STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

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

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

Explanation of agency authority:

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

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

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

Related statute or rule: Phar 6 and 8

Plain language analysis:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Comparison with rules in adjacent states:

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

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

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

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

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

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

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

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

Summary of factual data and analytical methodologies:

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

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

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

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

TEXT OF RULE

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

Chapter Phar 7
PHARMACY PRACTICE

Subchapter I — General

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

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

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

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

1. Date of issue.
2. First and last name and address of the practitioner.
3. Prescriptions ordered by a delegate of the practitioner shall include the first and last name of the delegate and the first and last name and address of the practitioner.

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

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

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

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

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

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

(4) VERBAL PRESCRIPTION. Verbal prescription orders may be received at a pharmacy via a telephone answering device or voice mail. The oral 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, gender, and other patient factors.
(e) Reasonable directions for use.
(f) Potential or actual adverse drug reactions.
(g) Drug interactions with food, beverages, other drugs or medical conditions.
(h) Therapeutic duplication.

(i) Reasonable utilization and optimum therapeutic outcomes.

(j) Potential abuse or misuse.

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

7.04 Transferring prescription order information. (1) GENERAL REQUIREMENTS. 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:

(a) The transfer of prescription order information is communicated in one of the following ways:

1. Oral communication between two pharmacists.
2. Electronically or by facsimile machine between the two pharmacies.

(b) A transfer of prescription information orally shall be reduced to writing or entered into a computer system under s. Phar 7.11 (2) and the prescription record shall indicate the pharmacist responsible for the accuracy of the prescription information.

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

(a) The prescription record of the transferred prescription shall include the following information:

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

(b) Unless a computer system meeting the requirements in sub. (4) is used, the transferred prescription order information shall include the following:

1. The word “TRANSFER" on the face of the transferred prescription order or recorded in a similar manner in a computer system.
2. The first and last name and address of the patient, the first and last name and address of the prescribing practitioner.
3. Name, strength, form and quantity of the drug product or device prescribed and the directions for use.
4. The date of issuance of the original prescription order, the original prescription order number, the original number of refills authorized on the original prescription order and the date of original dispensing if the prescription order has previously been dispensed.
5. The number of valid refills or total quantity remaining and the date of the last refill.
6. The pharmacy’s name and address from which the prescription order information was transferred.
7. The first and last name of the pharmacist transferring and receiving the prescription order information.

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

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

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

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

1. Write the word "VOID" on the face of the invalidated prescription. For electronic prescriptions, information that the prescription has been transferred shall be added to the prescription record.
2. Record on the reverse of the invalidated prescription or in the electronic prescription record all of the following:
    a. Name, address and DEA registration number of the pharmacy to which it was transferred.
    b. The first and last name of the pharmacist receiving the prescription order.
3. Record the date of the transfer.
4. Record the first and last name of the pharmacist transferring the information.

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

1. Date of issuance of the original prescription order.
2. Original number of refills authorized on the original prescription order.
3. Date of original dispensing.
4. Number of valid refills remaining and the date and location of previous refills.
5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
8. First and last name of the pharmacist making the transfer.
9. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

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

1. The date of the original dispensing.
2. The number of refills remaining and the dates and locations of previous refills.
3. The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.
4. The first and last name of the pharmacist transferring the prescription.
5. The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.

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

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

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

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

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

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

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

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

(e) Pharmacy name, address and telephone.

(f) Prescriber name.

(g) Date the prescription was filled.

(h) Prescription order number.

(i) Quantity.

(j) Number of refills or quantity remaining.

(k) Written or graphic product descriptions.

(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) Any cautions or other provisions.

(4) Sub. (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 with all the following components:
(a) Drug name, strength and form.
(b) Pharmacy control or manufacturer lot number.
(c) NDC number. If NDC number is unavailable the name of the manufacturer or distributor of the drug product.
(d) Beyond use date.
(5) Records of all repackaging for stock operations are maintained and include all the following:
(a) Name, strength, form, quantity per container, and quantity of containers.
(b) NDC number. If NDC number is unavailable the name of the manufacturer or distributor of the drug product.
(c) Manufacturer lot number.
(d) Original container's expiration date and the beyond-use date for the new containers.
(e) First and last name of the pharmacist or delegate that repackaged the drug and the first and last name of the pharmacist that verified the accuracy of the repackaging.
(f) Date of repackaging.

