

**STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD**

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**IN THE MATTER OF RULEMAKING :  
PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE  
PHARMACY EXAMINING BOARD : CR 19-145**

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**I. THE PROPOSED RULE:**

The proposed rule, including the analysis and text, is attached.

**II. REFERENCE TO APPLICABLE FORMS: N/A**

**III. FISCAL ESTIMATE AND EIA:**

The Fiscal Estimate and EIA is attached.

**IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:**

The purpose of the rule was to do a comprehensive review and update of chapter Phar 7 to ensure the chapter is statutorily compliant, remove obsolete or unnecessary provisions and current with professional standards and practices.

The proposed rule advances the goal of maintaining minimum standards necessary for the safety of the public.

**V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:**

**The Pharmacy Examining Board held a public hearing on December 17, 2019. The following people either testified at the hearing, or submitted written comments:**

Danielle Womack, representing Pharmacy Society of Wisconsin  
Andrew Gustafson, representing SSM Health  
Ken Schaefer  
John Long, representing CVS Health  
Kate Schaafsma  
Katherine Rotzenberg, representing UW Pharmacy School  
Michelle Violi and Gina Besteman, representing Women's International Pharmacy  
George Kowalski, representing Advocate Aurora Health  
Cindy Ten Pas, representing Serve You Rx  
Thad Schumacher, representing Fitchburg Family Pharmacy  
Daniel Strause, representing Hometown Pharmacy  
Peggy Breuer, representing Newhauser Pharmacy  
Abigail Linde, representing Beaver Dam Hometown Pharmacy

Rick Conner, representing Hartland Hometown Pharmacy  
Mike Zagelow, representing Fort Atkinson Hometown Pharmacy  
Dharmesh Ghelani, representing MadTown Pharmacy  
Dan Funk, representing Wisconsin Society of Pharmacy Students  
Erika Horstmann  
John Loxterman, representing Enclara Pharmacia  
Terry Audley, representing Pharmacy Clinical Manager Froedtert  
Betty Chewning  
Adonnas Johnson  
Brian Olson  
Brenda Jacobs  
Michael Kuckes, representing Monroe Hometown Pharmacy West  
Tyler Wallenfang  
Jessica Haufschildt  
Mackynzie Anderson  
Steve Nilson  
Jennifer Baerenwald  
Erin Orth  
Teri Welter-Knoke  
Kent Udulutch  
Jeremy Laffin, representing Wautoma Hometown Pharmacy  
Christopher Klink  
Jonathan McLachlan, representing AllianceRx Walgreens Prime  
John Sisto, representing Express Scripts  
Ryan Bender  
David Calabrese, representing OptumRx  
Michael Pochowski, representing Wisconsin Assisted Living Association  
Ann Zenk, representing Wisconsin Hospital Association  
Chris Gasser, representing Envision Pharmacies  
Thad Schumacher, representing CPESN Wisconsin  
Jennifer Matte  
Matthew Mabie, representing Forward Pharmacy  
Lisa Kostecki  
Kayla Rackow  
Michelle Farrell  
M.C. Jackson  
Dawn Wypiszynski, representing Morton LTC  
Thad Schumacher presenting petition with 43 signatures  
Michael Burns and Brad Schraut, representing InstyMeds  
Dimmy Sokhal  
Tomson George, representing Walgreen's  
Medical College of Wisconsin School of Pharmacy students (80 students)  
Cathy Winters  
Lauren Rowley, representing Pharmaceutical Care Management Association

**The Pharmacy Examining Board summarizes the comments received either by hearing testimony or by written submission as follows:**

Pharmacy Society of Wisconsin commented on the following:

