unique to that patient.

Wisconsin for many years felt this initial consultation was so important that it mandated on every fill. Any exemption to Pharm 7 which allows patients to get their first fill by mail order simply puts patient's safety and health at risk. It is dangerous and reckless. We shudder at the thought of a patient getting a new prescription and having to navigate all the 8 items above on their own.
We already field calls from our community members who are currently forced into mail order with no patient choice who feel abandoned and ask us to explain their medications and side effects.
We know one of the most critical times for a patient is upon release from a care facility and the transition of care including them being on their proper prescription protocols and being their chemistry "gatekeepers" is very important for them and reduces readmission and improves patient outcomes. If a patient is taking an OTC item or has a diet consisting of something that could negatively interact with a medication this is the time to consult the patient. To exempt this

critical and basic consulting component is not in the best interest of patients nor taxpayers. The Pharmacy Examining Board plays a critical role to help protect the public and removing this will endanger the public.

I will conclude with a basic thought – would you want your loved one to leave a care facility and receive medicines with no instruction and have their life at risk based on someone they have never met nor will likely ever meet make a judgment if they should have a phone conversation or not? Would you be confident your loved one, who is ill, would receive the care required for their best outcome?

Why is the PEB even considering an exemption for mail order? Is it worth risking patient safety for the potential to save a few bucks? To ask a person to ingest a substance that has to go through rigid regulation by the FDA to be approved and the manufacturing process has strict regulations and the side effects are mandated to be studied and disclosed and now upon actual ingestion for the first time – it is being considered to be randomized based on "professional judgment" that is not defined by someone the patient doesn't know . Please do the right thing and protect patients and taxpayers.

Mail order pharmacies should abide by all rules that community pharmacies do

Brian R Olson RPh
517 Blacks Grove Rd
Dodgeville, Wi 53533

Sent from my iPad

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Tuesday, November 5, 2019 4:29 PM
To: Henes, Sharon - DSPS
Subject: FW: Mail order pharmacies should not be exempt from patient Counseling

From: Brenda Jacobs <bjacobs@hometownpharmacywi.com>
Sent: Tuesday, November 5, 2019 4:16 PM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: Mail order pharmacies should not be exempt from patient Counseling

Mail order pharmacy wants to be exempt from patient counseling which is already required in Wisconsin by all community and hospital pharmacies. Mail order pharmacy needs to be held to the same standards as other pharmacies to ensure safe medication use in Wisconsin.. Counseling is the most important thing the pharmacist does to ensure patient's understand their medication therapy. They are saying that the job of mail order is to get the right drug to the right patient , as efficiently as possible, Wisconsinites deserve better.

Professionally,

Brenda Jacobs, RPh

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Wednesday, October 30, 2019 8:34 AM
To: Henes, Sharon - DSPS
Subject: FW: Pharmacist patient counseling in Wisconsin

From: Michael Kuckes <mkuckes@hometownpharmacywi.com>
Sent: Tuesday, October 29, 2019 10:29 PM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: Pharmacist patient counseling in Wisconsin

Debra,
I am an independent pharmacist and pharmacy owner in Wisconsin. I learned tonight something that is very disturbing. I understand that the Pharmacy board is fine-tuning the patient counseling requirements of Pharmacists serving patients in Wisconsin. If that leads to better patient care outcomes I am all for it. What is extremely disturbing to me is that mail-order pharmacy is exempt from the mandatory counseling requirement. How does that provide the same care that these patients would receive from pharmacists in community settings who follow the law of mandatory counseling and if they do not are fined and disciplined?

Our profession continues to be sold out to PBMs and their deep pockets. This needs to end and stop risking our patient's access to quality care given by community pharmacists every day.
I would like to be added to the email list concerning this legislation.
--
Michael Kuckes, Rph
Monroe Hometown Pharmacy West
608-426-6540

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Wednesday, October 30, 2019 8:34 AM
To: Henes, Sharon - DSPS
Subject: FW: WI PEB Phar 7.08 proposal

From: Tyler Wallenfang <twallenfang@hometownpharmacywi.com>
Sent: Tuesday, October 29, 2019 10:36 PM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: WI PEB Phar 7.08 proposal

Debra Sybell,

I would like to go on record and state the following.

When it comes to the WI pharmacy law (Phar 7.08) requiring consultation at new, first refills and renewals, I feel it is the right thing to do for patient safety, adherence and overall health. That's why I strongly feel it is WRONG that mail order pharmacy/pharmacists would be exempt from this requirement. There are patients that are FORCED to use mail order by their PBM who would love to use a local pharmacy and receive quality care, but can't. Under the proposed law they would potentially receive even less patient care by not being consulted by the pharmacy they are forced to use.

This is very important to me so please place me on the list to stay updated throughout the process.

Thanks you!

--
Tyler Wallenfang PharmD
Appleton Hometown Pharmacy
1350 W College Ave Ste A
Appleton, WI 54914

(920) 739-9232

Henes, Sharon - DSPS

From: Jessica Haufschildt <jhaufschildt@hometownpharmacywi.com>
Sent: Tuesday, December 17, 2019 9:01 AM
To: DSPS Admin Rules
Subject: Phar 7 Update Rule comments from current WI Pharmacist

Hello Pharmacy Board,
I am Jessica Haufschildt, RPh., a practicing pharmacist in Wisconsin since 1995. I have been made aware of the rule change proposal for patient counseling in WI.

I believe counseling patients is absolutely imperative for patient safety and care. I have always wondered why mail order pharmacies did not have to counsel patients and be readily available for questions. Countless times I have answered questions for local patients because they cannot get through to a pharmacist at the mail order or have to hold too long on the phone to talk to them or the patients simply does not trust them. I believe the mail order pharmacists should be held to the same standards as our local WI pharmacists.

I think that our Wisconsin patients deserve the highest quality of care and a pharmacist counseling a patient is of utmost importance in the safety of our patient population. I have always taken this law seriously and would not want to practice as a pharmacist any other way. I have discovered many problems with drug therapy, inappropriate medications prescribed, mistakes made by prescribers, confusion with medications in elderly, cost for patient (too much for patient and offer to help contact prescriber for a more cost effective choice) and many other issues during consult.
The mandatory counseling assures the people of Wisconsin have the pharmacist at their disposal and available for questions. I am in favor of keeping the rule that an offer for consult by a tech is not acceptable. The patients may not be aware of the safety concerns they are missing from the pharmacist or what there is to gain from talking with a pharmacist before taking a new medication. It is up to the board to protect the patients of Wisconsin with this rule and hold **all pharmacists** providing medications to Wisconsin population accountable including mail order out of state pharmacies. This is very important due to the fact that many patients are forced to use mail order by their insurance (PBM 's) and do not get the choice to get the quality care they get from their local pharmacists throughout our state.
Thank you for your time and consideration in this matter.
Sincerely,
Jessica Haufschildt, RPh.
Northland Hometown Pharmacy
420 E. Northland Ave. Suite H
Appleton, WI 54911
920-840-6033

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Saturday, November 2, 2019 3:45 PM
To: Henes, Sharon - DSPS
Subject: FW: Phar 7.08

From: Mackynzie Anderson <manderson@hometownpharmacywi.com>
Sent: Friday, November 1, 2019 10:03 AM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: Phar 7.08

Hi Debra,

My name is Mackynzie and I am the pharmacy manager at Pinnow Hometown Pharmacy in Brodhead, WI. I am emailing you because I recently became aware of the proposed rule change to patient counseling and that fact mail order pharmacies want to be exempt from this rule. Day in and day out, we see the negative effects that mail order has on our patients and their medication compliance and I think that mail order pharmacies being exempt from this will just add to that. We mail out and delivery medications to our patients and if a medication is new or there has been a change, we try our best to call the patient and counsel them over the phone about it. If we're able to do it at the retail level, I believe mail order pharmacies should have no issue doing this either. We should all be held to the same standard of care regardless of the type of pharmacy and all pharmacists should want to provide their patients with that care.
I would like to be on the e-mail list to get notified about updates regarding this rule change.

Thank you,

--
Mackynzie Anderson, Pharm.D., R.Ph.
Pharmacy Manager
Pinnow Hometown Pharmacy
P: 608-897-2595
F: 608-897-8301

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Saturday, November 2, 2019 3:57 PM
To: Henes, Sharon - DSPS
Subject: FW: Pharmacy Practice Chapter 7

From: Steve Nilson <snilson@hometownpharmacywi.com>
Sent: Thursday, October 31, 2019 7:21 PM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: Pharmacy Practice Chapter 7

Debra,
I was reading over the proposed rule changes in Chapter 7 of the Wisconsin Pharmacy Practice and was surprised to see a special exemption for mail order pharmacies. This special exemption pertains to the required counseling to patients receiving a new prescription, the first refill and at each new renewal. It is very appropriate for all patients to receive this counseling for their own safety. Understanding the medication's proper dosing schedule, side effects and possible drug interactions encourages the patient to be more adherent and increases efficacy of the medication. What I don't understand and consider unsafe for patients is why an exemption to this regulation is considered when Wisconsin brick and mortar pharmacies will be following this regulation.
My pharmacy has lost patients in the past when they are told they MUST get their prescriptions filled via mail order, whether they want to or not. Now I read this proposal that these same mail order pharmacies do not have to provide the same counseling services that we provide. How is that in the best interest of the consumer? The excuse that this regulation is not feasible under their business model or that it would delay care for their patients is ludicrous. A regulation should be applicable to all pharmacy providers for the betterment of all consumers.
Patients should either not be forced to get their prescriptions from a mail order pharmacy or that pharmacy should be made to follow the same regulations as other Wisconsin pharmacies. I ask that the Pharmacy Examining Board seriously reconsider and not allow this exemption.
Thank you!

Steve Nilson RPh
Homecare Pharmacy
1006 Woodward Ave
Beloit, WI 53511

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Tuesday, November 5, 2019 9:12 AM
To: Henes, Sharon - DSPS
Subject: FW: Phar 7 Rewrite - Patient counseling

From: Jennifer Baerenwald <jbaerenwald@hometownpharmacywi.com>
Sent: Monday, November 4, 2019 4:55 PM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: Phar 7 Rewrite - Patient counseling

Hi Debra,

My name is Jenny, and I have been a pharmacist in Wisconsin for over 11 years. Most recently, following Shopko's closure, I took a leap and opened my own Hometown Pharmacy. The past year has certainly been filled with adventure, but despite all of the change, one thing has remained constant, my belief that my role as a pharmacist is much more than just being an efficient pill dispenser. As I grow my business, I truly hope to show the people in our community that the pharmacist can be a valuable part of their health care team. I believe that being a part of someone's health should be interactive, and that an integral part of creating trust and connection is through patient counseling.

I am in favor of the proposed re-write for patient counseling. I do, however, believe that every pharmacist serving patients in Wisconsin should be held to the same standard, including mail order pharmacies.

I would like to be placed on the email list to receive updates on this rewrite.

Thank you kindly for your consideration,

Jennifer Baerenwald
Pharmacist/Owner
Kimberly Hometown Pharmacy

Pharmacy Examining Board

Dear Members of the Pharmacy Examining Board:

We thank you for receiving and considering comments on the proposed changes to Pharm 7.
The Pharmacy Examining Board, in our opinion, is the governing body to ensure proper procedures are in place for patients and taxpayers.

We strongly believe it is critical for patient safety that each patient receive their first prescription fill in person. Every member of the Pharmacy Examining Board understands that the first fill is a key patient interaction point to inform them of:

1) What they are ingesting,

2) How often to ingest

3) How to ingest with respect to an empty or full stomach

4) When to ingest

5) Potential side effects

6) Interactions with other medications or foods or supplements

7) Warning signs to be aware of if the body chemistry is negatively impacted

8) Instructions that may be unique to that patient.

Wisconsin for many years felt this initial consultation was so important that it mandated on every fill. Any exemption to Pharm 7 which allows patients to get their first fill by mail order simply puts patient's safety and health at risk. It is dangerous and reckless. We shudder at the thought of a patient getting a new prescription and having to navigate all the 8 items above on their own.

We already field calls from our community members who are currently forced into mail order with no patient choice who feel abandoned and ask us to explain their medications and side effects.

We know one of the most critical times for a patient is upon release from a care facility and the transition of care including them being on their proper prescription protocols and being their chemistry "gatekeepers" is very important for them and reduces readmission and improves patient outcomes. If a patient is taking an OTC item or has a diet consisting of something that could negatively interact with a medication this is the time to consult the patient. To exempt this critical and basic consulting component is not in the best interest of patients nor taxpayers. The Pharmacy Examining Board plays a critical role to help protect the public and removing this will endanger the public.

I will conclude with a basic thought – would you want your loved one to leave a care facility and receive medicines with no instruction and have their life at risk based on someone they have never met nor will likely ever meet make a judgment if they should have a phone conversation or not? Would you be confident your loved one, who is ill, would receive the care required for their best outcome?

Why is the PEB even considering an exemption for mail order? Is it worth risking patient safety for the potential to save a few bucks? To ask a person to ingest a substance that has to go through rigid

regulation by the FDA to be approved and the manufacturing process has strict regulations and the side effects are mandated to be studied and disclosed and now upon actual ingestion for the first time – it is being considered to be randomized based on "professional judgment" that is not defined by someone the patient doesn't know. Please do the right thing and protect patients and taxpayers.

Dr. Erin Orth, PharmD
901 Fond du Lac Avenue
Kewaskum, WI 53040
Hometown Pharmacies of Wisconsin

Henes, Sharon - DSPS

From: Teri Welter-Knoke <twelter-knoke@hometownpharmacywi.com>
Sent: Thursday, November 14, 2019 4:12 PM
To: DSPS Admin Rules
Subject: Phar 7 Comments

Pharmacy Examining Board

Dear Members of the Pharmacy Examining Board:

We thank you for receiving and considering comments on the proposed changes to Phar 7 and ensuring proper procedures are in place for patients and taxpayers.

We strongly believe it is critical for patient safety **that each patient receive their first prescription fill in person.** The patient consultation components, outlined in proposed Phar 7.08, reiterate the importance of patients being consulted on their medication, and especially the importance of the first fill patient-pharmacist interaction:

> ***Proposed* Phar 7.08 Patient consultation. (1)** Patient consultation shall include all of the following:
>
> (a) Name and description of the drug.
> (b) Form, dose, route of administration and duration for drug therapy.
> (c) Intended use of the drug and expected action.
> (d) Special directions and precautions for preparation, administration and use by the patient.
> (e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
> (f) Techniques for self-monitoring drug therapy.
> (g) Proper storage and appropriate disposal method of unwanted or unused medication.
> (h) Action to be taken in the event of a missed dose.

Wisconsin for many years felt this initial consultation was so important that it mandated on every fill.

> **Phar 7.01 Minimum procedures for compounding and dispensing. (1)** Except as provided in sub. (4), a pharmacist or pharmacist–intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist or pharmacist–intern as directed and supervised by a pharmacist shall:
>
> ...
>
> (e) Give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a location of the patient's choice if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a location of the patient's choice, is not satisfied by only offering to provide consultation.