Phar 7.07 Final check (1) The final check on the accuracy and correctness of the prescription drug product or device dispensing includes all of the following:
(a) Labeling requirements.
(b) Correct drug product or device.
(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 supervising pharmacist.

Phar 7.08 Patient consultation. (1) Patient consultation shall include all of the following:
(a) Name and description of the drug.
(b) Form, dose, route of administration and duration for drug therapy.
(c) Intended use of the drug and expected action.
(d) Special directions and precautions for preparation, administration and use by the patient.
(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
(f) Techniques for self-monitoring drug therapy.
(g) Proper storage and appropriate disposal method of unwanted or unused medication.
(h) Action to be taken in the event of a missed dose.
(2) A pharmacist shall give the patient or patient's agent consultation relative to the prescription for any new drug product or device which has not been dispensed previously to the patient or any change in the patient's therapy. Patient consultation shall meet all of the following requirements:

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

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

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

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

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

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

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

(5) Consultation is required upon patient request.

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

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

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

(1) The delivery method maintains appropriate environmental controls, including temperature and humidity, to prevent drug adulteration.

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

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

(a) Timeliness of delivery.

(b) Condition of the prescription drug upon delivery.

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

(4) Any prescription drug product or device which is compromised by delivery shall be replaced by the pharmacy. The pharmacy shall replace at no additional cost to the patient the prescription drug product or device by next-day delivery or the pharmacist shall contact the patient's

practitioner to arrange for a prescription for a minimum 7 day supply of the prescription drug product to be dispensed to the patient by a pharmacy of the patient's choice.

Phar 7.09 Procurement, recall and out-of-date drugs and devices.
(1) Procurement of prescription drugs and devices shall be from a drug wholesaler licensed by the board or U.S. food and drug administration to distribute to pharmacies or from another licensed pharmacy or licensed practitioner located in the United States.
(2) A pharmacy shall have a system for identifying any drugs or devices subjected to a product recall and for taking appropriate actions as required by the recall notice.
(3) Any drug or device may not be dispensed after the drug's or device's expiration date or beyond use date. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) The following minimum information shall be retrievable:

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

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

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

Phar 7.12 Delegation by a physician. The pharmacist shall document the delegation by a physician. The delegated act may not be started prior to the documentation. The documentation shall be maintained for a minimum of five years after the last delegated act under that delegation.

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

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

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

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

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

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

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

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

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

(a) Safe injection practices to prevent infections.

(b) Anatomy.

(c) Proper injection techniques.

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

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

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

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

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

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

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

(b) "Delegate-check-delegate" means the process in which one delegate conducts the task of product verification of technical dispensing functions completed by an unlicensed individual. A delegate may not conduct product verification as part of the final check of their own product preparation.

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

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

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

(a) Is at least 18 years old.

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

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

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

c. Wrong formulation.

d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

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

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

(e) Notwithstanding, par (a) to (d), a delegate who completed the 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 the dispensing meets all of the following:

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. Has a drug utilization review performed by a pharmacist prior to dispensing.

3. 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 the dispensing meets all of the following:

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. Has a drug utilization review performed by a pharmacist prior to dispensing.

3. Unless the drug product or device is in the original packaging from a manufacturer, the drug product or device includes a description of the drug product or device on the prescription label that allows for a non-pharmacist to check the accuracy of the medication after it is delivered.

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

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

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

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

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

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

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

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

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

Subchapter III — Central Shared Services

7.30 Definitions. In this subchapter:

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

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

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

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

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

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

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

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

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

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

Subchapter IV — Delivery Systems and Remote Dispensing

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

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

(a) Stocking of the delivery system.
(b) Determining access to the delivery system.
(c) Detection and mitigation of diversion and theft.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Be 18 years of age or older.

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

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

Subchapter V — Institutional Pharmacies

Phar 7.50 Definitions. In this subchapter:

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

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

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

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

(1) First and last name of the patient.