- Definitions of “managing pharmacist” in chapter 1 and chapter 7 do not match.
- In Phar 7.02(1)(4), remove the word “form” as prescribers often do not include in a prescription
- In Phar 7.02(3)(b)1., request language be modified to state that a pharmacist shall transfer a prescription upon patient request.
- Suggest using “verbal” throughout the rule instead of “oral”
- In Phar 7.02(4), clarify that prescriptions may be transmitted via direct conversation.
- In Phar 7.03(1)(b), request “rational therapy” be eliminated as a component in drug utilization review (DUR).
- In Phar 7.03(1)(d), request gender is not included in DUR.
- In Phar 7.05(1), request clinic-administered medications in an ambulatory, outpatient setting be exempt and treated as institutional pharmacies.
- In Phar 7.05(2)(k), while supporting the inclusion of written or graphic product descriptions on the label, many pharmacy software system vendors are not capable of printing these on labels. Therefore, recommend moving to optional items on a label.
- In Phar 7.06, request repackaging in an automated dispensing cabinet is exempt from these requirements.
- In Phar 7.07(2), the requirement for supervising pharmacist to be identified is problematic for most pharmacy software vendors and the supervising pharmacist is already documented in the policies and procedures required by the delegate-check-delegate rules.
- In Phar 7.085, strongly support including specific language allowing for delivery to any location of the patient’s choosing.
- In Phar 7.14(1)(c), request that the checking of the accuracy and correctness of expiration and beyond use date be removed from the product verification.
- In Phar 7.14(3)(b)3., while supporting product descriptions on prescription labels in delegate-check-delegate situations, many pharmacy software systems are not capable of printing this information. We recommend allowing the description to be on the label or allow a pharmacist to utilize show-and-tell.
- In Phar 7.14(b)(7), request a reference by corrected.
- In Phar 7.42(6), some health systems have reported that their workflow has the prescriber always completing the DUR and consultation, therefore, recommend flexibility in allowing the pharmacist or prescriber to provide the DUR and consultation.
- In Phar 7.43(5)(a)3., we request allowing the managing pharmacist to delegate visiting the remote dispensing locations monthly to another pharmacist.
- In Phar 7.51(7), request language be modified to state only delegates without independent prescriptive authority are required to document the name of the delegate and practitioner.
- In Phar 7.52(3) request removal of this provision because many software systems do not allow for lot number on the label.

- The Pharmacy Society of Wisconsin is not taking a position on the counseling requirements in Phar 7.08 given the broad spectrum of views its members hold and the clear lack of professional consensus on the topic. Due to the lack of consensus, request that a separate scope statement regarding counseling so as to not inhibit the countless other positive changes in Phar 7.

SSM Health commented on the following:

- The definitions in chapter Phar 1 and chapter Phar 7 do not match and would recommend the two definitions match.
- In Phar 7.02, recommend the language regarding a prescription must be sent to the pharmacy of a patient's choice.
- In Phar 7.04, recommend the receiving pharmacy only has to record the date of the last refill dispensed and not all date of previous dispenses.
- In Phar 7.085, very strongly recommend removing the pharmacy must replace the product at no cost by the next day as pharmacies are not able to control next day delivery.
- In Phar 7.11 recommend omitting the requirement to record all chronic conditions.
- In Phar 7.42(6), recommend removing because the prescriber does the DUR and consulting.
- In Phar 7.43, strongly recommend monthly pharmacist visits and quarterly managing pharmacist visits.
- In Phar 7.52, recommend omitting the lot number on the label for dispenses at an institutional pharmacy.
- In Phar 7.54, remove the requirement that the health care items are not commingled with a different health care item.

Ken Schaefer commented on the following:

- In Phar 7.02, add diagnosis on the prescription so the pharmacist can make a determination in the drug prescribed is appropriate for intended use.
- In Phar 7.03, add patient compliance
- In Phar 7.04(3)(d)4., date and location of refills should be singular not plural since it can only be transferred once.
- In Phar 7.05(2)(b), symptom or purpose should be mandatory on the label unless the provider indicates not to put on the label.
- In Phar 7.08, consulting should be mandatory on all prescriptions.
- In Phar 7.085(4), remove the requirement to replace at no additional costs.
- In Phar 7.13(c), add the state registry for vaccines is required.
- In Phar 7.14, use the term "technician" instead of "delegate".

Morton LTC commented on the following:

- Current long-term care practice does not include obtaining address of practitioner on the standing order; recommend removing.
- In Phar 7.05(1), correct the institutional pharmacy reference.
- In Phar 7.08, clarify physical location needs to post signage regarding a patient's rights to consultation.

- In Phar 7.51, clarify whether a pharmacist can add or change information on a chart order.
- In Phar 7.03 and 7.07(1)(c), clarify whether the DUR needs to be done with each new order.

CVS commented on the following:

- DUR should be done only on new drug product or device which has not been previously dispensed or change in patient's therapy.
- Transfer of prescription should be able to be done by oral communication between two delegates.
- In Phar 7.31 allow the prescription label to contain the name and address of the pharmacy best suited to serve the patient's needs.
- In Phar 7.51, remove the patient's medical record number or date of birth and clarify signature language.
- In Phar 7.50, include residential care apartment complexes in the institutional facility requirement.
- In Phar 7.55, remove the limitation that this technology can only be utilized in institutional pharmacies.
- In Phar 7.08, recommends consulting be communicated orally unless in the pharmacist's professional judgment oral counseling is not practicable.
- In Phar 7.085, remove maintains appropriate environmental controls and verification proof of receipt of all controlled substances.
- Believes the date 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 which is the current statute, in effect since September 1, 2017 instead of an outdated statute.