Any exemption to Phar 7 which allows patients to get their first fill by mail order, where no consultation exists, simply puts patient's safety and health at risk. We are very concerned about a process in which a patient would receive a new prescription and not receive the important patient consultation information contained in proposed Phar 7.08 (1) (a), (b), (c), (d), (e), (f) and (g) all on their own. And we question the situation in which professional judgment would deem that a patient should not receive consultation on new medications they are receiving.

One of the most critical times for a patient is when they are released from a care facility. That transition of care, especially starting their proper prescription protocols, is very important for their health and recovery. Studies have shown that proper adherence to prescription protocols, reduces readmission and improves patient outcomes. Without a consultation, how can someone "professionally judge" whether a patient is taking an over the counter (OTC) product or who has a diet consisting of something that could negatively interact with a medication? Removing this critical and basic consulting component is not in the best interest of patients nor taxpayers.

Under the current regulatory scheme, we already field calls from our community members who, with no choice, are forced into mail order. They feel abandoned. In fact, weekly there are many instances where our former patients, who have been forced into mail order, still call us and ask our pharmacists to explain their medications and the potential side effects.

The Pharmacy Examining Board plays a critical role to help protect the public. And we believe the consultation component requirements outlined in proposed **"Phar 7.08 Patient consultation."** We do however serious concerns that those requirements can be avoided if a patient is required or chooses to receive their medication via mail order. We urge the PEB to ensure every patient is protected and receives a consultation.

Sincerely,

Teri Welter-Knoke PharmD
Lancaster Hometown Pharmacy
1221 Highway 61
Lancaster, WI 53813
P 608-885-1155
F 608-885-1156
E twelter-knoke@hometownpharmacywi.com

Henes, Sharon - DSPS

From: Kent Udulutch <kudulutch@hometownpharmacywi.com>
Sent: Friday, November 15, 2019 11:19 AM
To: DSPS Admin Rules
Subject: PEB Chapter 7

Dear PEB,

I would like to voice my support for mandatory consultation for new and first refill for all Wisconsin patient's prescriptions.

Mail-order pharmacies would like to be relieved of this professional duty because they say that consultations do not fit into their business model. Relieving mail-order pharmacies from this professional duty is very dangerous to Wisconsin patients. Many patients that have been forced into getting their prescription through a mail-order pharmacy will simply come to a local pharmacy for consultation. Worse than that, many will simply NOT receive consultation from a pharmacist at all. It is unfair to ask local pharmacies in Wisconsin to do the consultation for these big PBM pharmacies so that their business model is not disrupted. If mail-order pharmacies want to dispense medications, then they must provide consultation in accordance with good pharmacy practice

Thank you.

--

Kent Udulutch, RPh/Owner
Plover Hometown Pharmacy
1600 American Drive
Plover, WI 54467
[P] 715-544-6272
[F] 715-544-6045
www.hometownpharmacyrx.com

3900 Erie St

Racine, WI 53402

Pharmacy Examining Board

1400 E Washington Ave,

Madison, WI 53703

Dear Members of the Pharmacy Examining Board:

Thank you for receiving and considering comments on the proposed changes to Phar 7 and ensuring proper procedures are in place for patients and taxpayers.

I strongly believe it is critical for patient safety **that each patient receive consultation on their first and first refill prescriptions.** The patient consultation components, outlined in proposed Phar 7.08, reiterate the importance of patients being consulted on their medication. Wisconsin for many years felt this initial consultation was so important that it mandated on every fill.

Any exemption to Phar 7 which allows patients to get their first fill and first refill without consultation simply puts patient's safety and health at risk. I am very concerned about a process in which a patient would receive a new prescription and not receive the important patient consultation information contained in proposed Phar 7.08 (1) (a), (b), (c), (d), (e), (f) and (g) all on their own. The information patients need to know to safely and effectively take their medications is no less critical, whether it is sourced through their local community pharmacy or a mail order pharmacy. I don't not understand the double standard that affords a Mail service pharmacy the opportunity to be excluded from this requirement.

It seems to me that the primary role of the Pharmacy Examining Board is to look out for the safety of the patient and establish a minimum standard of practice. I believe providing patients with the basic information they need to safely and effectively take their medications is critical regardless of how they choose to source their medications.

Sincerely,

Jeremy Laffin, RPh

Owner Wautoma Hometown Pharmacy

Manager Racine Hometown Pharmacy

Henes, Sharon - DSPS

From: Klink, Christopher <Christopher.Klink@aah.org>
Sent: Wednesday, November 20, 2019 5:05 PM
To: DSPS Admin Rules
Subject: Comments on Phar 7

I have just reviewed Pharm 7 and have a few questions/comments

1. The updated counseling requirements (Phar 7.08) appear to apply only to new RXs and not refills
    a. I would voice opposition to this, and would strongly encourage you to continue to include mandatory consultation on refills. There is great benefit in counseling on medication refills, particularly when performing show and tell consultation and having a semi-private consultation area where patient confidentiality can be protected. I would share several advantages of refill counseling from my own practice experience:
        i. When I supervised a pharmacy and managed our event reporting, half of our medication events were actually near misses because they were caught in the process of consultation. Without this step these events would have went from being near misses to actual med events.
        ii. With the lack of continuity in the drug supply chain and with frequent changes in generics, consultation is the place to perform show and tell and confirm the medication with the patient and that the change in size/color/imprint is intentional and not an error
        iii. When patients have a sit down semi-private area to meet with the pharmacist they frequently raise questions and concerns that they would not feel comfortable with when standing near the register with a line of patients behind them. Things like, "I am having trouble with constipation" or "This medication is affecting my sexual performance" or simply "I have noticed more swelling in my legs."
2. There is no mention of delivery or mail, so I am assuming these requirements would apply to all new meds, regardless of the setting/method of their delivery?
    a. If so, I would agree with them. Why should patients expect two different levels of care (and safety), as they experience now, depending on how they receive their medication. However I would advocate that refills followed this as well.
3. I am very glad to see the requirements for drug utilization review (Phar 7.03), although my concern is that I daily see examples of it not being done by pharmacies (in conjunction with poor/absent counseling) such as:
    a. Patients being dispensed duplicate medications from the same pharmacy at the same time (torsemide and furosemide, Advair and Symbicort) for up to six months in a row. This should be caught both in profile review, but also in refill counseling.
    b. Patient's being dispensed medications that were discontinued and replaced with a different dose/medication after specific instructions were submitted to the pharmacy that it was a replacement dose/drug and the old one was to be discontinued.

In conclusion, I see daily the patient safety benefits of DUR and counseling on all medications, as well as the patient adverse events of pharmacies skipping profile review and counseling. I worry that scaling back the requirements for consultation will only lessen patient safety, especially if there is no accountability/enforcement of profile review.

Thank you,

Chris Klink, PharmD, BCPS
Clinical Pharmacist Senior
Advocate Aurora St. Luke's Medical Center
(414)649-6483

Jonathan McLachlan, PharmD, R.Ph, CSP
Manager, Professional Practices
AllianceRx Walgreens Prime
41460 Haggerty Cir S
Canton, MI 48188
P: 734-477-9891
jonathan.mclachlan@alliancerxwp.com

December 10, 2019

Submitted via eMail
DSPSAdminRules@wisconsin.gov

Wisconsin Pharmacy Examining Board
4822 Madison Yards Way
Madison, WI 53708

To Whom It May Concern:

On behalf of our ten (10) nonresident pharmacies which provide care to patients living in the State of Wisconsin, AllianceRx Walgreens Prime appreciates the opportunity to provide comment on the impact of pending rulemaking on our provision of home delivery and specialty pharmacy services. Our feedback centers on two sections of the proposed revision[1] to Phar 7 – 7.08 regarding patient consultation and 7.085 regarding delivery by common carrier or delivery services.

Proposed Phar 7.08 – Patient Consultation

AllianceRx Walgreens Prime thanks the Rules Committee and the Board for its careful consideration of the language in this section throughout the rulemaking process. While we are concerned that the requirement of oral counseling prior to shipment of a prescription may introduce delays in care in order to comply, we are pleased that the current draft language provides some allowance for written communication when deemed appropriate, which is consistent with many other states that our pharmacies dispense to, including states that border Wisconsin. However, current version of the proposed language may imply that the expectation is that pharmacists exercise professional judgement on a case-by-case basis in order to deem alternative methods of counseling appropriate.

Our current process provides, at a minimum, comprehensive written counseling with clear information stating how to contact a pharmacist, available 24/7/365, via phone, if desired. Implementing process changes to comply for Wisconsin dispenses would introduce significant cost to implement system functionality to accommodate the requirement, as well as additional labor costs to dedicate staff to make the phone calls. Given that not all patients are immediately available for a phone call, requiring verbal counseling does present a very real risk of contributing to delays in patients having access to therapy.

[1] https://dsps.wi.gov/Documents/RulesStatutes/Phar7EIA.pdf

Proposed Phar 7.085 – Delivery by Common Carrier or Delivery Services
As written, the proposed rule states:

Utilization of common carrier or delivery services to deliver a prescription from the pharmacy which fills the prescription to the patient or patient's agent shall ensure all of the following:

1. The delivery method maintains appropriate environmental controls, including temperature and humidity, to prevent drug adulteration.
2. The delivery method provides for verification of receipt of all controlled substances.
3. The patient or patient's agent is provided a method by which the patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the prescription drug product or device, including all of the following:
    a. Timeliness of delivery
    b. Condition of the prescription drug upon delivery.
    c. Failure to receive the proper prescription drug product or device.
4. Any prescription drug product or device which is compromised by delivery shall be replaced by the pharmacy. The pharmacy shall replace at no additional cost to the patient the prescription drug product or device by next-day delivery or the pharmacist shall contact the patient's practitioner to arrange for a prescription for a minimum 7 day supply of the prescription drug product to be dispensed to the patient by a pharmacy of the patient's choice.

Discussion Regarding Sub(1)

While we completely understand the aim of this rule is to ensure that patients receive safe, quality drug products regardless of the method of distribution, there are specific items that we would like to present for the Board's consideration:

Requiring humidity control during drug delivery is a somewhat unique requirement. From a practical standpoint, when a drug is packaged for dispensing (if not dispensed in sealed unit-of-use packaging), the air that the drug would be primarily exposed to while enroute to the final destination is that of the pharmacy. AllianceRx Walgreens Prime follows USP dry place standards for drug storage in its pharmacies and the vials that drugs are packaged in follow USP guidelines for a "tight container", which protect the contents from contamination by extraneous liquids, solids or vapors." The relevant USP guideline, found in chapter 1079, does not provide expectations around humidity control in shipments. It is important to also note that URAC's accreditation standards, which are widely recognized as industry best practices, do not require accredited entities to incorporate humidity control into their shipping processes.

From a manufacturing standpoint, for drugs that are dispensed in manufacturer packaging, federal regulations around good manufacturing practices require that packaging be designed to "provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product."[2].

In summary, implementing humidity control requirements beyond the standards already discussed would require significant investment and increase in the cost to fill a prescription shipping to Wisconsin. AllianceRx Walgreens Prime respectfully requests that the Board consider citing specific standards for humidity control, or alternately, removing humidity control from its requirements for prescriptions delivered via common carrier or delivery services in light of the industry standards that already exist in this arena.

[2] 21 CFR 211.94

Discussion Regarding Sub(4)

AllianceRx Walgreens Prime supports the intent of the language around reshipping compromised drug product. Our current processes provides replacement product when necessary within 24-48 business hours. We do want to identify several practical points that the Board should consider around the requirement to provide next-day reshipment or arrange for a 7-day supply to dispensed locally:

1. A patient may not be available to accept and/or sign for delivery on the next day, or may not actually need the product immediately.
2. Major delivery services do not guarantee full service on the weekends or holidays, so providing true next-day service may be impossible, especially in more remote/rural areas.
3. In cases where a next-day delivery is not possible, possibly due to the above situations, the drug the patient is receiving may not be available locally for a 7-day supply to be obtained. This is true for limited distribution drugs in the specialty pharmacy space – which includes many oncology drugs.
4. It may be difficult to successfully contact the prescriber in an after-hour, holiday, or weekend scenario, so prescriber availability to provide a 7-day prescription may be limited.
5. If an alternate pharmacy that is not affiliated with the initial pharmacy is dispensing a short term supply for the patient, that pharmacy would need to be reimbursed for the interim dispense, which would seem to conflict with the goal of protecting the patient from additional financial responsibility. The rule does not define how payment is made for the interim dispensing, and it would be unfair for the interim pharmacy to not be reimbursed for services provided.

AllianceRx Walgreens Prime respectfully requests that the Board consider amending the language in the rule to allow for flexibility based on the above scenarios:

Any prescription drug product or device which is compromised by delivery shall be replaced by the pharmacy. The pharmacy shall replace at no additional cost to the patient the prescription drug product or device by next-day delivery or the next fastest ship method that is mutually agreed to with the patient. If unable to expeditiously provide a reshipment, the pharmacist shall make a reasonable effort to contact the patient's practitioner to discuss the situation, and if deemed appropriate and necessary, arrange for a prescription for a ~~minimum 7-day~~ short-term supply of the prescription drug product to be dispensed to the patient by a pharmacy of the patient's choice.

AllianceRx Walgreens Prime thanks the Board for considering our feedback. Please do not hesitate to contact me directly with any questions or for further information.

Sincerely,

Jonathan McLachlan, PharmD, R.Ph., CSP
Manager, Professional Practices
AllianceRx Walgreens Prime

December 12, 2019

Wisconsin Pharmacy Examining Board
Department of Safety and Professional Services
Madison, WI 53708

Dear Board Members,

Please accept this letter of support for the proposed revisions of Phar 7 patient counseling regulations under discussion at your December 17, 2019 meeting. As Doctor of Pharmacy students at the Medical College of Wisconsin School of Pharmacy, we would like to communicate our strong support for these proposed revisions. We believe they enable the patient-centered care approach to optimal healthcare and patient safety, which we, as future pharmacists, are being trained in. Please note that we are expressing our own opinions and are not representing the official views of the Medical College of Wisconsin.

The new revisions to Phar 7 regarding patient counseling state that all pharmacies are required to provide verbal consultations to patients, regardless of delivery method (Phar 7.085), before dispensing any new prescription or change in therapy. This revision emphasizes the value of proper patient counseling in order to protect the patient's autonomy, while ensuring appropriate and optimal drug therapy is accomplished through correct practice. We feel that this revision acknowledges and aims to address the current variability in counseling practices, which would improve care for patients in all settings.

