Report From Agency

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

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
Abbigail 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 polices 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 is 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 Chewning 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.