Kate Schaafsma commented on the following:

- In Phar 7.03, add a good faith effort to mitigate or resolve the problem identified in the DUR.
- In Phar 7.05, samples should be labeled the same way as prescriptions.
- In Phar 7.06, repackaging labels have limited space, recommend allowing a pharmacy control number in place of NDC number.
- In Phar 7.08, consultation should be provided on every prescription; support professional judgment on the elements included in the consultation.
- In Phar 7.085(2), verification of prescriptions received should be on all prescriptions not just controlled substances.
- In Phar 7.085(4), replace the section with a pharmacy is responsible to ensure patient maintains access to the drug product or device.
- In Phar 7.09(1) replace the word "wholesaler" with "entity."
- In Phar 7.11(3)(b) change birthdate of pet not owner.
- In Phar 7.52, support flexibility to use the NDC or pharmacy control number.

AllianceRX Walgreens Prime commented on the following:

- Oral counseling prior to shipment of a prescription may introduce delays in care and are pleased the current draft language provides some allowance for written communication when deemed appropriate, however, the language may imply an

expectation that pharmacist exercise professional judgment on a case-by-case basis in order to deem alternative methods of counseling appropriate.

- In Phar 7.085(1), remove humidity controls.
- In Phar 7.085(4), supports the intent of the language around reshipping compromised drug product but requests amending the language to allow for flexibility.

Wisconsin Hospital Association commented on the following:

- The re-write of counseling adds complexity and regulation without an associated benefit. When a patient is in a pharmacy the default to oral counseling makes sense; patients who opt for delivery should have the same right to timely access to their prescription. Incorporate the same wording of current counseling rules for delivery of prescriptions to a patient's location of choice in the re-write of Phar 7.
- In Phar 7.42(6), remove this requirement and allow prescriber DUR and consultation continue to meet the requirements.

Express Scripts

- In Phar 7.08, recommends the intent of the Pharmacy Examining Board expressed in the economic impact analysis requires a change of wording to "when it is in the best interest of the patient or patient's agent to be communicated orally" instead of stating in the negative which gives it a different meaning and significant economic impact.
- In Phar 7.085(4), support the intent and suggest modifying language to require the replacement be sent via a method that would ensure that the patient does not have an interruption in therapy.

Thad Schumacher submitted a petition with 43 signatures to remove gender from the list of DUR requirements.

UW Pharmacy School provided information on studies which show pharmacist counseling has been demonstrated to reduce morbidity and mortality related to drug therapy in addition to reducing costs of drug therapy. No studies exist relating to mail order pharmacies and oral counseling. 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. Studies show states with strong consultation regulation such as Wisconsin had the highest frequency of oral consultation with medication.

Women's International Pharmacy commented that requiring oral consultation can result in delay of delivery of medications and recommended oral consultation is required except when not practicable.

Advocate Aurora Health asks the draft to be revised to continue allowing mail order pharmacies to provide safe, efficient and convenient service to their patients by trusting their pharmacists' professional judgment.

Serve You Rx commented that it would difficult and costly to provide oral consultation for every new and change in therapy prescription. The recommendation is to amend the language be in line with the rest of the country.

Walgreen's recommended Phar 7.08 be amended to read "be communicated orally to the patient or patient's agent when, using the pharmacist's professional judgment, it is in the best interest of the patient to be communicated orally."

Enclara Pharmacia requested that hospice pharmacies be exempt from consulting.

Dr. Betty Chewing provided research results will be published in the Journal of Opioid Management that most of the caregivers of children who were prescribed opioids did not know the medication was an opioid or the risks. Caregivers expected all healthcare providers, especially pharmacists, to have provided information on opioid risks. Equally important, the prescribers believed the pharmacists were giving this information to their patients. Research on adults 65 and older shows 25% of patients 65 and older have experienced an adverse drug event in the past 6 months and a high percent of hospitalizations is due to patients not using their medications effectively.

Hometown Pharmacy, Beaver Dam Hometown Pharmacy, Hartland Hometown Pharmacy, Fort Atkinson Hometown Pharmacy, Monroe Hometown Pharmacy West, Wautoma Hometown Pharmacy, CPESN Wisconsin, Wisconsin Society of Pharmacy Students, Medical College of Wisconsin School of Pharmacy Students, Erika Horstmann, terry Audley, Adonnas Johnson, Brian Olson, Brenda Jacobs, Tyler Wallenfang, Jessica Haufschildt, Mackynzie Anderson, Steve Nilson, Jennifer Baerenwald, Erin Orth, Teri Welter-Knoke, Ryan Bender, Jennifer Matte, Lisa Kosecki, M.C. Jackson commented on patient care necessitates oral consulting regardless of the type of pharmacy or delivery method.