Why we stand **for** the revision:

- It details the required counseling points which will standardize the quality of counseling for mandatory consultations, improve patient trust in the pharmacist, and potentially address high patient wait times in community pharmacies.
- It contains a stricter set of guidelines on delivered medications for which patients are traditionally less likely to receive pharmacist counseling. These guidelines will help patients establish a closer relationship with the pharmacist who fills their prescriptions and improve medication outcomes.
- Requiring a consultation for a new medication or dose change can allow for an enhanced patient-pharmacist relationship by establishing a trust-based relationship.
- Other states like Illinois, Iowa, Michigan, and Minnesota have had success with similar regulations which allow a pharmacist to make their best judgment on a consultation, thus addressing a patient's best interest.
- It is viewed as a positive change to ensure that everyone in the healthcare field understands the importance of pharmacists, their current roles for the patient, and potentially what roles they can play in the future.

We stand with the need to progress the field of pharmacy through constant revisions and advocacy of the profession. We appreciate the dedication and steps board members are taking to ensure the health, safety, and well-being of the citizens of Wisconsin. We feel that Phar 7 revisions as proposed will positively impact the way we, as students, will practice as Wisconsin's future pharmacists.

Thank you,

Corrina Lyster, Sanaya Bhathena , Alex Sperry, Holly Maize
Pharm.D. Candidates

PRINT NAME	SIGNATURE	CLASS OF
Aristo tel Bitz		2021
TRACY ZOUK		2022
Jessica Barazowski		2021
STEPHANIE KUEHN		2021
Anthony Suaverdez		2021
Pakou Lee		2021
Rachael Jaszczenski		2021
Mackenzie Berry		2021
Aubrey Cutler		2021
Dillon Glaser		2022
Hyunwoo Park		2021
ABBY ANGELROTH		2021
Alex Sperry		2021
Jose Roig		2022
Crystal VandenBloomen		2022
Corrina Lyster		2021
Sanaya Bhachena		2021
Emily Tolliver		2022
JWith Sreeja		2022
Jose Rojas		2022
Ellary Schwarzbrun		2022
Mohammad Rifai		2022

PHAR 7 REVISION SIGNATURE SHEET

PRINT NAME	SIGNATURE	CLASS OF
Hannah patricia Gilbert		2022
Hue Xiong		2022
N.O.e SOMO		2022
Abby Mabie		2021
Duc Nguyen		2021
Thomas Ringsred		2021
Sam Michels		2022
Sean Blaeser		2021
Amy Duong		2021
Christy Freeman		2021
Andrea Medina		2022
Tyler Jones		2021
Jaclyn Utrie		2021
Mandy Walter		2021
Glenn M. Hartle II		2021
Melissa Hallmann		2021
John Tierney		2021
McKenzie Yerks		2021
Obada Salsour		2021
Megan Grochowski		2021
Kevin Yang		2021

PHAR 7 REVISION SIGNATURE SHEET

PRINT NAME	SIGNATURE	CLASS OF
SANDY HER-ALLEY		2021
Jacqueline Pawlak		2021
Roberto Flotte		2021
JOHN WINTERS		2021
Holly Maize		2021
MICHAEL STUBENVOLL		2021
Asia Mian		2021
Ly Huynh		2021
Amy Kaczmarowski		2021
Jacob Voyles		2021
Adrienne Wallace		2021
Jackson Straughan		2022
Kerchia Lee		2022
Callie Wessel		2022
Parker Knueppel		2021
Eric Ripley		2021
Dani Schmaus		2022
Casslynn Choy		2021
Alyssa Amrhein		2022
Melissa Staffin		2022
Olivia Osinski		2022

PHAR 7 REVISION SIGNATURE SHEET

PRINT NAME	SIGNATURE	CLASS OF
Anamarie Tomaich		2021
Isabelle Sviatoslavsky		2021
Abdul Jamaleddin		2021
Le Pham		2022
Haley Sedo		2022
Hayley McDaniel		2022
Andrés Maldonado Rodríguez		2022
Alexis Bartels		2022
Peter Iteanu		2022
Michael Keeney		2022
Kyle Braithwaite		2022
TACTK YUSSIF		2022
Jake Paget		2022
Danayi Vila	Danayi Vila	2022
Andy Saavedra		2022
Rawan Oudeh		2022
Sean Le Boeuf		2022

December 13, 2019

Ms. Debra Sybell
Executive Director
Wisconsin Pharmacy Examining Board
4822 Madison Yards Way
Madison, WI 53705

Via Email

Dear Executive Director Sybell

I am writing this letter in my capacity as Senior Director of Pharmacy Regulatory Affairs for Express Scripts Holding Company Inc. (ESI), which includes all mail order and specialty pharmacies that hold licensure and service patients that reside in the state of Wisconsin, to supply comments concerning the proposed repeal and recreation of pharmacy regulations governed by Chapter Ph7.

ESI welcomes and appreciates the Board's effort to simplify the Chapter's language and format. However, ESI has several concerns with the proposed rule changes as currently drafted.

The proposed regulation Phar 7.08 mandates counseling by the pharmacist on all new prescriptions not previously dispensed or when there is a change in existing therapy. This new section replaces the language currently in *Phar 7.01(e) Minimum procedures for compounding and dispensing,* which exempts the mandate allowing for an offer to counsel if the prescription is delivered to the patient's location of choice.

> *Phar 7.01(e): Give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a location of the patient's choice if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and,* ***except when prescriptions are delivered to a location of the patient's choice****, is not satisfied by only offering to provide consultation.* [Emphasis added]

Currently ESI and virtually all others in the industry, provide comprehensive written information with each dispensed prescription. In addition, all prescription(s) contain a written offer to counsel the patient, which includes a toll free number for the patient to contact the pharmacy at their convenience and in the privacy of their own home. ESI pharmacists are available to the patient twenty-four hours a day, seven days a week. Since the patient initiates the counseling encounter, it is at a time the patient is most receptive to the receipt of the information. In addition, ESI pharmacists perform outbound calls to patients to close gaps in care, increase adherence and offer guidance on medication use when a pharmacist determines the need based upon their professional judgement. This format allows for the most efficient use of pharmacist resources which is reflected by the average call time of seventeen minutes for each of the one and a half million telephonic patient counseling encounters we currently conduct annually.

The proposed rule requiring a pharmacist to reach out to counsel the patient on each new prescription or change in existing therapy would potentially divert pharmacy resources from those patients who are most at risk while increasing the overall cost of providing health care. The Board has dismissed the fiscal concerns expressed by the Pharmaceutical Care Management Association (PCMA) stating that:

> *The proposed rule, as written, does not require a phone call for every new prescription. During the discussion Pharmaceutical Care Management Association member pharmacies did represent that the current practice is for their pharmacists to call a patient when the pharmacist deems a phone call to be in the patient's best interest. In light of that representation, the Pharmacy Examining Board recognizes that the current practice of calling a patient when the pharmacist utilizes professional judgment to determine a phone call is in the best interest of the patient is in compliance with the proposed rule, disputes the Pharmaceutical Care Management Association's*

cost estimate provided to the Pharmacy Examining Board and deems no action is necessary to mitigate this economic concern.

This response does not accurately reflect the language of the proposed rule:

> *(b) Be communicated orally unless in the pharmacist's professional judgment it is* ***not in the best interest of the patient*** *or patient's agent to be communicated orally.* [Emphasis added]

The proposed language implies that the oral communication is not needed only if there is a specific reason that the communication would not be in the patient's best interest (i.e. cause harm). This small cohort is a very small subset of the patients who do not have an affirmative reason to be contacted. If the Board believes that the current practice meets the intent of the proposed rules then they should amend the rule to read:

> *(b) Be communicated orally when in the pharmacist's professional judgment it is in the best interest of the patient or patient's agent to be communicated orally.*

If the suggested language does not reflect the intent, then the Board would need to re-evaluate the fiscal impact of the rule as outlined by PCMA, as the number of contacts would be significantly larger than today.

Additionally the Board uses potential cost savings in various other sections of the rule package to offset the cost of this provision of the proposed rule. This assumes an "either or" scenario which is a false assumption. Each section of the rule can be promulgated in a standalone fashion and all of the believed cost savings can be achieved without removing the face-to-face exception in the current rule. Therefore, when looking at the fiscal impact on the residents of Wisconsin, the Board should consider the fifteen million dollar annual impact submitted by PCMA to determine if that increase in cost is worth whatever marginal benefit, if any, would be gained.

ESI would also like to comment on proposed Rule 7.085 (4). This proposal would require the pharmacy to replace medications by next day delivery. While ESI fully supports the intent, experience shows that there are times when next day delivery may not be convenient for or available to the patient. Therefore, ESI would suggest that the proposed rule be modified to require the replacement be sent via a method that would ensure that the patient does not have an interruption in therapy.

In summary, ESI believes that written counseling material combined with patient access to pharmacists at a time when the patient is best able to absorb the information, twenty-four hours a day every day of the year is an effective use of valuable health care resources. The Board's proposed rule requiring an outreach to the patient when they may or may not have time or be in the proper environment to effectively receive information only adds cost without any significant benefit.

Sincerely,

John Sisto
Sr. Director of Regulatory Affairs
ESI Holding Company Inc.
717-609-7361

Henes, Sharon - DSPS

From: Ryan Bender <rabender@gmail.com>
Sent: Monday, December 16, 2019 2:29 PM
To: DSPS Admin Rules
Subject: Phar 7 Public Hearing and Comment

To: Members, Pharmacy Examining Board

From: Ryan A. Bender, PharmD

RE: Support of Proposed Rule Change to Phar 7

I am writing to register my support for the proposed rule change to Phar 7 pertaining to patient consultation of prescription medications by a pharmacist. This rule change would apply the same standard for pharmacist consultations on prescriptions for all pharmacies, local and mail order alike. This rule change is important because what pharmacists do is important. We provide valuable information on medications. We check for accuracy of the prescription, appropriateness of the medication based on age, weight, disease state, comorbidities, best practices, and interactions with other medications. When dispensing medications we provide consultations and are proud of it. We ask the patient questions and listen thoughtfully to the answers. We provide patients with an opportunity to ask questions about their medications and disease states. In short, we are medication experts.

In order to help control healthcare costs, employers are turning to insurance plans that utilize mail order pharmacy. Many patients would prefer to use their local pharmacy, but their medications are not covered by their insurance company and pharmacy benefit manager there. Community pharmacists routinely answer questions and provide consultations on medications dispensed by a mail order pharmacy because the patients were unable to speak to a pharmacist when they called. Medications can be dangerous, even deadly, if not used correctly. Moreover, they need to be used correctly to provide a therapeutic benefit. By requiring the pharmacist to reach out and offer to provide consultation on new medications, this rule change would help protect the health and safety of the public and give patients a voice.

This rule change is about protecting the public. Allowing prescription medications to be dispensed to a patient without at least offering consultation would be protecting out-of-state special interests.

Thank you,

Ryan Bender, Pharmacist

--
Ryan A. Bender
(608)206-5866
649 Orion Trail
Madison, WI 53718
rabender@gmail.com

OPTUMRx®

1600 McConnor Parkway
Schaumburg, IL 60173

www.optum.com

December 15, 2019

Ms. Sharon Henes, Administrative Rules Coordinator
Division of Policy Development
Department of Safety and Professional Services
PO Box 8366
Madison, WI 53708-8935

DSPSAdminRules@wisconsin.gov

Sent via electronic mail

Dear Ms. Henes:

On behalf of OptumRx, thank you for the opportunity to comment in opposition to the proposed change to Phar 7.08 Patient Counseling, provision (2) and (6).

OptumRx pharmacists work every day to improve the quality of pharmacy care services, simplify the health care experience, and ensure that the individuals we are privileged to serve have affordable access to the drugs they need. OptumRx employs over 50 licensed pharmacists in Wisconsin. OptumRx pharmacist services help improve health outcomes for patients and reduce costs in the system.

In Wisconsin, OptumRx pharmacy services delivery channels include nine on-site full-service pharmacies for the Mental Health Community operating under the Genoa Healthcare banner. We understand the unique and special needs of the severe and persistent mentally ill (SPMI) population.

Our comments focus on Phar 7.08 Patient Counseling, provisions (2) and (6), which have been drafted to read:

> . *(2) A pharmacist shall give the patient or patient's agent consultation relative to the prescription for any new drug product or device which has not been dispensed previously to the patient or any change in the patient's therapy*
> *(6) A pharmacist shall utilize professional judgement in determining whether to give the patient or patient's agent appropriate consultation relative to the prescription for any refill.*

While OptumRx fully supports the Board's role in protecting the public, we believe that this significant change may not align with most patients' expectations and will lead to consequences that can potentially put Wisconsin patients at risk.

OPTUMRx®

1600 McConnor Parkway
Schaumburg, IL 60173

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The requirement for counseling patients prior to dispensing especially raises concerns within our nine Wisconsin Genoa pharmacies serving mental health patients. In these pharmacies, nearly all of our patients live with a severe and persistent mental illness. Due to their special needs, we often dispense medications in compliance packaging, where different medications are combined to reflect the necessary daily dosing schedules. Today, approximately **3200** Wisconsin patients receive this unique and well-received packaging option.

Where the risks come into play is when new medications, or changes in therapy, are prescribed by physicians at different points in time. Each compliance package may have one or more of these new or revised prescription drug regimens enclosed in this packaging, which now would necessitate counseling under the proposed rule. Consequently, in such instances, the patient may be subject to a delay in the receipt of **all** of their medications provided via this compliance packaging due to mandatory counseling required on only the one or two new/revised medications.

OptumRx has significant concerns that the changes being proposed in Phar 7.08 will yield high risk of harm to Wisconsin patients should they not receive needed medications in a timely, consistent manner. Many of these patients are homeless, do not have stable phone access, or are in group homes without personal phone service. If a patient's adherence is impacted because of delays in receiving their full array of behavioral health drugs, they stand a greater likelihood of negative clinical outcomes, loss of employment, incarceration risk and/or costly hospitalization.

The Pharmacy Examining Board, in modifying these regulations, must also recognize that such action will create impediments that can delay or deny patients needed medications for non-behavioral health conditions as well. For example, patients with diabetes may not receive needed insulin or oral hypoglycemic meds; patients with blood clotting disorders may not receive medications to prevent bleeding; and patients with cancer may not receive needed oncology medications.

We fully appreciate the intent of the Pharmacy Examining Board in creating these counseling requirements and recognize that they were not devised to create regulatory barriers to optimal patient care. However, we feel it is important for the Board to consider the potential ramifications of these requirements in situations like what we have put forth here. At a time when medication adherence is recognized as one of the primary barriers to optimal health outcomes, this regulatory action will run in direct conflict with medication adherence programs that OptumRx, and other pharmacies, have implemented.

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Schaumburg, IL 60173

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To our knowledge, there have been no complaints from patients in Wisconsin regarding lack of proper access to consultation with pharmacists concerning prescription drugs obtained through our home delivery and/or Genoa behavioral health pharmacies. In fact, patient surveys have repeatedly shown high satisfaction with the convenience of home delivery with their prescription drugs, and adherence rates amongst individuals using our pharmacies remain high. These pharmacies provide a wealth of information with all dispensed medications, as well as a year-round, 24-hour, toll-free phone access staffed by a pharmacist should patients have clinical questions or concerns.