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

(3) Date of issuance.

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

(5) Directions for use.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Located within a licensed pharmacy.

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

(c) Validated by the following process:

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

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

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

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

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

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

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

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

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

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

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

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

4. Documentation of the dates of all software upgrades.

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

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

Subchapter VI — Unlicensed Persons

7.60 Definitions.

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

(2) "General supervision" means 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 perform any of the following:

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

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

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

(END OF TEXT OF RULE)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R03/2012)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Administrative Rule Chapter, Title and Number
Phar 7

3. Subject
Practice of Pharmacy

4. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

5. Chapter 20, Stats. Appropriations Affected
20.165(1)(g)

6. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☒ Could Absorb Within Agency's Budget
☐ Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

8. Would Implementation and Compliance Costs Be Greater Than $20 million?
☐ Yes ☒ No

9. Policy Problem Addressed by the Rule
This is an update of the Phar 7 chapter on the practice of pharmacy, which has not had a comprehensive review and update in at least 15 years. Topics which have been updated include prescription, drug utilization review, transferring of a prescription, label contents, repackaging of stock, patient consultations, delivery, procurement and recall, return or exchange of drugs, pharmacy records, physician delegation, administration of drugs, automated technology product verification, delegate-check-delegate, central shared services pharmacies, delivery systems, remote dispensing, institutional pharmacies and delegation to unlicensed persons. During the rule promulgation process, the Pharmacy Examining Board reviewed the National Association of Boards of Pharmacy's model rules, and the rules of surrounding states (and other states) and considered stakeholder input.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.
This rule was posted for economic comments. Economic comments were received from April Alexander representing Pharmaceutical Care Management Association; Thad Schumacher representing Fitchburg Family Pharmacy; Peggy Breuer representing Neuhauser Pharmacy: Michelle Farrell representing Boscobel Pharmacy; George Kowalski and Andrew Hanus representing Advocate Aurora Health; Jonathan McLachlan representing Alliance Rx Walgreens Prime; Stephen Shuda representing Ascension; and Allyson Snow representing GenRx. The Board invited those who submitted economic comments to attend a Pharmacy Examining Board meeting to discuss economic concerns raised. The following people met with the Pharmacy Examining Board on November 15, 2019 to discuss economic concerns: John Long, John Sisto, and Cindy Ten Pas representing Pharmaceutical Care Management Association member pharmacies; Thad Schumacher; Andrew Hanus; Stephen Shuda; Allyson Snow; and Tomson George representing Walgreens.
The first economic concern was requiring pharmacies to have a toll-free number for patients to contact the pharmacy with any consultation questions. The small pharmacies indicated this would be an unnecessary economic burden. The Pharmacy Examining Board mitigated this economic concern by modifying the requirement to the patient or patient's agent be advised of the method which the pharmacist may be contacted for consultation.
The second economic concern related to the requirement that a managing pharmacist visit a remote dispensing location twice a month instead of monthly. The hospital system pharmacies indicated this would require additional staff to comply. The Pharmacy Examining Board mitigated this economic concern by modifying the requirement to monthly visits to remote dispensing locations.
The last economic concern relates to the consultation requirements. The proposed rule requires an oral consultation if it is in the best interest of the patient to do so on all new prescriptions (defined as the drug product or device has not previously been dispensed to the patient) or change in therapy. Ascension, Advocate Aurora Health and GenRx raised a concern about the delay in therapy if an oral consultation could not be done *prior* to dispensing the drug product or device. The proposed rule does not indicate when the consultation needs to occur. Pharmaceutical Care Management Association representatives were unable to provide the assumptions or economic data provided to Pharmaceutical Care Management Association in preparation of the cost amount submitted in

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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.

11. Identify the local governmental units that participated in the development of this EIA.
None

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.

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.

14. Long Range Implications of Implementing the Rule
The long range implication is clarity in professional standards.

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.

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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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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.

17. Contact Name	18. Contact Phone Number
Sharon Henes, Administrative Rules Coordinator	(608) 261-2377

This document can be made available in alternate formats to individuals with disabilities upon request.