Newhauser Pharmacy, MadTown Pharmacy, Christopher Klink and Kayla Rackow commented on patient care necessitates oral consulting on all prescriptions.

Kent Udulutch and Michelle Farrell commented that mail order pharmacies being exempt from consulting creates a burden on their pharmacies because patients bring their mail order medications into their pharmacies to ask questions due to not being able to reach a pharmacist through the mail order pharmacy.

Thad Schumacher commented that consulting leads to better outcomes and all pharmacists should use professional judgment.

Forward Pharmacy recommended changing Phar 7.08 to say, "give the patient or agent appropriate consultation relative to the prescription". In addition 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 Wisconsin.

Envision Pharmacies comments that the proposed language requires proving a negative by determining whether not providing oral consultation is in the patient's best interest which is vastly different than the current practice of providing consultation when it is in

the patient's best interest. Requests keeping the current exemption or providing a practicality exception to the proposed rule.

Wisconsin Assisted Living Association requests an exemption from oral counseling for those patients in community-based residential facilities, residential care apartment complexes and adult family homes which could create delays in receiving medications.

OptumRx creates compliance packaging with one or more prescription drug regimens enclosed for mental health patients and is concerned that the proposed Phar 7.08 may create delays in receiving medications.

Insty Meds commented in opposition to Phar 7.42 due to limiting prescriber dispensing through direct-to-patient dispensing systems.

Cathy Winters commented on the process and recommended the Pharmacy Examining Board start over with a new scope statement for consulting.

Pharmaceutical Care Management Association objects to the proposed rule for using an outdated statute instead of the statute in effect since September 1, 2017 for preparation of the Economic Impact Analysis. Their belief is the date on which the Pharmacy Examining Board prepared and submitted its Economic Impact Analysis to legislative council staff is the date that dictates which statute must be followed.

**The Pharmacy Examining Board explains modifications to its rule-making proposal prompted by public comments as follows:**

The Pharmacy Examining Board made the following changes:

- Throughout the rule, the word “oral” was replaced by “verbal”.
- Phar 7.01(4) created a definition for “repackaging for stock” to clarify when used in this chapter it means product from an original manufacturer container and placed into different stock containers as a source for subsequent dispensing. This definition clarifies an exemption is not necessary for automated dispensing cabinets as it will not apply to them.
- Phar 7.01(5) created a definition to clarify the rule refers to a standing order for the purposes of a pharmacist dispensing or administering and not for the type of standing orders used by institutional facilities to submit prescription orders.
- In Phar 7.02 (1) and (4), the word “form” was removed.
- In Phar 7.02(3), a modification was made to clarify that a practitioner may transmit a prescription order electronically only if the patient approves the transmission and the prescription order is transmitted to a pharmacy designated by the patient.
- In Phar 7.03(1)(d), the word “gender” was removed.
- In Phar 7.04(3)(b), the board added “Notwithstanding sub. (1)(a)” to clarify controlled substances can only be communicated directly between 2 licensed pharmacists which is based upon federal law.
- In Phar 7.05, written or graphic product descriptions was moved from mandatory to optional on a label.
- Phar 7.06(4)(b) was modified to clarify the identifier options.

- In Phar 7.07(2), the requirement to record the supervising pharmacist was removed.
- Section Phar 7.08 was modified to create clarity. In addition, the following specific modifications were made:
  - Consultation shall contain any of the consultation elements that, in the pharmacist's professional judgment, serves the best interest of the patient.
  - Consultation is required to be communicated verbally when, in the pharmacist's professional judgment, it is in the best interest of the patient.
  - Written patient drug education monographs shall be provided to the patient whenever a consultation is required.
  - Clarifies a consultation may occur before or after delivery of the prescription.
  - Clarifies prescription drugs or devices picked up at a drive through window shall include a copy of the patient's rights to pharmacist consultation and information on how to file a complaint to the board.

The Pharmacy Examining Board, while recognizing that best practices would be a verbal consultation on all prescriptions, believes these modifications to be a compromise, for the minimal standard of the profession necessary to protect the public, based upon the public comments received and the representation that currently pharmacists (regardless of delivery method) provide a verbal consult when it is in the best interest of the patient.