Again, we appreciate the opportunity to comment. We firmly believe this proposed rule will lead to decreased adherence, delays in patients receiving much-needed medications, and increase the possibility of hospitalization due to gaps in therapy.

Please feel free to contact me if you have any questions or if you would like to further discuss the matter.

Sincerely,

David Calabrese, R.Ph, MHP
Chief Pharmacy Officer

CVSHealth

John Long, RPh, MBA | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 614-572-9008

Via Electronic Mail

December 3, 2019

Ms. Sharon Henes
Administrative Rules Coordinator
Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way
Madison, WI 53708-8366

Re: Comments Proposed Language Chapter Phar 7 - Pharmacy Practice

Dear Ms. Henes:

I am writing to you in my capacity as Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide care with diverse access points to patients in the state of Wisconsin through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments to the Pharmacy Examining Board ("Board") pertaining to Chapter Phar 7 – Pharmacy Practice.

Please see our comments below:

I. Administrative Rules Fiscal Estimate & Economic Impact Analysis use of out dated Statute.

CVS Health believes that the Board is using the incorrect threshold in its preparation of the Fiscal Estimate and Economic Impact Analysis. Based on the current statute, in effect since September 1, 2017, the Board must stop proposed rulemaking if a $10,000,000 threshold is determined when conducting a Fiscal Estimate & Economic Impact Analysis. In that regard, the Act provides that "*if an economic impact analysis... indicates that $10,000,000 or more in implementation and compliance costs are reasonably expected to be incurred by or passed along to businesses ... over any 2-year period as a result of the proposed rule, the agency proposing the rule shall stop work on the proposed rule and may not continue promulgating the proposed rule.. unless a member of the legislature introduces a bill authorizing the agency to issue the rule.*" W.S.A. 227.139. This statute has been in effect for over two years, and it applies when the Board prepares and submits its Fiscal Estimate & Economic Impact Analysis to legislative council staff, even though the Board may have been drafting these proposed rule changes long before it took effect. Under the version statute that was in effect until September 1, 2017, both the threshold and the steps required when the threshold is met were different; When an economic impact analysis indicated that a proposed rule would result in more than $20,000,000 in implementation and compliance costs, the department of administration was required to review the rule and issue a report, but there was no requirement that all work on the rule stop after just $10,000,000 in impact, as there is today.

CVS Health believes that the date that the Board prepared and submitted its Fiscal Estimate and Economic Impact Analysis to legislative council staff is the date that dictates which statute to follow and therefore disputes the Fiscal Estimate & Economic Impact Analysis based on the use of the incorrect statute was used as the basis for the analysis.

John Long, RPh, MBA | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 614-572-9008

II. Fiscal Impact Study feedback from the Board members during Board meeting on November 15, 2019.

During the November 15, 2019 Board meeting there was extensive discussion regarding the fiscal impact of Phar 7, specifically Phar 7.08 Patient consultation. The Board members explained multiple iterations of the analysis representing several million dollars in cost to execute the proposed rule. Independent community pharmacies also explained the negative fiscal impact of the rule to their business. The Pharmaceutical Care Management Association (PCMA) provided a letter reporting that the estimated 2-year financial impact within Wisconsin would be close to $30,000,000 for Phar 7.08 only and for their members only. Additionally, the Board added section "Phar 7.085 Delivery by common carrier or delivery services", which regulates the utilization of common carrier or delivery services to deliver a prescription from the pharmacy which fills the prescription to the patient or patient's agent, without a discussion of Fiscal Estimates & Economic Impact Analysis. CVS Health believes that the Board ignored the economic impact information and testimony provided despite the requirements of Wisconsin Statute 227.137 Economic impact analyses of proposed rules section (3): "*An economic impact analysis of a proposed rule shall contain information on the economic effect of the proposed rule on specific businesses, business sectors, public utility ratepayers, local governmental units, and the state's economy as a whole. The agency or person preparing the analysis shall solicit information and advice from businesses, associations representing businesses, local governmental units, and individuals that may be affected by the proposed rule. The agency or person shall prepare the economic impact analysis in coordination with local governmental units that may be affected by the proposed rule. The agency or person may also request information that is reasonably necessary for the preparation of an economic impact analysis from other businesses, associations, local governmental units, and individuals and from other agencies. The economic impact analysis shall include... the policy problem that the proposed rule is intending to address and the implementation and compliance costs that are reasonably expected to be incurred by or passed along to the businesses...*".

Based upon CVS Health's belief that the Board did not conduct a Fiscal Estimate and Economic Impact Analysis in accordance with statutory requirements and because Board members publically questioned the chaotic process and the rush to make a decision regarding the Fiscal Estimate & Economic Impact Analysis, CVS Health disputes the cost estimates for the implementation and compliance for Phar 7.

III. Understand the origin for the development of the proposed rules Phar 7.08 Patient Consultation and Phar 7.085 Delivery by common carrier or delivery services.

As previously quoted, "*the impact analysis... shall include the policy problem that the proposed rule is intended to address*". The Board stated that the policy problem and the reason for this historical change from common practice regarding patient counseling in other states was due to complaints. When asked on numerous occasions for an analytical explanation of the number of complaints, no such number or analysis was produced. A Board member stated during the November 15, 2019 meeting that she has reviewed Board complaints for the last two years and there has not been a complaint regarding mail service as it pertains to patient counseling. Alternatively, a Board member has repeatedly stated that this rulemaking is necessary to "level the playing field" for consultation requirements between retail and mail service pharmacy, which is a position not related to patient safety thus not part of the Board's mission. Therefore, CVS Health objects to the changes to Phar 7.08 Patient consultation that do not accommodate for prescriptions being mailed or delivered to the patient by common carrier or delivery services. CVS Health believes that the consultation requirement should continue to be satisfied by the provision of written information to the patient regarding the medication being dispensed and the availability of the pharmacist to answer questions via a toll-free phone number.

There has also been no "policy problem" explanation or rationale provided by the Board for the proposed changes to Phar 7.085 Delivery by common carrier or delivery services, as it relates to the "verification of receipt" for schedule III through Schedule V medications. This is not the industry standard today and would not only create an economic impact on business but may also increase the potential for diversion, as deliveries by common carrier may be targeted when identified as controlled substances via the verification of receipt designation. Note, this is not a requirement for neighboring states. Therefore, CVS opposes Phar 7.085 as written.

IV. Neighboring states analysis for patient consultation Phar 7.08

Wisconsin Statute 227.137 Economic impact analyses of proposed rules (3)(a) also requires "*An analysis and quantification of the policy problem that the proposed rule is intending to address, including comparisons with the approaches used by the federal government and by Illinois, Iowa, Michigan, and Minnesota to address that policy problem. If the approach chosen by the agency to address that policy problem is different from those approaches, an economic impact analysis prepared by an agency shall include a statement as to why the agency chose a different approach.*" When a prescription is mailed or delivered in these neighboring states, as detailed below, a pharmacy may provide "written information", "electronic/digital materials" or "alternative forms of patient information" concerning the medication dispensed to the patient, and some of these states require a toll free number for the patient to contact the pharmacist with any questions they may have regarding their prescriptions. On several occasions during public sessions, Board meetings and rules review meetings, the Board was asked to harmonize their proposed counseling rules with neighboring state language, but this recommendation was ignored with no justification for the decision.

As CVS Health believes that the Fiscal Estimate & Economic Impact Analysis failed to include the required statement as to why the agency chose a different approach, did not always include an accurate depiction of counseling allowances in these neighboring states, and failed to compare Phar 7.085 with neighboring states, we object to the proposed changes to Phar 7.08 Patient consultation.

- *Minnesota 6800.0910 PATIENT ACCESS TO PHARMACIST Subp. 2. Description of procedure (B)* ... When a new filled prescription or a refilled prescription for which counseling is required is being mailed or delivered to the patient by common carrier or delivery services, the consultation must still be provided but may be accomplished by providing written information to the patient regarding the medication being dispensed and the availability of the pharmacist to answer questions, and through the provision of a toll-free phone number for long distance calls.
- *Michigan R 338.589 Professional responsibility; "caregiver" defined.* Rule 89... (4)(a) The information must be communicated orally and in person, except when the patient or patient's caregiver is not at the pharmacy or when a specific communication barrier prohibits oral communication. In either situation, providing printed or electronic/digital material designed to help the patient use the medication safely and effectively satisfies the requirements of this subrule.
- *Illinois Section 1330.700 Patient Counseling (b)...* If, in the pharmacist's professional judgment, oral counseling is not practicable for the patient or patient's agent, the pharmacist shall use alternative forms of patient information. When used in place of oral counseling, alternative forms of patient information shall advise the patient or agent that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free or collect telephone service.
- *Iowa 657—6.14(155A) Patient counseling and instruction .... 6.14(4) Oral counseling not practicable.* If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may select and use alternative forms of patient information which shall include information for the patient or patient's caregiver to contact the pharmacist for further consultation. The manner in which the patient or caregiver contacts the pharmacist shall not cause the patient to incur any expense. "Not practicable" refers to patient

variables including, but not limited to, the absence of the patient or patient's caregiver, the patient's or caregiver's hearing impairment, or a language barrier.

V. Clarification of the proposed rule Phar 7.08 Patient consultation operational detail for prescriptions that require delivery or distribution by common carrier or delivery service.

The current proposed counseling language is ambiguous based upon Board discussions during the last several meetings and, in its current form, will require policy creation in order to clarify the many outstanding questions that still remain unanswered, such as:

- How many failed outbound phone calls are required to comply with the rule before initiating delivery?
- How long should a prescription be held before initiating delivery if oral counseling efforts are impractical, impossible or have failed?
- What are the recordkeeping and record retention requirements of the proposed rule?
- If a patient does not have, is unwilling to supply, or supplies an incorrect phone number, may delivery be initiated?
- Is there a patient confidentiality exception for drivers who hand the patient a mobile phone for live pharmacist consultation when delivering prescriptions for a community pharmacy?
- For patients who do not answer the phone, may leaving a message satisfy the proposed rule?

As the Board should not regulate via policy, as opposed to clarifying during rulemaking, CVS Health objects to the proposed changes to Phar 7.08 Patient consultation.

VI. Suggested change to Phar 7.08 Patient Consultation

Based on our public testimony and the discussion above, CVS Health recommends the following changes to Phar 7.08 to align with surrounding states and continue to protect the patients of Wisconsin:

Phar 7.08 Patient consultation.

(2) A pharmacist shall give the patient or patient's agent consultation relative to the prescription for any new drug product or device which has not been dispensed previously to the patient or any change in the patient's therapy. Patient consultation shall meet all of the following requirements:

b. Be communicated orally unless in the pharmacist's professional judgment ~~it is not in the best interest of the patient or patient's agent to be communicated orally~~ oral counseling is not practicable for the patient or patient's agent, the pharmacist shall use alternative forms of patient information. When used in place of oral counseling, alternative forms of patient information shall advise the patient or agent that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free or collect telephone service.

~~(3) The consultation requirement is not satisfied by only offering to provide consultation.~~

VII. Suggested change to Phar 7.085 Delivery by common carrier or delivery services.

Although based on Wisconsin Statute 227.137 as stated above the Board has not provided any reasoning, rationale or fiscal impact analysis for a the addition of Section Phar 7.085, CVS Health believes the following recommended amendments to section 7.085 protect the public while minimizing economic impact to pharmacies.

John Long, RPh, MBA | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 614-572-9008

Phar 7.085 Delivery by common carrier or delivery services. Utilization of common carrier or delivery services to deliver a prescription from the pharmacy which fills the prescription to the patient or patient's agent shall ensure all of the following:

(1) The delivery method ~~maintains appropriate environmental controls, including temperature and humidity, to prevent drug adulteration.~~ shall ensure that all prescription medications are delivered to the patient in accordance with standards of the manufacturer, United States Pharmacopeia, Federal Food and Drug Administration and other recognized standards.

(2) The delivery method provides for ~~verification~~ proof of receipt of all controlled substances.

(3) The patient or patient's agent is provided a method by which the patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the prescription drug product or device, including all of the following:

(a) Timeliness of delivery.
(b) Condition of the prescription drug upon delivery.
(c) Failure to receive the proper prescription drug product or device.

(4) Any prescription drug product or device which is compromised by delivery shall be replaced by the pharmacy. The pharmacy shall replace at no additional cost to the patient the prescription drug product or device by next-day delivery or the pharmacist shall contact the patient's practitioner to arrange for a prescription for a minimum 7 day supply of the prescription drug product to be dispensed to the patient by a pharmacy of the patient's choice.

We appreciate the opportunity to submit comments to the Pharmacy Examining Board for review. Please also see the attached comments that were submitted on October 17th, 2019 that detail several studies that review the exceptional quality results of mail service pharmacy. As you consider our comments, please contact me directly at 614-572-9008 if you have any questions.

Best regards,

John Long, RPh, MBA
Director, Pharmacy Regulatory Affairs CVS Health

cc: Debra Sybell
Jameson R. Whitney Esq.

Enclosure:

December 16, 2019

VIA E-MAIL @ DSPSAdminRules@wisconsin.gov

Sharon Henes
Administrative Rules Coordinator
Department of Safety and Professional Services
Division of Development
4822 Madison Yards Way
Madison, WI 53708-8366

RE: Pharmacy Examining Board and Phar 7 Comments

Dear Ms. Henes:

Thank you for the opportunity to submit comments on a permanent rule to repeal and recreate ch. Phar 7 relating to the practice of pharmacy.

The Wisconsin Assisted Living Association (WALA) represents the majority of Wisconsin's assisted living providers, with over 1,500 members. This includes community-based residential facilities (CBRF), residential care apartment complexes (RCAC), and adult family homes (AFH).

Our concerns pertain to Phar 7.08 Patient consultation. In particular, Phar 7.08 (2)(b) states - Patient consultation shall meet all of the following requirements: Be communicated orally unless in the pharmacist's professional judgement it is not in the best interest of the patient or patient's agent to be communicated orally.

While the proposed rule exempts health care providers from this requirement, it is not clear whether assisted living facilities fall under this exemption.

A main service provided by assisted living facilities is to assist with or administer a resident's medication(s). Individuals are usually living in an assisted living facility because they cannot manage their medications or identify side effects. Assisted living facilities have trained staff that can provide the necessary education to their residents about the medications while working and communicating directly with pharmacies. In doing so, assisted living facilities contract with a pharmacy to deliver those medications on behalf of the resident(s) to the facility. The assisted living facility staff communicate directly with the pharmacy(ies) to ensure the medications are administered safely and directly to the resident.

Adding another layer of communication will cause significant delays of receiving medications in a safe and cost-effective way.

Therefore, we respectfully request the proposed requirements pertaining to oral communication within Phar 7.08 (2)(b) be removed and that assisted living facilities can continue working directly with pharmacies to provide the best possible care to their residents and avoid any confusion, delays, or increased costs.