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R03/2012)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

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)

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

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:

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

5. Describe the Rule's Enforcement Provisions

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

☐ Yes ☐ No

LCRC
FORM 2

WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit S. Kelley
Clearinghouse Assistant Director

Jessica Karls-Ruplinger
Legislative Council Deputy Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **19-145**

AN ORDER to repeal and recreate ch. Phar 7, relating to the practice of pharmacy.

Submitted by **PHARMACY EXAMINING BOARD**

11-18-2019 RECEIVED BY LEGISLATIVE COUNCIL.
12-10-2019 REPORT SENT TO AGENCY.

SG:SM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☑ NO ☐

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☑ NO ☐

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

Scott Grosz
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Legislative Council Deputy Director

CLEARINGHOUSE RULE 19-145

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]

1. Statutory Authority

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.

2. Form, Style and Placement in Administrative Code

a. The rule does not contain a "subchapter II". Should subchs. III-VI be renumbered accordingly?

b. In s. Phar 7.02 (1), further subdivisions should be lettered paragraphs.

c. In s. Phar 7.05, 7.07, and 7.62, a period should be inserted at the end of each section title.

d. In s. Phar 7.14 (2) (e), the comma after "Notwithstanding" should be removed and "par" should be replaced by "pars.".

e. The board should revise s. Phar 7.14 (3) (a) and (b) so that each subunit following an introduction forms a complete sentence when read with the introduction. [s. 1.03 (3), Manual.]

f. The material in s. Phar 7.08 (1) (a) to (h) and (2) (a) 1. to 8. appear to be redundant. Consider deleting the material in s. Phar 7.08 (1) as it is unclear for what purpose that material serves.

g. The definitions for "direct supervision" and "general supervision" are both numbered s. Phar 7.60 (2).

h. The board should revise s. Phar 7.62 (3) (a) to (d) so that each subunit following an introduction forms a complete sentence when read with the introduction. [s. 1.03 (3), Manual.]

4. Adequacy of References to Related Statutes, Rules and Forms

a. The plain language analysis section of the rule summary appears to describe the substance of the proposed rule, but does not indicate how the proposed rule differs from the current ch. Phar 7. The reader would benefit from additional explanation of how the proposed rule changes the current rule.

b. The material in s. Phar 7.02 (1) for what must be specified in a prescription drug order generally matches the statutory requirements under s. 450.11 (1), Stats., except that the statute requires the symptom or purpose for which the drug is being prescribed to be specified on the order in certain limited circumstances, but the rule contains no such requirement. Should the rule be changed to match the statute, or should the board delete the material in s. Phar 7.02 (1) and instead include a cross-reference to the statutory list of prescription drug order requirements?

c. The material in s. Phar 7.05 (2) for what must be disclosed on a prescription drug or device label differs in a number of ways from the statutory label requirements under s. 450.11 (4) (a), Stats. For example, the statute requires that "Directions for use of the prescribed drug or device as contained in the prescription order" must be included in the label, but the rule contains no such requirement. Furthermore, the rule appears to require items on the label not required by statute, such as the rule's requirement that "Written or graphic product descriptions" be disclosed on the label. Should the material be changed to more closely match the statute, or should the board delete the material in s. Phar 7.05 (2) and instead include a cross-reference to the statutory list of label requirements?

d. In s. Phar 7.05 (4), "Subsection" should replace "Sub.".

e. For clarity, should the material in s. Phar 7.12 include a reference to s. 450.033, Stats.?

f. The material in s. Phar 7.14 (2) (e) references "the pilot program validation process" but does not adequately identify the pilot program, including what entity administered the pilot program.