- In Phar 7.085(intro), the phrase "to a location of the patient's choice" was added.
- Phar 7.085(1) was modified to "appropriate to prevent drug adulteration"; removing environmental controls, including temperature and humidity.
- Phar 7.085(2) was deleted (provision requiring verification of receipt of controlled substances) and subsequent subsections were renumbered.
- Phar 7.085(4) was modified to read "Any prescription drug product or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, a pharmacist at the dispensing pharmacy shall take steps to mitigate patient harm."
- Phar 7.09(1) was deleted (provision relating to limiting obtainment of products only from licensed wholesalers) and subsequent subsections were renumbered.
- Phar 7.14(1)(c) was modified to reflect the elements of the final check and also that the product has not reached its expiration or beyond use date.
- Phar 7.14(3)(b)3. was modified to all three different ways a non-pharmacist (i.e. patient or patient's agent) can check the accuracy of the medication being received: in the original manufacturer packaging; a description on the prescription label; or the pharmacist shows the patient or agent (also known as "show and tell") and provides a monograph which contains the description.
- Phar 7.14(4)(b)7. was modified to reflect the correct references.
- Phar 7.31(5) was modified to allow the label to contain the name and address of either the labeling or originating pharmacy.
- Section 7.42 was modified to allow an automated direct-to-patient dispensing system for practitioner dispensing. A supervising practitioner is responsible for ensuring requirement are met including: stocking, inventory, and monitoring; labeling; maintaining records for 5 years; reporting to the prescription drug monitoring program; and establishing written policies and procedures. This

section removed the references to a pharmacy or pharmacist and the requirements for a DUR and consult.

- Phar 7.43(1) created a definition for supervising pharmacist and then all subsequent subsections were renumbered.
- Phar 7.43(6) was modified to include supervising pharmacist which allows a pharmacist other than the managing pharmacist to visit the remote location monthly.
- In Phar 7.50(2), the reference s. 146.903(1)(b), which is the definition of clinic, was added in order to be treated as institutional facilities. This will allow clinic administered medications in an ambulatory, outpatient setting to meet chart order and labeling requirements consistent with the practice occurring in those settings.
- In Phar 7.51(6) modification was made to clarify the methods for signature.
- Phar 7.52(3) was removed (NDC and lot number) and subsequent subsection was renumbered.
- In Phar 7.54(3)(c) was removed (prohibition on comingling health items) and subsequent paragraph was renumbered.

The Pharmacy Examining Board did not make modifications for the reasons below:

- In Phar 7.01: The Pharmacy Examining Board recognizes managing pharmacist has two definitions and will be doing a subsequent rule project to update the definition in ch. Phar 1.
- In Phar 7.02: The Pharmacy Examining Board did not add diagnosis as an element required on the prescription due to there are reasons for a prescriber to not include the diagnosis or purpose. Both the statute and the rule only require the diagnosis on the prescription if the patient indicates in writing to the practitioner that the patient wants the symptom or purpose to be displayed on the label. However, it is always optional for this information to be included.
- In Phar 7.03: It is not in the interest of patient safety and welfare to limit the DUR to only new prescriptions or change in therapy prescriptions because there can be a change in patient circumstances which requires review with each prescription. Including as an element of DUR, patient's compliance with refills is not a minimal standard for patient safety. During a DUR it is important to consider whether there is a rational therapy for the drug to ensure that the prescription does have the correct drug or dosage listed on it. There is no need to add the phrase "a good faith effort" to mitigate or resolve the problem" due to the rule already stating the same thing with "take steps" which does not require mitigation or resolution.
- In Phar 7.04: The Pharmacy Examining Board has an option for transfers to occur between delegates by utilizing electronic means or facsimile. Federal law requires the dates and locations of previous dispenses.
- In Phar 7.05: Samples are excluded from labeling requirements per s. 450.11(4)(b), Stats. Pursuant to 450.11, Stats., a symptom or purpose is only mandatory if the prescriber specifies the symptom or purpose on a prescription order because a patient indicates the patient wants it disclosed on the label, therefore the Pharmacy Examining Board is not requiring this information to be on all labels. However, the Pharmacy Examining Board lists symptom or purpose in the option items on a label to clarify that a patient may ask a pharmacist to include on the information on the label.

- In Phar 7.085: The responsibility for delivering a non-compromised prescription drug product or device is with the pharmacy. A patient paying for replacement medication can create a burden for the patient or result in interruption of therapy.
- In Phar 7.11: Recording of any chronic conditions does not mean all chronic conditions need to be captured; the minimum standard is only those chronic conditions that may impact the efficacy or safety. The Pharmacy Examining Board decided not to change “if not human birthdate of the owner” to “if not human birthdate of the pet” in order to be consistent with the requirements of the prescription drug monitoring program.
- In Phar 7.13: This section refers to the administration of drug products and devices other than vaccines so including a requirement to report the administration to the state registry for vaccines is inappropriate.
- In Phar 7.50: Residential care apartment complexes are not included in the institutional facility definition because medications may or may not be administered by health care personnel. Therefore, patient safety may be compromised by including these facilities.
- In Phar 7.51: The patient’s medical record number or date of birth are necessary for patient safety and wellbeing by ensuring correct patient identification. There is no purpose in adding “without independent prescribing authority” after delegate because if the person is doing the chart order as a delegate it is irrelevant whether the person has independent prescribing authority because the action is not being done independently.
- In Phar 7.55: The automated technology pilot program conducted by the Pharmacy Examining Board from October 1, 2016 to September 30, 2019 only included product which will be administered by an individual authorized to administer medications at the institution where the medication is administered. The Pharmacy Examining Board has not evaluated the patient safety of utilizing automated technology in a setting where there is not a health care provider providing a check to ensure the proper drug was delivered. The Pharmacy Examining Board is willing to consider a pilot program to evaluate the safety, quality or efficiency of using automated technology in other pharmacy settings.