Thank you again for allowing us the opportunity to submit our comments on the proposed rule. If you have any questions or require additional information, please feel free to contact me at (608) 442-0377.

Respectfully submitted,

Michael S. Pochowski
CEO

WISCONSIN HOSPITAL ASSOCIATION

ADVOCATE. ADVANCE. LEAD.

5510 Research Park Drive
P.O. Box 259038
Madison, WI 53725-9038
608.274.1820 | FAX 608.274.8554 | www.wha.org

To: The Honorable Chair Dr. Philip Trapskin
Members, Pharmacy Examining Board

From: Ann Zenk, Vice President Workforce and Clinical Practice
Wisconsin Hospital Association

Date: December 17, 2019

Re: Proposed Phar 7

Thank you for the opportunity to comment on proposed Phar 7 relating to the practice of pharmacy. The Wisconsin Hospital Association (WHA) and its more than 140 members appreciate the importance of the Pharmacy Examining Board's (PEB's) work to re-write this chapter that establishes minimum standards for the practice of pharmacy.

WHA hospital and health system members operate pharmacies and institutional pharmacies and strategically utilize automated direct-to-patient dispensing systems, common carrier or delivery service and remote dispensing sites to ensure access to pharmacy services in the communities they serve.

WHA has been following the revision process for Phar 7 and appreciates the time and effort expended on your endeavor. Pharmacy leaders at our member organizations have taken note of helpful changes to this chapter, including, but not limited to, separating institutional pharmacies, counseling for new and revised prescriptions and maintaining monthly visits to dispensing pharmacies.

On behalf of our members WHA would like to offer constructive comments on counseling requirements:

7.42 (6) requires for direct-to-patient dispensing that if the associated pharmacy is open the pharmacist shall do a drug utilization review (DUR) and consultation. This creates unnecessary complexity and redundancy for institutional pharmacies who contract with vendors, such as Instymeds, to ensure timely access for patients in the communities they serve. Many communities do not have access to a 24-hour, or even a 16-hour pharmacy, and automated direct-to-patient dispensing systems provide a safe method for timely continuity of care. In rural and underserved communities, pharmacies cannot sustain the volume necessary to require evening and night hours, and direct-to-patient dispensing systems fill the gap for patients. Likewise, a single institutional pharmacist may be providing clinical services during these same hours. Reallocating this pharmacist's resources to DUR and consultation currently safely provided by a prescriber may inhibit the ability of hospitals and pharmacies to make direct-to-patient dispensing systems available and create a delay in care as patients and families wait for a pharmacy to open or travel long distances to find an open pharmacy.

WHA requests that prescriber DUR and consultation continue to meet the requirements for direct-to-patient dispensing systems.

Similarly, the re-write of section 7.08 adds complexity and regulation without an associated benefit. The current rule -- 7.01(e) -- requires appropriate written directions and instructions for how to contact a pharmacist. Giving patients and families this choice allows them to receive their medications in a timely and safe manner without the burden of additional phone calls, voice messages and outreach to determine their desire or need for oral counseling. PEB must ensure minimum safe practice. The unclear benefit of making oral counseling the default for delivery service does not balance or outweigh the additional burden and risk this will place on patients and pharmacies as they wait for delivery that is contingent on their pharmacist correctly predicting how long it will take to contact a patient by phone and whether a phone conversation will be welcome or beneficial to a patient unable or unwilling to travel to a pharmacy. When a patient is in person in a pharmacy, the default to oral counseling makes sense; the patient is immediately present to indicate their preference in a way that will not delay filling their prescription. Patients who opt for delivery should have the same right to timely access to their prescription.

WHA requests that PEB incorporate the same wording of current Phar 7 counseling rules for delivery of prescriptions to a patient's location of choice into the re-write of Phar 7.

Pharmacists fill key roles and provide invaluable expertise in Wisconsin hospitals and health systems. As the "Silver Tsunami" increases health care demand and shrinks the available workforce, we need to wisely utilize all professionals on the health care team, and carefully consider new regulations that add burden to the workforce.

We support PEB's effort to create safe pharmacy practice that works for patients and providers and appreciate PEB's careful consideration before adding new requirements that our workforce cannot afford.

Sincerely,

Ann Zenk
Vice President Workforce and Clinical Practice
Wisconsin Hospital Association

ENVISIONPHARMACIES

December 16, 2019

VIA ELECTRONIC MAIL (DSPSAdminRules@wisconsin.gov)

Ms. Sharon Henes
Administrative Rules Coordinator
Wisconsin Division of Policy Development

Re: Comments on Proposed Wisconsin Code Phar § 7.08

Dear Ms. Henes:

The attached comments are submitted in response to the above-referenced proposed rule. We thank you for the opportunity to participate in the regulatory process. As a licensed non-resident pharmacy in the State of Wisconsin, we have a particular interest in the successful development and implementation of the revised rules governing pharmacies licensed by the State of Wisconsin.

We invite you to contact us if you need further clarification on our comments or for any questions you may have: by telephone at 330-491-4287 or via email at cgasser@envisionpharmacies.com

Sincerely,

Chris A. Gasser PharmD, R.Ph.
Pharmacist in Charge
EnvisionPharmacies

Proposed Wisconsin Code Phar § 7.08

The proposed rule will create substantial challenges for pharmacies that ship prescription drugs to patients residing in the State of Wisconsin, ultimately resulting in significant burdens and costs.

The proposed rule requires all pharmacists, including those delivering medication by mail, to provide oral consultation unless one of the following criteria is met: (1) in the pharmacist's professional judgment it is not in the best interest of the patient or patient's agent; (2) the patient or patient's agent refuses consultation; or (3) a health care provider is administering the medication. This requirement deviates from the existing consultation rule[1], which allows for delivered medication to be accompanied by appropriate directions and the option to contact a pharmacist for consultation.

While the goal of the proposed rule may be to ensure oral consultation for every patient, such a broad application fails to adequately address the unique challenges created for mail order pharmacies and their patients. Retail pharmacies have the advantage of providing oral consultation upon medication pick-up when the patient is undoubtedly available. But mail order pharmacies are beholden to the patient's availability, willingness to answer the phone, and diligence in maintaining accurate and up-to-date contact information. Thus, mail order pharmacies will expend significant added costs to employ more staff to manage patient contact, including the additional time required for repeated attempts and locating patients with incorrect or outdated information.

Moreover, adoption of the proposed rule would result in a significant departure from surrounding states, despite the Economic Impact Analysis' ("EIA") assertion to the contrary. Instead of oral consultation, Michigan and Minnesota allow pharmacists to provide written information about the medication and availability of counseling[2]. Similarly, pharmacists in Iowa and Illinois may provide written information to patients when oral counseling is "not practicable[3]." In contrast, the proposed rule requires pharmacists to provide oral consultation even in instances where it would be unnecessary and impractical.

The Pharmaceutical Care Management Association represented that their member pharmacies' current practice is to contact a patient when it is in their best interest. Based on this representation, the EIA concludes that the proposed rule is consistent with this practice and, thus, will not result in additional burdens on member pharmacies. This conclusion is incorrect. The proposed rule essentially requires pharmacists to prove a negative by determining whether not providing oral consultation is in the patient's best interest. This is vastly different than the current practice of providing consultation when it is in the patient's best interest.

Based on the foregoing, we urge the State of Wisconsin Pharmacy Examining Board to maintain the consultation requirements under the existing rule for delivered medication. In the alternative, providing a practicality exception to the proposed rule would address many of the concerns shared by mail order pharmacies delivering medication to patients in Wisconsin.

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[1] Wis. Admin. Code Phar § 7.01(e)

[2] See Mich. Admin. Code r. 338.490 and Minn. R. 6800.0910

[3] See Iowa Admin. Code r. 657-6.14 and Ill. Admin. Code tit. 68, § 1330.700

Henes, Sharon - DSPS

From: M Jackson <jottingsbbac@gmail.com>
Sent: Monday, December 16, 2019 7:04 PM
To: DSPS Admin Rules
Subject: Phar 7

To Whom It May Concern:

Regarding the proposed changes, I would like to comment on the current requirements for consultation. I am "only a tech" at a retail pharmacy, but it startled me to find out that delivered prescriptions legally require no consultation at all. So in theory, I could deliver a new medication--even something like Warfarin--and the patient could legally receive no warnings about side effects.

From my experience, doctors don't always know the ins-and-outs of medications like pharmacists do (which is fair, we all play different roles), and I have seen so many patients who know almost nothing about the medication they were prescribed. How many potential problems are solved by something as simple as "Take it with milk or food so it doesn't upset your stomach"?

In short, I am in favor of the proposed changes.

Thank you for your time.

Sincerely,
M.C. Jackson
Pharmacy Technician

12/16/19

Wisconsin Board of Pharmacy,

The pharmacies of CPESN-WI would like to comment on the counseling requirements being proposed in the Phar 7 rewrite. Our organization represent 41 community pharmacies in Wisconsin. CPESN Wisconsin is a high-performance network that has adopted the tenets of value-based health care—increase the quality of patient care and reduce overall health care costs. CPESN WI is focused on improving the health of our patients by working collaboratively with other health care providers and ensuring that patients are achieving their therapeutic outcomes with safe and effective therapy.

We wanted you to know what CPESN-WI pharmacist thought about your proposed rules. We polled our member pharmacist about the proposed change in counseling requirements. The overwhelming majority of pharmacists agreed with the following statement.

We believe that community pharmacies, delivery pharmacies, and mail order pharmacies should counsel every new and refill prescriptions.

As you can see these represented pharmacies hold patient counseling in high regard, considering it a core part of their relationships with their patients. This patient centered focus to medication use leads to better adherence and better outcomes.

It is imperative that the Board mandate that all Wisconsinites receive counseling that the Board requires, no matter what pharmacy fills their prescriptions. Pharmacies that mail their prescriptions to their customers should be mandated to counsel.

Sincerely,
CPESN-WI

Henes, Sharon - DSPS

From: Jen Matte <jen.matte@forwardpharmacywi.com>
Sent: Monday, December 16, 2019 9:57 PM
To: DSPS Admin Rules
Subject: Revision of Pharmacy 7 comments

I am writing today with my comments for the revision of Pham 7, because I cannot attend the meeting today. I will busy working at our small town community pharmacy. I have been a community pharmacist for the last 18 years, and I have prided myself with providing quality care for my patients. The revision of Pharm 7 is necessary to help even the playing field in the world of pharmacy. Community pharmacist are held to a higher standard than mail order pharmacies when it comes to patient consultations. The required consultation on all new or changed medications should be universally applied to both retail and mail order pharmacies. Patients should be able to expect the same level of care from both retail and mail order pharmacies. In many instances patients are forced to use mail order pharmacies and they shouldn't have to accept subpar patient care also. Patient safety is at stake, and should not be compromised. I personally ensure that my patients receive quality consultations on all of their medications, so why does a mail order pharmacist not have to do the same? The current law is unfair and favors big corporations and mail order pharmacies, this is unacceptable. Patient care should be paramount when considering a change to Pharm 7. Please help ensure that patients are given the same level of care irregardless which pharmacy they choose,or are forced to use. Thank you for considering my opinion when deciding the changing of Pharm 7.

Jennifer Matte Pharm D
Forward Pharmacy of Deerfield

2108 Uphoff Road
Cottage Grove, WI 53527

Date: December 17th, 2019
To: Dr. Philip Trapskin, Chairman
Members of Pharmacy Examining Board
From: Matthew R. Mabie RPh, Owner
Forward Pharmacy
Subject: Phar 7: Practice of Pharmacy

To begin, I would first like to thank all members of the Pharmacy Examining Board for their service to our profession and for putting in the time to rewrite, update, and modernize the rules and regulations that govern our profession. The board has done a magnificent job opening up our rules to allow for future growth of our profession in ways we may not even consider. Many of the changes that have already been discussed in previous meetings have removed barriers to practice that existed before the rewrite. So how do we go about rewriting Phar 7 with the same vision and mantra of removing practice barriers that we might not think are barriers today; yet keeping the spirit of the rules intact and most importantly, protect the citizens of WI?

My testimony in this letter will focus primarily on Phar 7.08 Patient consultation. I would like everyone to close their eyes and think for a moment, how will prescriptions be delivered, picked up, or handed to patients in 5, 10, 15, even 20 years? I would bet if I asked each of you to give me your vision, we would have very different thoughts between just the board members. If some companies have their way, everything will just be sent directly to a patient's door the next day. Or a drone will drop off prescriptions where you want them to; when you want it. Or you will walk over to your computer and type in a symptom and your 3D printer will just print the needed medication for you right at your desk. What I am trying to get across is we have to have rules that guide our profession that allow for innovation and technology advances yet continue to protect the citizens of WI. In my humble opinion, it appears to me that we took 2 steps backwards with the new proposed requirements of a patient consultation. Why are we specifically outlining everything that must be said during that consultation? Didn't we just work really hard at removing specific language from other sections of our pharmacy code that was restrictive and handcuffing to our profession and our professional advancement? Do doctors and nurses have specific lines in their codes that describe what must happen or occur during an office visit? Do they have specific lines in their codes that state when and how an X-ray, CT scan, MRI, or any diagnostic tool should be used? Of course not. They use these technologies to assist in their diagnosis but only after the doctor or nurse deem it necessary or important to the care of that individual patient. We should be thinking along those same lines for consultation to our patients or agents of our patients. In an effort to keep my comments succinct, I would like to propose 2 suggestions to the board.

forward pharmacy

2108 Uphoff Road
Cottage Grove, WI 53527

1. Rewrite Phar 7.08 to say, "Give the patient or agent appropriate consultation relative to the prescription."
2. A consultation is not required when a health care provider or designee of the health care provider is administering the medication while the patient is residing in a health care facility such as a SNF, ALF, RCAC, or any health care facility that is licensed by the State of WI.

As you can see and read, I have not placed restrictions or limitation on what must be included on the consultation. In addition, I have not exempted any pharmacy or type of pharmacy from consultation. The PEB licenses only 2 types of pharmacy, in state and out of state. Both should comply with the new rules. I have seen the huge piles of medications that patients bring me due to mail order sending medications to patients when they aren't needed or even worse, have been discontinued. I have numerous pictures of boxes upon boxes of unopened insulin that was being sent to patients, all because there was no consultation. This would never happen at any one of my locations. If a patient walked in and I had insulin ready for them to pick up, they simply refuse if they have some at home. If a consultation doesn't occur, we have patients who don't stop a medication when prescribed a new one to replace it. Just today, I spoke to a patient who remembers speaking to her MD about changing her dose of Metoprolol. I had the new dose filled and ready for her when she approached the counter and after consultation with me, realized, she should stop the other dose, NOT add the new pill to the current pill. Had she combined the 2 medications she may have ended up back in the hospital from dizziness, lightheadedness, or fallen and hit her head, only to be found by her husband hours later. Call me old fashioned or old school in this regard but a consultation for any medication can only be beneficial.