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In s. Phar 7.01 (4), the board should choose a single term, either "verbal" or "oral" and use it consistently throughout the subsection.

b. The material in s. Phar 7.07 (1) should be revised for clarity. Though the plain language analysis section of the rule summary and references to s. Phar 7.07 (1) within the proposed rule suggest a final check is required, the rule could be modified to make clear that a final check is required and that the final check must include a review of the items specified in s. Phar 7.07 (1) (a) to (c). Furthermore, the material in s. Phar 7.07 (1) also needs revision so that each subunit following an introduction forms a complete sentence when read with the introduction. [s. 1.03 (3), Manual.]

c. Section Phar 7.50 (3) provides that the definition of "institutional pharmacy" "is not for the purposes under s. 450.09 (1) (a), Stats.". Though the rule does not alter the definition of "institutional pharmacy" that applies to ch. Phar 7 under s. Phar 1.02 (4), consider clarifying whether the s. Phar 1.02 (4) definition satisfies the requirements of s. 450.09 (1) (a), Stats. Additionally, the s. Phar 7.50 (3) definition only applies within subch. V of ch. Phar 7, though the term "institutional pharmacy" is used elsewhere in the rule. Is it the board's intent to apply to s. Phar 1.02 (4) to the use of "institutional pharmacy" outside of subch. V?

d. Should the reference to "pharmacy" in s. Phar 7.54 (2) be changed to "institutional pharmacy" for clarity?

e. The definition for "general supervision" under s. Phar 7.60 (2) needs revision in order to be read as a complete sentence.

Henes, Sharon - DSPS

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

Hello,

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

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

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

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

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

https://forms.gle/Bpv8MWnGzBF3GNF39

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

Best,

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

December 9, 2019

Dear esteemed members of the Wisconsin Pharmacy Examining Board,

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

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

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

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

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

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

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

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

Cordially,

Erika Horstmann Pharm.D.

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

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

SSM Statement on Proposed Changes to Phar 7 Summary

Rule Change Recommendations

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

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

SSM Statement on Proposed Changes to Phar 7 Summary

Rule Change Recommendations

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

Need Additional Clarification on the Following Sections:

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

November 29, 2019

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

RE: Comments on Proposed Oral Counseling Rule

Dear Ms. Henes:

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

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

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

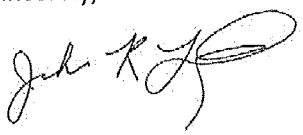
Enclara Pharmacia believes requiring verbal counseling prior to dispense would not be in the best interest of patients on hospice. Our patients often lose their ability and/or capacity to communicate verbally which would make a phone call an ineffective form of counseling. As mentioned above, hospice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

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

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

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

Sincerely,



John R. Loxterman
SVP, Chief Ethics and Compliance Officer

Henes, Sharon - DSPS

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

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

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

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

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

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

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

PROPOSED REQUIREMENTS

Phar 7.08 Patient consultation.

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

(a) Name and description of the drug.

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

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

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

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

(f) Techniques for self-monitoring drug therapy.

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

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

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

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

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

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

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

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

same issue as above, too much subjectivity allowed

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

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

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

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

(5) Consultation is required upon patient request.

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

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

Again a lack of consistency related to requirement or defer based upon professional judgment, it needs to be all or none. A verbal offer to consult which is refused should be acceptable as noted in (7).

CURRENT REQUIREMENTS

Phar 7.01 Minimum procedures for compounding and dispensing.

or pharmacist student under the direction of the pharmacist

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

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

November 15, 2019

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

Dear Pharmacy Examining Board:

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

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

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

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

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

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

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

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

Sincerely,

Betty Chewning

Betty Chewning, Ph.D., Professor

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

Henes, Sharon - DSPS

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

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

Pharmacy Examining Board

Dear Members of the Pharmacy Examining Board:

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

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

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

Thank you for your time.

Sincerely,

Adonnas Johnson

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

Henes, Sharon - DSPS

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

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

Pharmacy Examining Board

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

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

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

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

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

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

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

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

Sent from my iPad

Henes, Sharon - DSPS

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

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

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

Professionally,

Brenda Jacobs, RPh

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Wednesday, October 30, 2019 8:37 AM
To: Henes, Sharon - DSPS
Subject: FW: PEB proposed rule change Phar 7.01(1)(e)

From: Dan Strause <dstrause@hometownpharmacywi.com>
Sent: Tuesday, October 29, 2019 5:09 PM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: PEB proposed rule change Phar 7.01(1)(e)

Dear Debra Sybell:

We would like to provide input into the discussion and be willing to assist / comment/ provide written comments/ or testify depending on what's best for Wisconsin Citizens .