The Pharmacy Examining Board applied the correct statute to the Economic Impact Analysis. The statement of scope was approved by Governor Walker on June 19, 2013 and 2017 Act 57 applies to a proposed rule whose statement of scope is presented for approval under section 227.135 (2) of the statutes on September 1, 2017.

## **VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:**

**Comment 1:** It appears that s. Phar 7.42(6) regulates the conduct of nonpharmacists by requiring that prescribers must complete drug utilization review and consulting requirements under certain circumstances within an automated direct-to-patient dispensing system. The board should more specifically describe its authority to regulate prescribers in this manner.

**Response:** Section 450.02 (3)(a) “The board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs. Section 961.31 “The pharmacy examining board may promulgate rules relating to the

manufacture, distribution and dispensing of controlled substances within this state.” The explicit rule authority relating to dispensing of prescription drugs and specifically controlled substances is with the Pharmacy Examining Board. The automated direct-to-patient dispensing systems are dispensing prescription drugs, including controlled substances, therefore, the Pharmacy Examining Board has the authority to regulate prescribers who dispense prescriptions drugs and controlled substances.

The statutory authority section of the analysis has been updated to include s. 961.31, Stats.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

## **VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS:**

This rule will not have an economic impact on small businesses.

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD

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IN THE MATTER OF RULE-MAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 19-145)

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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.

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ANALYSIS

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

**Statutory authority:** ss. 15.08 (5) (b), 450.02 (2), and 450.02 (3) (a) to (e), and 961.31, 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.]

The pharmacy examining board may promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state. [s. 961.31, 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 of issue, name and address of the prescriber (and if delegated that person's name), directions for use, the drug's name, strength, and quantity, whether there are any refills authorized, name and address of the patient (unless omission is required by statute) 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 abuse or misuse. If there is a concern with any of these items, the pharmacist will take steps to mitigate or 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, for non-controlled substances 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 issue of the original prescription, the original prescription order number, original number of refills authorized, dates of last fills, 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 communication directly between 2 licensed pharmacists utilizing 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, and dates and locations of previous fills..

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, and number of refills or quantity remaining, and directions for use. 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, written or graphic product descriptions 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 repack non-sterile 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, beyond use date and a set of identifiers (pharmacy control or national drug code (NDC) and manufacturer lot number, or manufacturer or distributor name, and manufacturer lot number. 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 delegate.

A pharmacist must consult the patient or patient's agent for every new prescription which has not been dispensed previously to the patient, any change in the patient's therapy, upon request of a patient or patient's agent and whenever it is in the pharmacist's professional judgement a consultation should occur. Consultation is not required when the drug or device is administered by or in the presence of an individual with a scope of practice that includes administration of a drug or device or the individual's delegate or a patient or patient's agent refuses consultation. Patient consultation includes, based upon the pharmacist's professional judgment, 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, 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. The consultation is required to be verbal when the pharmacist deems it is in the patient's best interest to do so. In addition, when a consultation is required, the pharmacist shall provide a written patient drug education monograph. Every pharmacy shall post a sign stating a patient's right to consultation and information on how to file a complaint to the board and board approved information stating patient's rights shall accompany all delivered prescriptions by common carrier or delivery service or picked up at a drive through window.

Delivery of prescription drugs by common carrier or delivery services shall ensure the delivery method is appropriate to prevent drug adulteration. 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 or lost must be

replaced at no additional cost to the patient. If the timing of the replacement will lead to interruption in therapy, steps must be taken by a pharmacist to mitigate patient harm.

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. The DEA does not permit the return of controlled substances to a pharmacy under any circumstances. Only returned health items that are prepackaged for consumer use without a prescription 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 for documentation if dispensing and refills are authorized 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 (other than vaccines) 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 (other than vaccines) 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 (other than vaccines), 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 supervising pharmacist to delegate 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 an original 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 have a method for a patient to be able 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. 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 either pharmacy. 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 must 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 for stocking, access, and mitigation of diversion or theft.