I will leave you one last tidbit: An appropriate consultation will almost always end in no harm to the patient, BUT no consultation has the potential to cause great harm to the patient. I ask you, which side do you want to be on? The side that protects our citizens with appropriate consultations or the side that plays a game of chance with every medication?

Respectfully submitted,

Matthew R. Mabie RPh/Owner
Forward Pharmacy of Cottage Grove, Columbus, Deerfield, and McFarland

Henes, Sharon - DSPS

From: Cross Plains Pharmacy <cppharm@chorus.net>
Sent: Tuesday, December 17, 2019 2:17 AM
To: DSPS Admin Rules
Subject: Comment on proposed changes to Phar 7

Wisconsin Pharmacy Examining Board:

Thank you for the opportunity to comment on the proposed Rule changes to Phar 7. I had hoped that I would be able to attend in person, but my presence is needed in my pharmacy as I was unable to find coverage for the day.

I am writing to you today to express some concerns with regards to patient counseling.

I believe that all pharmacies that do business in the State of Wisconsin, community, chain, hospital outpatient, delivery and mail order pharmacies, should be required to counsel on all new and refill prescriptions. We are health care professionals who dispense medications that can have profound effects on the life of a patient, but the medications need to be taken correctly. I believe that Wisconsinites deserve counseling from a pharmacist, no matter how they receive their medications.

All pharmacies doing business within the State of Wisconsin should be held to the same standard. But, if you feel that mail order pharmacies are exempt from these counseling rules, then the rest of the pharmacy providers should be exempt as well.

I thank you all for your time and your consideration.

Respectfully,

Lisa Kostecki R.Ph.
Cross Plains Pharmacy
1840 Main St.
Cross Plains, WI 53528
608-798-3031

Henes, Sharon - DSPS

From: Kayla Rackow <ksrackow@gmail.com>
Sent: Tuesday, December 17, 2019 8:17 AM
To: DSPS Admin Rules
Subject: Phar 7 comment

To the Pharmacy Examining Board,

My comment is in regard to the consultation changes that are being proposed. As a retail pharmacist, there are numerous benefits to consultations on refill medications. Every day I have patients state "I have no questions" or "I feel bad to waste your time on a refill" before I even get up to the counter. A perfect example of this is a patient who was picking up blood pressure medications, stated he had no questions before I got there, and after telling him which medications he was picking up and what they were used for he did have a question because he used our blood pressure machine and wanted advice on his reading. His numbers that day were elevated to the point he was at a high risk of a stroke occurring, so I advised he go to the emergency department. Had that consultation not taken place, I guarantee that patient would not have asked about his blood pressure and just went home. While there are patients who will not have questions, each day there are patients who end up actually having questions once I go over which medications they are taking, and sometimes it is during that refill consultation that patients state "I'm no longer taking that medication" or "my doctor stopped that medication." Had there not been a refill counsel that took place, patients would be leaving with medications they no longer use, and I feel like we see that happening more often with patients wanting medications on autofill or replying to a text notification when they don't really know what they are receiving. While I understand that patients will have the option to speak with a pharmacist on a refill if this change is approved, I fear there are numerous patients who will be complacent because they do not want to bother the pharmacist and just state "no questions" since that is what we already experience, when in fact there are patients who have questions. One of my favorite aspects of my job is interacting with my patients and getting to know them so that they trust me and feel comfortable asking questions. I did not go into retail pharmacy to stand at a computer all day and just check scripts, I chose this career path to make a different in patients' lives and interact with them. It's amazing how much a patients' perspective changes on refill consultations when you tell them that talking to them is one of your favorite parts of your job.

Another reason I feel that mandatory refill consultations are important is because a lot of patients will only see their physician once a year and come to the pharmacy once every three months. As the most accessible healthcare providers, I feel that it is our responsibility to build rapport with our patients and check in on their healthcare. Pharmacists should be asking how a patient's blood pressure is doing, have they noticed if their fasting blood sugar has decreased or maybe they have started experiencing low sugars, have they developed muscle pain from their statin that they've been taking for years, or how has their mood been after starting a depression medication. Numerous medications can take months to provide benefit, so not checking in on these patients can lead to patients stopping necessary therapy before the medication has had a chance to work, leading to failed therapy when in reality it wasn't failed but patients forgot it can take time to work. Refill consultations are also a perfect time to discuss patient adherence to medications and see if they are up-to-date on their immunizations. Taking away that ability to counsel and making it optional, I feel will result in decreased adherence and even further decreases in immunization rates that are already low.

Finally, my concern with this change is that there will be a negative impact on the job market. Wisconsin has already been seeing a decline in available jobs with pharmacies closing and more schools opening. If this change occurs, we will again see pharmacists losing their jobs. I have spoken with a manager who oversees Wisconsin and Illinois stores, and she stated that if this change passes her Wisconsin stores will be over-staffed and cuts will occur. I was told that when you take the same volume store between Wisconsin and Illinois, the Wisconsin pharmacy has significantly more hours specificly because of this law. As a pharmacist who worked for Shopko and lost my job earlier this year, it makes me sad to know that a law change such as this will risk me and others losing our jobs and negatively impact patient safety with pharmacies operating even more understaffed at some of the large chain pharmacies.

Sincerely,

Kayla Rackow, PharmD

Boscobel Pharmacy, Inc.

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(608) 375-4466 Fax (608) 375-2383
www.boscobelpharmacy.com

Wisconsin Board of Pharmacy,

Thank you for receiving and considering comments on the proposed changes to Phar 7 and ensuring safety of patients who receive services from pharmacies.

The role of the PEB is to define the active practice of pharmacy and ensure minimum standards for the practice of pharmacy. I own Boscobel Pharmacy, an independent pharmacy located in rural southwest Wisconsin. I have practiced within this pharmacy for 19 years and have seen first hand the positive impact counseling can have on my patient population.

My pharmacists and I provide consultation to all new and refill prescriptions. At least once a week, we have a mail order patient present to the pharmacy looking for assistance with their mail order medications because they cannot reach the mail service that is sending them medications in a timely manner. These matters often could result in medication misadventures if we were not available to assist the patient. We have assisted patients in side effect avoidance, drug-drug or drug-disease interaction avoidance, and ensured efficacy of their medications through a consultation. For example, recently I had a patient with Parkinson's disease experiencing increasingly worse side effects from her maintenance medications—she had attempted to reach mail order pharmacist and was unable. She presented to my pharmacy in tears as she wanted to enjoy one of her last Thanksgivings with family and didn't know what to do. She was embarrassed she had to ask for these services from my pharmacy when her mandated pharmacy was receiving payment for services. I believe the authors of this rule intended that a dispensing pharmacist would provide consultation and be available to screen for situations of this type.

The current rule Phar 7.03 exempts mail order pharmacy from counseling requirements. I believe that community pharmacies, delivery pharmacies, and mail order pharmacies should counsel every new and refill prescriptions. I urge the PEB to hold all pharmacists and pharmacies to the same standard.

Thank you for your time and consideration.

Sincerely,

Michelle Farrell, PharmD
Owner, Boscobel Pharmacy

InstyMeds

We Make Patients Better, Quicker!™

December 12, 2019

Via email and UPS Overnight

Sharon Henes, Administrative Rules Coordinator
Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way
Madison, WI 53708
DSPSAdminRules@wisconsin.gov

Re: In the Matter of Rule-making Proceedings Before the Pharmacy Examining Board
InstyMeds Comment to Proposed Order of the Pharmacy Examining Board Adopting Rules (Clearinghouse Rule)

Dear Ms. Henes, Members of the Pharmacy Examining Board, and Staff:

InstyMeds Corporation (formerly known as Mendota Healthcare) appreciates the time and attention that you will spend reviewing and considering our comments to the Pharmacy Examining Board's (the "Board's") Proposed Order Adopting Rules (the "Proposed Order") to repeal and recreate Chapter Phar 7 – Pharmacy Practice.

1. Introduction and review of data

To prepare the following comments, InstyMeds evaluated both quantitative and qualitative data available to it. For instance, InstyMeds reviewed comments it has received from its customers with a focus on what aspects of InstyMeds' product and services seem to be of particular value to patients (attached as Exhibit 1), reviewed an objective study of InstyMeds' accuracy in dispensing (Elizabeth A. Flynn, PhD, RPh, *A Study of the Accuracy of the InstyMeds Automated Prescription Dispensing System* (2013) (attached as Exhibit 2[1])), as well as a study of primary adherence to medication in the outpatient setting when choosing InstyMeds (Jacob G. Moroshek, *Improving outpatient primary medication adherence with physician guided, automated dispensing*, CLINICOECONOMICS AND OUTCOMES RESEARCH 2017:9 59-63) (attached as Exhibit 3[2])).

[1] Dr. Flynn's cross-sectional descriptive study involved 41 randomly selected InstyMeds sites that agreed to participate from 12 different states, including Wisconsin, 1001 medications entered and dispensed (comprised of 99 different types of medications), and resulted in an accuracy rate of 100% of dispensed prescriptions by the InstyMeds system. As Dr. Flynn notes, InstyMeds' 100% accuracy rate compares very favorably to the accuracy rate of traditional prescription filling systems, which measured at 98.3% (or, over 5 million prescriptions each year that are filled in error by human-inspection systems). (Exhibit 2.)

[2] Mr. Moroshek's research de-identified and analyzed the InstyMeds dispensing database, providing a sample size of 1,493,869, and concluding that InstyMeds' emergency department

InstyMeds is proud that research has confirmed its system's accuracy and increase in outpatient primary medication adherence precisely because InstyMeds takes public health and safety, as well as applicable laws, rules, and regulations very seriously. Since InstyMeds' inception, InstyMeds has worked diligently to collaborate with state agencies and representatives, to help others understand the benefits of a system that safely and accurately dispenses outpatient prescriptions in a way that substantially improves primary medication adherence by increasing patient access and decreasing the number of challenges patients face in filling outpatient prescriptions while decreasing costs such as additional treatment specific to primary medication non-adherence (e.g., decrease in hospitalizations as outcomes improve), costs associated with dispensing errors, and improved pharmacy workplace productivity and employee satisfaction (e.g., by allowing pharmacists to focus on activities that allow them to use their advanced training).

InstyMeds hopes this comment will be helpful as we both work towards our shared pursuit of enhancing the lives of patients, improving patient outcomes, and ensuring safe and secure manufacture, distribution, and dispensing of prescription drugs.

2. About InstyMeds and its long history in Wisconsin

InstyMeds' founding and ongoing work. InstyMeds, located in Eden Prairie, Minnesota, was founded in 1999 by Dr. Ken Rosenblum, who worked as an emergency room physician in Minneapolis. After taking his own child to an ER at night, Dr. Rosenblum needed to fill a prescription for the common antibiotic amoxicillin. As Dr. Rosenblum drove around in the middle of the night looking for a pharmacy, he wondered why patients have to work so hard to get their medications. As a result, Dr. Rosenblum partnered with engineers, physicians, and pharmacists to build what is now known as the InstyMeds Medication Adherence System ("InstyMeds" or the "InstyMeds system")—the world's most advanced, most tested, and safest automated dispensing system at the point of care. InstyMeds dispensed its first prescription to a patient in Minnesota in 2001 and has since dispensed millions of prescriptions in more than half of the states in the U.S., as well as in Europe and the Middle East. This year, two years after reaching the 3-million-dispensed-prescriptions mark, InstyMeds first dispensed to patients at a Veterans Affairs Medical Center. The Board will not be surprised to learn that InstyMeds was vetted and approved by the Department of Veterans Affairs before being allowed to dispense at the VA. The vetting and approval process touched all areas of the InstyMeds system such as patient medication safety, formulary development, security tests and requirements associated with becoming a business associate.
Now, having successfully completed this vetting process with the VA, the dispenser there is one of three dispensers in the patient service area of Tomah, Wisconsin, and InstyMeds is excited to continue to work with the VA to address the needs of its patient population.

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installations have an average primary adherence rate of 91.7% with an upper level of 98.5%. According to Mr. Moroshek, other research has indicated that only between 68.7 and 71.7% of prescriptions are dispensed to patients. (Exhibit 3.)

Wisconsin's approval of InstyMeds' operation. InstyMeds has worked with the State of Wisconsin almost since the company's inception. After InstyMeds (then Mendota Healthcare) inquired about whether it would meet the requirements for dispensing prescription drugs in the state, on October 9, 2002, the Wisconsin Medical Examining Board confirmed that the use of the InstyMeds system would meet the Medical Board's standards and would be consistent with the Medical Board's statute and administrative code. (Exhibit 4.) About a year later, the Wisconsin Pharmacy Examining Board also confirmed that InstyMeds' operation would be subject to the Medical Examining Board's regulations and would therefore be permissible under the Pharmacy Board's regulations. (Exhibit 5.)

Positive patient reaction to InstyMeds and how it works successfully in Wisconsin. Since January 2004, InstyMeds has dispensed over 800,000 prescriptions in Wisconsin and currently has 54 sites, all of which operate safely and successfully in the state.[3] No problems or concerns

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[3] In 2019, InstyMeds released a study performed at a Wisconsin emergency department. It compared outcomes for patients that presented with a Urinary Tract Infection (UTI) who received a prescription to InstyMeds versus to a traditional retail pharmacy. The study definitively showed that patients given a prescription to receive medication at an InstyMeds dispenser had dramatically improved outcomes as the probability of a return visit within two weeks for patients that used the InstyMeds dispenser was 1.3% versus a 5.3% probability in the control group of traditional pharmacies. In short, when more patients receive their medication, more take their medication, more get well, and fewer have return visits and hospitalizations. While this outcomes study focused on UTIs, the results may be generalized to other infectious illnesses treatable with antibiotics (e.g., pneumonia, cellulitis, bronchitis, etc.).

InstyMeds estimates that healthcare payers and Wisconsin Citizens have had savings of approximately $3,919,363 as calculated below, based on findings from the outcomes study.

-InstyMeds has had 800,000 dispenses in the state of Wisconsin

-According to the Agency for Healthcare Research and Quality at AHRG.gov, UTI infections are approximately 2.5% of patient visits. (2.5% of 800,000 patients is 20,000 InstyMeds patients with a UTI)

-The InstyMeds Outcomes study showed that 1.3% of patients receiving a prescription to an InstyMeds dispenser had a return visit or 260 patients. (20,000 UTI patients X 1.3%)

-The InstyMeds Outcome study showed that 5.3% of the patients who did not use the InstyMeds dispenser had a return visit or 1060 patients. (20,000 UTI patients X 5.3%)

-InstyMeds saved 800 return patient visits. (1060 - 260)

- According to the Agency for Healthcare Research and Quality at AHRG.gov, 14.1% of UTI visits result in hospitalization or 113 patients. (800 X 14.1%) and 687 patients (800-113) did not return to the ED.

- According to the Agency for Healthcare Research and Quality at AHRG.gov, the average cost for a patient hospitalized by a UTI infection is $26, 240

- InstyMeds patients saved $2, 965,120 in hospitalization costs ($26,240 X 113)

- According to the Health Care Cost Institute the average cost of an ED visit is $1,389

- InstyMeds patients saved $954,243 in return ED visits ($1,389 X 687)

- InstyMeds saved payors and patients over $3.9M ($2,965,120 + $954,243).