My name is Dan Strause and am one of many partners at Hometown Pharmacy. We take pride is providing health care advice and helping our patients understand the medications they are taking, the potential side effects, the potential interactions , the potential nutrients depleted and other care tips depending on the patient and their needs.

The first fill of any medication we feel is the most important as the ingestion of a new prescription is significant and communicating to a patient potential side effects, interactions with other items they may be ingesting, and other impacts on their health is vital to health care.

We were appalled to find out that mail order was exempted from this very fundamental and crucial step.

To learn today that the pharmacy examining board is creating a change to applying the consult rule to first fill/refill and renewals we believe makes a lot of sense as follow up visits during the interim fills can be spent discussing how their body has reacted versus the same initial messaging.

To also find out that mail order wants to " carve out" mail order from having to consult is just plain wrong and inappropriate.

I wish to be part of ongoing public messages if possible as well as offer our services in testifying.

Best regards

Dan Strause

608-516-2076

Henes, Sharon - DSPS

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

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

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

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

Henes, Sharon - DSPS

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

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

Debra Sybell,

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

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

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

Thanks you!

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

(920) 739-9232

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Thursday, October 31, 2019 9:39 AM
To: Henes, Sharon - DSPS
Subject: FW: Proposed rule change Phar 7.08

From: Jessica Haufschildt <jhaufschildt@hometownpharmacywi.com>
Sent: Wednesday, October 30, 2019 5:36 PM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: Proposed rule change Phar 7.08

Hello Debra,
I am Jessica Haufschildt, RPh., a practicing pharmacist in Wisconsin since 1995. I have been made aware of the rule change proposal for patient counseling in WI. I would like to be kept informed on this and be a stakeholder in this matter.

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

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

Henes, Sharon - DSPS

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

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

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

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

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

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

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

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

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

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

Mike Zagelow, RPh.

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

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

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

Henes, Sharon - DSPS

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

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

Hi Debra,

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

Thank you,

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

Henes, Sharon - DSPS

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

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

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

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

Henes, Sharon - DSPS

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

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

Hi Debra,

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

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

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

Thank you kindly for your consideration,

Jennifer Baerenwald
Pharmacist/Owner
Kimberly Hometown Pharmacy

Henes, Sharon - DSPS

From: Sybell, Debra - DSPS
Sent: Friday, November 15, 2019 9:38 AM
To: Henes, Sharon - DSPS
Subject: FW: Phar 7.08

From: Mackynzie Anderson <manderson@hometownpharmacywi.com>
Sent: Friday, November 15, 2019 8:27 AM
To: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Subject: Phar 7.08

Good morning Debra,

I had emailed you previously about the Phar 7.08 rule change and I know there is a meeting scheduled at noon today where they will be reviewing public comments in regards to this rule change, so I thought it would be a good time to touch base with you. A letter has been drafted up by myself and my fellow colleagues to the PEB, addressing this rule change and how it could impact mail order patient's negatively. This letter highlights some of the main issues we see daily with patients who are forced to go mail order and issues we will continue to see if mail order is exempt from this new rule change. See letter below:

Dear Members of the Pharmacy Examining Board:

We thank you for receiving and considering comments on the proposed changes to Phar 7 and ensuring proper procedures are in place for patients and taxpayers.
We strongly believe it is critical for patient safety that each patient receive their first prescription fill in person. The patient consultation components, outlined in proposed Phar 7.08, reiterate the importance of patients being consulted on their medication, and especially the importance of the first fill patient-pharmacist interaction:

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

Phar 7.01 Minimum procedures for compounding and dispensing. (1) Except as provided in sub. (4), a pharmacist or pharmacist–intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist or pharmacist–intern as directed and supervised by a pharmacist shall:
...
(e) Give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be

delivered by an agent of the pharmacist to a location of the patient's choice if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a location of the patient's choice, is not satisfied by only offering to provide consultation. Any exemption to Phar 7 which allows patients to get their first fill by mail order, where no consultation exists, simply puts patient's safety and health at risk. We are very concerned about a process in which a patient would receive a new prescription and not receive the important patient consultation information contained in proposed Phar 7.08 (1) (a), (b), (c), (d), (e), (f) and (g) all on their own. And we question the situation in which professional judgment would deem that a patient should not receive consultation on new medications they are receiving.