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 may operate for purposes of practitioner dispensing. The supervising practitioner is responsible for: ensuring the stocking, inventory, and monitoring is limited to the supervising practitioner or delegate; labeling of the prescriptions in compliance with Phar 7.05; records of all prescription fills and dispenses are maintained for 5 years; and all monitored prescription drugs dispensed are reported to the prescription drug monitoring program.

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. The managing pharmacist will designate a supervising pharmacist for the remote dispensing. 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 or supervising 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 completed 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 prepared by a delegate of the practitioner the delegate's signature and name of the practitioner. 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, 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 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 for product verification 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 person authorized to administer drugs within the 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 an 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 pharmacists 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.

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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) “Control number” means a unique number used to identify a repackaged drug or drug product in reference to a record that contains NDC, expiration date, and lot number.
- (2) “Managing pharmacist” means a pharmacist 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.
- (3) “NDC” means national drug code.
- (4) “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.
- (5) “Standing order” means an order transmitted electronically or in writing by a practitioner for a drug or device that does not identify a particular patient at the time it is issued for the purpose of drug or device dispensing or administration to individuals that meet criteria of the order.

**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, 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, a practitioner may transmit a prescription order electronically only if the patient approves the transmission and the prescription order is transmitted to a pharmacy designated by the patient. Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

(b) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided electronically with a prescription order.

**(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) Notwithstanding sub. (1) (a), 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 dates and locations of previous refills.
  5. Pharmacy’s name, address, DEA registration number, and prescription number from which the prescription information was transferred.
  6. First and last name of the pharmacist making the transfer.
  7. 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 a complete record of all prescriptions filled and dispensed.

**Phar 7.05 Label requirements.** (1) This section does not apply to institutional pharmacies as defined in s. Phar 7.50 (3).

(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 number.
- (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.
- (d) 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, form and beyond use date.
  - (b) One of the following identifiers:
    - 1. Pharmacy control number.
    - 2. NDC number and manufacturer lot number.
    - 3. Name of manufacturer or distributor of the drug product, and the manufacturer lot number.
- (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.
  - (g) Any pharmacy control numbers.

**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 provide the patient or patient's agent consultation to optimize proper use of a prescription drug or device, that meets any of the following:

- (a) Has not been dispensed previously to the patient.
  - (b) Is a change in therapy.
  - (c) Upon request of a patient or patient's agent.
  - (d) Whenever deemed necessary based upon the professional judgement of the dispensing pharmacist.
- (2) Notwithstanding sub. (1), consultation is not required when one of the following occurs:
- (a) A drug or device will be administered, by ingestion, inhalation, injection, or any other route, by or in the presence of one of the following:
    - 1. An individual with a scope of practice that includes the administration of a drug or device.
    - 2. A delegate of an individual with authority to delegate the administration of a drug or device.
  - (b) A patient or patient's agent refuses consultation.

(3) Consultation shall contain any of the following information that, in the pharmacist's professional judgment, serves the best interest of the patient:

- (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) Directions and precautions for preparation, administration, and use.
- (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) Action to be taken in the event of a missed dose.
- (h) Proper storage and appropriate disposal method of unwanted or unused medication.

(4) The consultation required in this section shall be communicated verbally when in the pharmacist's professional judgment it is in the best interest of the patient.

(5) A pharmacist shall provide the patient or patient's agent, for all consultations required under sub. (1), a written patient drug education monograph.

(6) The consultation required in this section may occur before or after delivery of the prescription to the patient or patient's agent.

(7) Every licensed pharmacy dispensing directly to a patient or patient's agent inside the pharmacy shall conspicuously post a board approved sign stating a patient's rights to pharmacist consultation and information on how to file a complaint to the board.

(8) A prescription drug or device delivered by common carrier, mail, or delivery service or picked up at a drive through window shall include a copy of information which is board approved stating a patient's rights to pharmacist consultation and information on how to file a complaint to the board.

**Phar 7.085 Delivery by common carrier or delivery services.** Utilization of common carrier or delivery services to deliver a prescription to a location of the patient's choice 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 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.

(3) Any prescription drug product or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, a pharmacist at the dispensing pharmacy shall take steps to mitigate patient harm.

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

(1) A pharmacy shall have a system for identifying a drug or device subjected to a product recall and for taking appropriate actions as required by the recall notice.

(2) A 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, as part of the final check and ensure the product has not reached its expiration or beyond use date.

(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. A non-pharmacist shall be able to check the accuracy of the medication by one of the following:
  - a. The drug product or device is in the original packaging from a manufacturer.
  - b. The drug product or device includes a description of the drug product or device on the prescription label.
  - c. The pharmacist shows the patient or patient's agent the drug product or device and provides a monograph that includes a description of the drug product or device.