These savings do not include estimate for reduction in hospitalizations for far more expensive diseases such as pneumonia. Thus, it is not hyperbolic to estimate that InstyMeds' total positive

have ever been communicated to InstyMeds regarding its operations in Wisconsin. To the contrary, over the course of these 16 years, patients have repeatedly expressed their appreciation for InstyMeds generally and its services in particular. (*See* Exhibit 1)

Many of InstyMeds' dispenser locations are in areas with limited pharmacy access, especially during evening and late at night.[4] InstyMeds' formulary is limited to a selection of acute-care medications, with claims adjudicated and bottles labeled just as those from a conventional pharmacy. Medications are sourced via a Verified-Accredited Wholesale Distributors ("VAWD") accredited facility, repackaged into unit-of-use containers, packaged into serialized magazines or cartridges (the contents of which are of all the same drug, strength and quantity with expiration and lot# included in the bar code) and shipped to the sites to be loaded into dispensers. Unlike a vending machine,[5] InstyMeds is an invitation-only, closed system that, among other controls: requires providers to be granted access to write orders to the InstyMeds dispenser; requires patients to be seen in person by the provider; requires the prescriber, patient, and prescription medication to be in the same location; and, requires a patient to have two forms of authentication (date of birth, and a unique secure code given to the patient by the provider) to begin the dispensing process.

In contrast to other prescription-dispensing systems, including conventional pharmacies, other automated systems, and manual systems commonly in use today, InstyMeds:

(a) does not use loose dosage forms;
(b) monitors the exact inventory in each dispenser at all times;
(c) monitors the exact expiration dates of each bottle or package at all times and prevents further dispensing of that product 30 days before reaching the expiration date by locking down the magazine in the dispenser;
(d) monitors manufacturer information, enabling the system to identify instantly where a product is in any dispenser anywhere and prevent dispensing of the product in the event of a manufacturer recall, for example, all with the push of a button;
(e) uses a triple barcode technology that is 100% accurate and, if any of the three barcode identifiers do not match, will discontinue the dispensing process;
(f) for sites with controlled substances, not only is inventory accurately monitored at all times, but InstyMeds also informs the site what they need to order and automatically

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economic impact for Wisconsin likely exceeds $10 million through reduction of unnecessary healthcare expenditures caused by patients' primary medication nonadherence.

[4] The busiest days for InstyMeds' are times when conventional pharmacies are usually closed, including holidays, Saturdays, Sundays, and evenings. Indeed, the busiest day of the year for InstyMeds is Christmas day.

[5] InstyMeds respectfully notes that to the extent the Board conceives of its systems as a "vending machine" (*see* Proposed Order at 6), such an understanding is mistaken. An InstyMeds user cannot simply choose from any number of available medications as someone might choose an over-the-counter pain reliever from an airport vending machine. Rather, as noted above, the InstyMeds system (1) requires a prescription from a licensed practitioner; and (2) includes numerous controls and extensive monitoring that make it impossible for someone to choose a medication from the machine at their own whim.

submits all prescription drug monitoring program ("PDMP") reporting on behalf of each client every 24 hours in Wisconsin;
(g) is able to quickly identify potential drug diversion due to InstyMeds' extensive and accurate inventory monitory and ordering process;
(h) has a Patient Service Center open 24/7, 365 days a year to assist patients with insurance issues or any related questions to help them get the medication prescribed to them;
(i) has been shown to be 100% accurate in dispensing (Exhibit 3);
(j) has been shown to improve primary medication adherence (Exhibit 4); and
(k) dispensing machines are constructed to prevent break in and are most often located in areas such as waiting rooms or near registration desks.

Importantly, especially for purposes of this comment, InstyMeds has always operated from a physician/practitioner-dispensing model rather than a pharmacy model. This is also why approvals from the Wisconsin Medical Examining Board (Exhibit 4) and Wisconsin Pharmacy Examining Board (Exhibit 5) were properly framed and understood as requiring InstyMeds to comply with the Medical Examining Board's regulations and, therefore, be permissible under the Pharmacy Board's regulations.

3. The Proposed Order unnecessarily restricts use of the InstyMeds system and inhibits InstyMeds' ability to continue to safely increase patient access to prescription medication and achieve positive outcomes.

The Proposed Order inhibits prescribers' ability to dispense prescription medication in the safest and most accurate manner. It also curtails InstyMeds' business of safely and accurately dispensing prescription medication in at least three ways. *First*, both the plain-language analysis and the text of the proposed rule require pharmacists to be involved in dispensing prescription medication regardless of involvement of physicians or practitioners. *Second*, the plain-language analysis and the text of the proposed rule require automated direct-to-patient dispensing systems to be associated with a pharmacy regardless of the involvement of physicians or practitioners. *Third*, the proposed rule constitutes an illegal anticompetitive and unfair method of competition by pharmacists against competitors such as physicians and other prescribers, as well as those whose services rely on a physician-dispensing model such as InstyMeds.

a. The Proposed Order curtails prescribers' ability to dispense prescription medication and inhibits InstyMeds' business of safely and accurately dispensing prescription medication directly to patients.

Both the plain-language analysis and the proposed rule require pharmacists to be involved in dispensing prescription medication even in instances where practitioners are involved. Thus, under this new rule, *pharmacists* must dispense prescription medication—a requirement that runs contrary to Wisconsin law (addressed further below at 3.c.). Examples of the topics in which both the plain-language analysis and proposed text of the rule require involvement of pharmacists notwithstanding practitioners' ability to meet the proposed requirements are provided in the table immediately below for ease of reference.

Topic	Plain-language analysis	Board's Proposed text of rule
Regarding drug-utilization reviews	"If there is a concern with any of these items, the pharmacist will take steps to resolve the matter." (Proposed Order at 2.)	"A pharmacist shall complete a drug utilization review by reviewing the patient record prior to dispensing each prescription drug order . . . . Upon recognizing a concern with any of the items in sub. (1)(a) to (j), the pharmacist shall take steps to mitigate or resolve the problem." (Proposed Order at 14-15, § Phar 7.03(1) and (2).)
Regarding final check prior to dispensing	"All prescription drugs and devices must have a final check prior to dispensing. . . . The check can be done by one or more multiple pharmacists, with the prescription record reflecting which pharmacist was responsible for each part of the final check." (Proposed Order at 3.)	"For all prescription drug product or device dispensing, the prescription record shall identify the pharmacist responsible for each part of the final check. If sub. (1) (a) or (b) is completed by delegate check delegate [sic] under s. Phar 7.14 or automated technology under s. Phar 7.55, the prescription record shall identify the supervising pharmacist." (Proposed Order at 18, § Phar 7.07(2).)
Regarding pharmacist involvement in automated direct-to-patient dispensing systems	"Stocking, inventory, and monitoring the machine shall be limited to a pharmacist or pharmacist delegate." (Proposed Order at 6.)	"A prescriber may not dispense utilizing an automated direct-to-patient dispensing system. . . . Individuals with access to the automated direct-to-patient dispensing system for the purpose of stocking, inventory, and monitoring shall be limited to a pharmacist or a pharmacist delegate. . . . If the associated pharmacy is open, the pharmacist shall do a drug utilization review under s. Phar 7.03 . . . The managing pharmacist is responsible for maintaining records of the automated direct-to-patient dispensing system. . . . The managing pharmacist shall establish written policies and procedures for automated direct-to-patient dispensing system [sic] . . ." (Proposed Order at 26-27, § Phar 7.42(2) – (8).)

Importantly, the text of the proposed rule makes clear that there is no compelling safety reason for the restriction of these actions to pharmacists when practitioners are likewise able to fulfill

these duties as part of their licensed areas of practice. For example, when an "associated pharmacy is not open, then the *prescriber* is responsible for the drug utilization review and consulting." (Proposed Order at 27, § Phar 7.42(6) (emphasis added).) And as the Board is aware, Wisconsin's statutes already allow practitioners or their agents to "prepare, compound, dispense, or prepare for delivery for a patient any prescription drug." *See* Wis. Stat. §§ 450.11(3) ("no person other than a pharmacist *or practitioner* or their agents and employees as directed, supervised, and inspected by the pharmacist *or practitioner* may prepare, compound, dispense, or prepare for delivery for a patient any prescription drug" (emphases added)), 450.11(4) ("no prescribed drug or device may be dispensed unless there is a label attached to the container disclosing all of the following: 1. The name and address of *the dispensing practitioner* or licensed facility from which the prescribed drug or device was dispensed . . ." (emphasis added)).

Modifications to the proposed rule to include practitioners and those abiding by applicable statutes and rules under a physician-dispensing model are easily made to the text of the proposed rule by adding "practitioner" or "prescriber" to provisions that currently mention only pharmacists or by adding a short additional section to the chapter that clarifies the existing state of law under Wisconsin's statutes. For example:

> ***Phar 7.[XX] Dispensing by Practitioners.*** *A dispensing practitioner shall personally perform all dispensing functions described in Chap Phar 7 that are required of a pharmacist when the dispensing is being done in a pharmacy. A practitioner may delegate functions that may be delegated in accordance with [proposed] Phar 7.14.*

This suggested language closely mirrors that found in Minnesota's Board of Pharmacy Rules. *See, e.g.*, Minn. Admin. R. 6800.9952 "Dispensing"; *see also id.* at 6800.9950 *et seq.* (regarding requirements for dispensing practitioners related to, *inter alia*, drug storage, labeling, and records). Many of InstyMeds' concerns would be alleviated through provisions such as these coupled with the suggested language below (*see* 3.b.) regarding use of automated direct-to-patient dispensing systems. Indeed, InstyMeds' proposed language would allow practitioners to safely dispense prescription medication as they have been doing for decades—so long as they continue to follow Wisconsin's statutes and rules applicable to their licenses.

b. The Proposed Order requires association with a pharmacy, again unnecessarily preventing InstyMeds from working with prescribers to dispense prescription medication to patients.

As with the Proposed Order's requirements of pharmacist involvement in dispensing prescription drugs (*see supra*), so too does the Proposed Order unnecessarily require association with a pharmacy to use an automated direct-to-patient dispensing system.

Plain-language analysis	Board's proposed text of rule
N/A	"A pharmacy may utilize an automated direct-to-patient dispensing system in a secure and professionally appropriate environment in any locations under s. 450.062 (1) to (4), Stats" (Proposed Order at 26, § Phar 7.42(1).)

Plain-language analysis	Board's proposed text of rule
"The automated direct-to-patient dispensing system shall be associated with a pharmacy (a prescriber may not dispense utilizing an automated direct-to-patient dispensing system, however, a prescriber may submit a prescription for dispensing by such a system)." (Proposed Order at 6.)	"An automated direct-to-patient dispensing system shall be associated with a pharmacy. A prescriber may not dispense utilizing an automated direct-to-patient dispensing system. A prescriber may submit a prescription for dispensing by an automated direct-to-patient dispensing system." (Proposed Order at 26, § Phar 7.42(2).)
"Stocking, inventory, and monitoring the machine shall be limited to a pharmacist or pharmacist delegate." (Proposed Order at 6.)	"Individuals with access to the automated direct-to-patient dispensing system for the purpose of stocking, inventory, and monitoring shall be limited to a pharmacist or a pharmacist delegate." (Proposed Order at 26, § Phar 7.42(3).)
"If the associated pharmacy is open, the pharmacist shall do drug utilization review and consultation. If the pharmacy is closed, the prescriber is responsible for the drug utilization review and consulting." (Proposed Order at 6.)	"If the associated pharmacy is open, the pharmacist shall do a drug utilization review under s. Phar 7.03 and consulting requirements in s. Phar 7.08. If the associated pharmacy is not open, then the prescriber is responsible for the drug utilization review and consulting." (Proposed Order at 27, § Phar 7.42(6).)
"Labeling and recordkeeping requirements are to be met." (Proposed Order at 6.)	"The managing pharmacist is responsible for maintaining records of the automated direct-to-patient dispensing system." (Proposed Order at 27, § Phar 7.42(7).)
N/A	"The managing pharmacist shall establish written policies and procedures for automated direct-to-patient dispensing system . . ." (Proposed Order at 27, § Phar 7.42(8).)

Absent from the Proposed Order is any articulated reason as to why a pharmacy may use an automated direct-to-patient dispensing system but a prescriber may not. Again, prescribers may dispense prescription drugs. *See* Wis. Stat. §§ 450.11(3) ("no person other than a pharmacist *or practitioner* or their agents and employees as directed, supervised, and inspected by the pharmacist *or practitioner* may prepare, compound, dispense, or prepare for delivery for a patient any prescription drug" (emphases added)), 450.11(4) ("no prescribed drug or device may be dispensed unless there is a label attached to the container disclosing all of the following: 1. The name and address of *the dispensing practitioner* or licensed facility from which the prescribed drug or device was dispensed . . ." (emphasis added)), 448.01(9) (defining practice of medicine to include prescribing, advising, and treatment by any means or instrumentality). And, again, prescribers are required to fulfill the associated pharmacy's duties of drug utilization review and consulting if the associated pharmacy is closed. (Proposed Order at 27, § Phar 7.42(6).)

This begs the question: What legitimate basis is there to allow physician dispensing to occur with an error prone manual system while prohibiting prescribers from using an automated direct-to-patient dispensing system particularly where, as here, the technology being withheld from practitioners (and therefore their patients) has been shown to be 100% accurate and result in higher rates of primary medication adherence? (*See* Exhibits 3 and 4.) As addressed below (*see* c.3.), InstyMeds' concern is that this Board's proposal is not intended to further a legitimate goal but is instead intended to illegally curtail competition in this market. To the extent the Board's goal is instead rooted in public protection, the Board's Proposed Order could be modified to address safety concerns by using language similar to the examples below.

i. Example 1: Iowa Code Ann. § 147.107 (West 2018)

2. a. A prescriber who dispenses prescription drugs, including but not limited to controlled substances, for human use, may delegate nonjudgmental dispensing functions to staff assistants only when verification of the accuracy and completeness of the dispensing is determined by the practitioner in the practitioner's physical presence. However, the physical presence requirement does not apply when a practitioner is utilizing an automated dispensing system. When using an automated dispensing system, the practitioner shall utilize an internal quality control assurance plan that ensures accuracy for dispensing. Verification of automated dispensing accuracy and completeness remains the responsibility of the practitioner and shall be determined in accordance with rules adopted by the board of medicine, the dental board, the board of podiatry, and the board of psychology for their respective licensees.

(*See* Exhibit 6 for full text.)

ii. Example 2: Proposed rule in Michigan, September 2019 (*see* proposed MI ADC R 338.588 "Automated devices")

Rule 88. *(1) "Automated device" means a mechanical system that performs an operation or activity, other than compounding or administration, relating to the storage, packaging, dispensing, or delivery of a drug and that collects, controls, and maintains transaction information.*
(2) An automated device may be used only in the following locations:
(a) A pharmacy.
...
(g) An office of a dispensing prescriber.
...
(3) A pharmacy that operates an automated device under this section shall notify the department of the automated device's location on a form provided by the department. An automated device located within a licensed pharmacy must be used only by a pharmacist or his or her pharmacy personnel under the personal charge of a pharmacist.
(4) If an automated device is used in a dispensing prescriber's office, the device must be used only to dispense medications to the dispensing prescriber's patients and only

under the control of the dispensing prescriber. A pharmacy shall not own, control, or operate an automatic dispensing device in a dispensing prescriber's office, unless the prescriber's office is affiliated with a hospital consistent with section 17760 of the code, MCL 333.17760.

(a) If a dispensing prescriber delegates the stocking of the automated device, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing a board-approved error prevention technology that complies with R 338.3154.

(b) A dispensing prescriber operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.

(c) If any medication or device is dispensed from an automated device in a dispensing prescriber's office, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility must be maintained by the dispensing prescriber for review by an agent of the board. This documentation must include at least all of the following information:

(i) Manufacturer name and model.

(ii) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.

(iii) Policy and procedures for system operation that addresses at a minimum all of the following:

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

(D) Data retention or archival records.

(E) Downtime procedures.

(F) Emergency procedures.

(G) Medication security.

(H) Quality assurance.

...

(8) Policy and procedures for the use of the automated device must include a requirement for pharmacist review of the prescription or medication order before system profiling or removal of any medication from the system for immediate patient administration. This subrule does not apply to the following situations:

...

(e) The automated device is located in a dispensing prescriber's office.

(9) A copy of all policies and procedures related to the use of an automated device must be maintained at the pharmacy responsible for the device's specific location or at the dispensing prescriber's office and be available for review by an agent of the board.

(*See* Exhibit 7 for the full text.)

c. The Proposed Order constitutes an illegal anticompetitive restriction on trade.

As you are likely aware, anticompetitive conduct engaged in by a subordinate governmental entity such as this Board (as opposed to actions of a state legislature[6] or state supreme court[7]), is illegal unless the Board can establish application of antitrust immunity by demonstrating: (1) that the challenged restraint is one that is "clearly articulated and affirmatively expressed as state policy"; and (2) the policy is "actively supervised by the State itself." *See California Retail Liquor Dealers Ass'n v. Midcal Aluminum*, 445 U.S. 97, 105 (1980) (internal citations and quotation marks omitted). To show that the Board's anticompetitive regulatory conduct is "clearly articulated," the key question is whether "the State as sovereign clearly intends to displace competition in a particular field with a regulatory structure." *S. Motor Carriers Rate Conference, Inc. v. United States*, 471 U.S. 48, 64 (1985) (finding the State intended to displace competition because the legislature created a regulatory scheme to set trucking rates).

Active supervision by the State, in turn,

> stems from the recognition that "[w]here a private party is engaging in the anticompetitive activity, there is a real danger that he is acting to further his own interests, rather than the governmental interests of the State." *Hallie v. Eau Claire*, 471 U.S. 34, 47 (1985) . . . . The mere presence of some state involvement or monitoring does not suffice. *See 324 Liquor Corp. v. Duffy*, 479 U.S. 335, 345, n.7 (1987) (holding that certain forms of state scrutiny of a restraint established by a private party did not constitute active supervision because they did not "exer[t] any significant control over" the terms of the restraint). The active supervision prong of the *Midcal* test requires that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy. Absent such a program of supervision, there is no realistic assurance that a private party's anticompetitive conduct promotes state policy, rather than merely the party's individual interests.

Patrick v. Burget, 486 U.S. 94, 100–01 (1988) (internal parallel citations omitted; alterations in original). To the extent the Board believes that its classification as a public agency under state law is sufficient to meet the active supervision requirement under *Midcal*, the United States Supreme Court has held otherwise:

> The Board argues entities designated by the States as agencies are exempt from *Midcal's* second requirement. That premise, however, cannot be reconciled with the Court's repeated conclusion that the need for supervision turns not on the formal designation given by States to regulators but on the risk that active market participants will pursue private interests in restraining trade.
>
> State agencies controlled by active market participants, who possess singularly strong private interests, pose the very risk of self-dealing *Midcal*'s supervision requirement

[6] *Parker v. Brown*, 317 U.S. 341 (1943).
[7] *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977).

was created to address. *See* Areeda & Hovenkamp ¶ 227, at 226. This conclusion does not question the good faith of state officers but rather is an assessment of the structural risk of market participants' confusing their own interests with the State's policy goals. *See Patrick*, 486 U.S. at 100-101, 108 S. Ct. 1658.

...

The similarities between agencies controlled by active market participants and private trade associations are not eliminated simply because the former are given formal designation by the State, vested with a measure of government power, and required to follow some procedural rules. *See Hallie*, *supra*, at 39, 105 S. Ct. 1713 (rejecting "purely formalistic" analysis). *Parker* immunity does not derive from nomenclature alone. When a State empowers a group of active market participants to decide who can participate in its market, and on what terms, the need for supervision is manifest. *See* Areeda & Hovenkamp ¶ 227, at 226. The Court holds today that a state board on which a controlling number of decisionmakers are active market participants in the occupation the board regulates must satisfy *Midcal*'s active supervision requirement in order to invoke state-action antitrust immunity.

N.C. Bd. of Dental Examiners v. FTC, 574 U.S. 494, 135 S. Ct. 1101, 1113-14 (2015). Indeed, in the context of State supervision, "[t]he supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it." *Id.* at 1116 (citing *Patrick*, 486 U.S. at 102-103, 108 S.Ct. 1658).

Here, the Board is required to be comprised of five licensed pharmacist members (i.e., market participants) and two public members. Currently, the Board is comprised *only* of pharmacists, with both of the two required public member seats vacant.

Members

The members of the Pharmacy Examining Board are appointed by the Governor and confirmed by the Legislature to serve 4-year terms. The Board consists of 5 licensed pharmacist members and 2 public members.

Member	Officer	Member Type	Term Expiration
Trapskin, Philip J	Chairperson	Pharmacist Member	7/1/2021
LaDien, Franklin J.	Vice Chairperson	Pharmacist Member	7/1/2020
Winters, Cathy J.	Secretary	Pharmacist Member	7/1/2021
Peterangelo, Anthony D.		Pharmacist Member	7/1/2023
Veitekamp, John G.		Pharmacist Member	7/1/2022
Vacant		Public Member	
Vacant		Public Member	

(*See* https://dsps.wi.gov/pages/BoardsCouncils/Pharmacy/Default.aspx (last visited Dec. 9, 2019).) The Board is comprised only of market participants—horizontal competitors—who are regulating the market in which they participate. By raising this concern, InstyMeds does not intend to cast aspersions on the good faith of the Board members but, as the U.S. Supreme Court has explained, these factors contribute to "an assessment of the structural risk of market participants' confusing their own interests with the State's policy goals." *See N.C. Dental*, 135 S. Ct. at 1113-14.

In addition to the current membership (and vacancies) on the Board, Wisconsin's statutes, as approved by the legislature, demonstrate that the State's supervision has resulted in a framework that runs contrary to the proposed text of the rule. For example, Chapter 450—applicable to this Board—includes numerous instances where practitioners are specifically allowed to administer or dispense prescription drugs, and expressly exempts practitioners who are lawfully practicing medicine or surgery under Chapter 448[8] from the pharmacist licensure requirements. *See, e.g.*, Wis. Stat. §§ 450.01(17) ("'Practitioner' means a person licensed in this state to prescribe *and administer* drugs or licensed in another state and recognized by this state as a person authorized to prescribe *and administer* drugs." (emphases added)), 450.01(1) ("'Administer' means the direct application of a vaccine or a prescribed rug or device, whether by injection, ingestion or any other means to the body of a patient by any of the following: (a) A *practitioner* or his or her authorized agent. (b) A patient or research subject at the direction of a practitioner. (c) A pharmacist. ..." (emphasis added)), 450.03 "Pharmacist; licensure" (exempting from required licensure as pharmacist (including "engag[ing] in the practice of pharmacy or us[ing] the title 'pharmacist' or sell[ing], giv[ing] away or barter[ing] drugs), *inter alia*, "(e) Any person lawfully practicing within the scope of a license, permit, registration, certificate, or certification granted to . . . practice medicine and surgery under ch. 448"), 450.09(6) "Pharmacy practice" ("*Every practitioner* shall maintain a record of all drug products dispensed to each patient according to standards established by the appropriate examining board by rule." (emphasis added)), 450.11(1)(e)(1) ("No identification card is required under par. (b) if any of the following applies: 1. The drug is administered or *dispensed directly to the ultimate user by a practitioner*. . . ." (emphasis added)), 450.11(3) ("no person other than a pharmacist *or practitioner* or their agents and employees as directed, supervised, and inspected by the pharmacist *or practitioner* may prepare, compound, dispense, or prepare for delivery for a patient any prescription drug" (emphases added)), 450.11(4) ("no prescribed drug or device may be dispensed unless there is a label attached to the container disclosing all of the following: 1. The name and address of *the dispensing practitioner* or licensed facility from which the prescribed drug or device was dispensed . . ." (emphasis added)).

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[8] *See also* Wis. Stat. § 448.01(9) (defining practice of medicine broadly to include not only prescribing drugs but also treatment by any means or instrumentality; "'Practice of medicine and surgery' means: (a) To examine into the fact, condition or cause of human health or disease, or to treat, operate, prescribe or advise for the same, by any means or instrumentality. (b) To apply principles or techniques of medical sciences in the diagnosis or prevention of any of the conditions described in par. (a) and in sub. (2) ['Disease']. . . ."); *id.* at § 448.01(2) ("'Disease' means any pain, injury, deformity or physical or mental illness or departure from complete health or the proper condition of the human body or any of its parts.").

In short, there is no clear indication that the State as sovereign "intends to displace competition in [this] particular field with a regulatory structure." *See S. Motor Carriers Rate Conference*, 471 U.S. at 64. To the extent the State has supervised the actions of this Board, it has supervised and accepted a statutory structure that *allows*, and indeed, *fosters* competition. The physician-dispensing model is contemplated by, and allowed under, Wisconsin's statutes—even though it results in competition between not only physicians and pharmacists, but also automated dispensing systems such as InstyMeds that operate under statutes and rules governing practitioners rather than through pharmacies and pharmacists. Here, where the State's statutes specify requirements of, and exemptions applicable to, practitioners who dispense prescription medication, there is no doubt that the State does not intend to displace competition. The Proposed Order, here, therefore cannot meet the *Parker* immunity requirements under the state-action doctrine. And because the remaining agreement constitutes an agreement by competitors to specifically exclude another from the market, it will be adjudicated as illegal *per se*.

4. Conclusion

Thank you for the opportunity to provide this comment. While this comment does not include each and every fact relating to InstyMeds' issues with the Proposed Order, it provides an important framework that we believe demonstrates how the Proposed Order is not in the best interests of Wisconsin's citizens. And we want to emphasize again, we do not intend to cast aspersions or question the integrity of the Board in any way; we simply wish to point out that the Proposed Order, without modification, will not only irreparably injure Wisconsin citizens, but it will irreparably injury InstyMeds by constituting an illegal *per se* agreement under applicable antitrust law as well as Due Process Clauses contained in the U.S. and Wisconsin Constitutions.

InstyMeds anticipates attending the public hearing on December 17, 2019. In the interim, we appreciate the opportunity to provide comments on the Proposed Order. If you have any questions regarding this letter, please contact Brad Schraut at the contact information below.

Sincerely,

Brad Schraut
Chief Executive Officer
Phone: (962) 653-2556
Brad.Schraut@instymeds.com

Ed Zeman
Chief Financial Officer

Michael Burns, RPh
Vice President of Pharmacy Services

PCMA

December 16, 2019

Ms. Sharon Henes, Administrative Rules Coordinator Division of Policy Development
Department of Safety and Professional Services
PO Box 8366
Madison, WI 53708-8935

Via email: DSPSAdminRules@wisconsin.gov

Re: Economic Impact of Proposed Amendments to Phar 7.08 – Patient Consultations for New Prescriptions

Dear Ms. Henes:

I am writing in response to the Pharmaceutical Care Management Association's (PCMA) November 13, 2019 comment letter on the economic impact statement related to the Pharmacy Examining Board's proposed amendments to Chapter Phar 7, Pharmacy Practice, regarding oral consultations for new prescriptions (Phar 7.08).

PCMA is the national trade association representing pharmacy benefit managers, which manage prescription drug benefits for large employers, health insurance carriers, labor trusts, government programs, and other payers. Many of our organizations operate mail service pharmacies that serve Wisconsin patients.

Our mail service pharmacies provide the opportunity for patients to have any question answered and to talk to a pharmacist to learn about their prescription currently on every prescription – new and refill – 24 hours a day, 7 days a week. However, as we previously commented, including mail service pharmacies in the regulation for oral consultations to patients for new prescriptions would have a significant impact on mail service pharmacies and our patients, would cause delays in therapy and add cost to the system. All with no added benefit to patients.

We estimate this proposed rule would cost our pharmacies $30,000,000 over two years. These costs will ultimately be borne by the people who purchase healthcare services – tax payers and consumers. Below are the issues that will drive the cost:

- Increased pharmacists staffing and hours;
- Increased technician staffing to route calls;
- Increase in pharmacy management system workstations;
- System development;

To blanketly call every patient that has a new prescription will divert resources from patients with greater needs or those that have requested counseling. In addition, waiting to send a prescription before this conversation can happen will cause a delay in patients getting their necessary medications sent to them.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

PCMA

PCMA also has concerns related to the preparation of the Fiscal Estimate and Economic Impact Analysis and the conclusions drawn by the Board at the November meeting. PCMA believes that the Board is using the incorrect threshold in preparing the estimate and analysis and should be using the current statute in effect since September 1, 2017, rather than the older, outdated version. The date on which the Board prepared and submitted its Fiscal Estimate and Economic Impact Analysis to legislative council staff is the date that dictates which statute must be followed and the associated requirements the Board must follow.

Under the current statute, W.S.A. 227.139, when an economic impact analysis indicates that $10,000,000 or more in implementation and compliance costs are reasonably expected to be incurred by or passed along to businesses over any 2-year period as a result of the proposed rule, the agency proposing the rule shall stop work on the proposed rule and may not continue promulgating the proposed rule unless a member of the legislature introduces a bill authorizing the agency to issue the rule.

PCMA submitted an estimated cost impact of $30,000,000, which clearly exceeded the $10,000,000 threshold and therefore disputes the Fiscal Estimate & Economic Impact Analysis.

It is for these reasons that PCMA objects to this proposed rule change. Thank you for the opportunity to provide comments. Please contact me at 202-756-5740 if you have any questions.

Sincerely,

Lauren Rowley
Senior Vice President, State Affairs

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