**(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) 2. a. through c. and e.

(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 or originating 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)** In this section “supervising practitioner” means the practitioner who is responsible for the operation of the automated direct-to-patient dispensing system and requirements of this section.

(2) 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. may operate for purposes of practitioner dispensing. The supervising practitioner will ensure all of the following requirements are met:

(a) Individuals with access to the automated direct-to-patient dispensing system for the purpose of stocking, inventory, and monitoring shall be limited to the supervising practitioner or a delegate.

- (b) The automated direct-to-patient dispensing system shall label the prescription in compliance with s. Phar 7.05.
- (c) The automated direct-to-patient dispensing system shall maintain records of all prescription fills and dispenses in compliance with s. Phar 7.11 (1).
- (d) The reporting of all monitored prescription drugs dispensed from the automated direct-to-patient dispensing system to the prescription drug monitoring program.
- (3) The supervising practitioner or delegate shall establish written policies and procedures for automated direct-to-patient dispensing system for all of the following:
  1. Stocking.
  2. Determining access.
  3. Detection and mitigation of diversion and theft.

**Phar 7.43 Remote dispensing.** (1) In this section, “supervising pharmacist” means a Wisconsin licensed pharmacist, appointed by the managing pharmacist, who is responsible for the remote dispensing and compliance with this section.

(2) 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.

(3) 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.

(4) 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.<sup>54</sup>
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. Patient has a right to pharmacist consultation and information on how to file a complaint to the board.

(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.

(5) 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.

**(6) RESPONSIBILITIES OF MANAGING PHARMACIST OR SUPERVISING PHARMACIST.** (a) The managing pharmacist of the supervising pharmacy or the supervising pharmacist 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.
5. Documentation indicating accepting 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 the dates the supervision responsibilities begin and end.

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

**(7) 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, 146.903(1)(b), 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) The signature by one of the following methods:
  - (a) If handwritten, the practitioner's or delegate's signature.
  - (b) Electronic signature of the practitioner or delegate.
- (7) Chart orders prepared 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) 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 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.

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(END OF TEXT OF RULE)

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This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor and Legislature.

Dated January 9, 2020

Agency   
Chair of the Pharmacy Examining Board



## ADMINISTRATIVE RULES

### Fiscal Estimate & Economic Impact Analysis

economic comments to the Pharmacy Examining Board; however, the letter implied one of the assumptions is that the requirement proposed is to call every patient even when the call is not needed. 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.

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11. Identify the local governmental units that participated in the development of this EIA.

None

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12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

The Pharmacy Examining Board did not find an economic or fiscal impact on public utility rate payers, or local governmental units. The Pharmacy Examining Board recognizes various factors play into the State's economy as a whole and the Pharmacy Examining Board does not have the resources or access to economic data to determine the economic impact to the state's economy as a whole.

The Pharmacy Examining Board did determine there may be an economic impact to pharmacies.

This proposed rule creates several cost-savings measures, especially to small pharmacy businesses. These include the following:

- A significant cost savings resulting from pharmacies no longer being required to provide a consultation on all prescriptions and instead providing a consultation only on new (defined as the drug product not previously dispensed to patient) or a change in therapy, which are the two riskiest factors for patient safety.
- Allowing for transfer of prescriptions to occur electronically between the two pharmacies without verbal communication required directly between two pharmacists.
- Increasing the tasks which may be delegated by a pharmacist to an unlicensed person.

Throughout the development of the rule, differing opinions have been offered by stakeholders as to the compliance costs to be incurred. The Pharmacy Examining Board's position is the rule represents current pharmacy practices and therefore, there will be a minimal economic impact.

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13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit is having rules which reflect current professional standards of practice.

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14. Long Range Implications of Implementing the Rule

The long range implication is clarity in professional standards.

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15. Compare With Approaches Being Used by Federal Government

Generally, the practice of pharmacy is under state jurisdiction. There are federal regulations related to controlled substance and drug supply chain. These rules reflect federal requirements in these areas.

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16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Our neighboring states have rules regarding the practice of pharmacy. The Pharmacy Examining Board reviewed the surrounding states' rules while promulgating the rule and have taken similar approaches.

**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

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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

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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

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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.

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17. Contact Name Sharon Henes, Administrative Rules Coordinator	18. Contact Phone Number (608) 261-2377
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This document can be made available in alternate formats to individuals with disabilities upon request.

**ADMINISTRATIVE RULES**  
**Fiscal Estimate & Economic Impact Analysis**

**ATTACHMENT A**

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1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

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2. Summary of the data sources used to measure the Rule's impact on Small Businesses

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3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

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4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

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5. Describe the Rule's Enforcement Provisions

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6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes    No
-