One of the most critical times for a patient is when they are released from a care facility. That transition of care, especially starting their proper prescription protocols, is very important for their health and recovery. Studies have shown that proper adherence to prescription protocols, reduces readmission and improves patient outcomes. Without a consultation, how can someone "professionally judge" whether a patient is taking an over the counter (OTC) product or who has a diet consisting of something that could negatively interact with a medication? Removing this critical and basic consulting component is not in the best interest of patients nor taxpayers. Under the current regulatory scheme, we already field calls from our community members who, with no choice, are forced into mail order. They feel abandoned. In fact, weekly there are many instances where our former patients, who have been forced into mail order, still call us and ask our pharmacists to explain their medications and the potential side effects. The Pharmacy Examining Board plays a critical role to help protect the public. And we believe the consultation component requirements outlined in proposed "Phar 7.08 Patient consultation." We do however serious concerns that those requirements can be avoided if a patient is required or chooses to receive their medication via mail order. We urge the PEB to ensure every patient is protected and receives a consultation.

Sincerely,

Mackynzie Anderson

Hometown Pharmacies of Wisconsin

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

Pharmacy Examining Board

Dear Members of the Pharmacy Examining Board:

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

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

1) What they are ingesting,

2) How often to ingest

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

4) When to ingest

5) Potential side effects

6) Interactions with other medications or foods or supplements

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

8) Instructions that may be unique to that patient.

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

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

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

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

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

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

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

Henes, Sharon - DSPS

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

Pharmacy Examining Board

Dear Members of the Pharmacy Examining Board:

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

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

> ***Proposed* Phar 7.08 Patient consultation. (1)** Patient consultation shall include all of the following:
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> (g) Proper storage and appropriate disposal method of unwanted or unused medication.
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> **Phar 7.01 Minimum procedures for compounding and dispensing. (1)** Except as provided in sub. (4), a pharmacist or pharmacist–intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist or pharmacist–intern as directed and supervised by a pharmacist shall:
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Any exemption to Phar 7 which allows patients to get their first fill by mail order, where no consultation exists, simply puts patient's safety and health at risk. We are very concerned about a process in which a patient would receive a new prescription and not receive the important patient consultation information contained in proposed Phar 7.08 (1) (a), (b), (c), (d), (e), (f) and (g) all on their own. And we question the situation in which professional judgment would deem that a patient should not receive consultation on new medications they are receiving.

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

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

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

Sincerely,

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

Tyler Wallenfang

Appleton Hometown Pharmacy

1350 W College Ave STE A

Appleton, WI 54914

Statement of Financial Impact*

Dear Members of the Pharmacy Examining Board:

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

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

> ***Proposed*** **Phar 7.08 Patient consultation. (1)** Patient consultation shall include all of the following:
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> (a) Name and description of the drug.
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> (f) Techniques for self-monitoring drug therapy.
> (g) Proper storage and appropriate disposal method of unwanted or unused medication.
> (h) Action to be taken in the event of a missed dose.

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

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

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

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

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

*I would argue that if mail order pharmacies are not required to complete the counseling required of all other pharmacies, they are at an economic advantage by not needing as much staff to handle the increased work load of consultations. I would also argue that non-mail order pharmacies then have an additional work load and staff time to field questions from patients that were not able to reach their mail order pharmacists.

The Pharmacy Examining Board plays a critical role to help protect the public. And we believe the consultation component requirements outlined in proposed "**Phar 7.08 Patient consultation"** should remain unchanged. We urge the PEB to ensure every patient is protected and receives a consultation in all situations.

Sincerely,

Tyler Wallenfang

Appleton Hometown Pharmacy

Statement of Economic Impact

11/15/2019

Abbi Linde, PharmD

Owner Beaver Dam Hometown Pharmacy

Hometown Pharmacy Director of Clinical Services

920.356.1500

Dear Members of the Pharmacy Examining Board:

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

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

Any exemption to Phar 7 which allows patients to get their first fill and first refill without consultation simply puts patient's safety and health at risk. I am very concerned about a process in which a patient would receive a new prescription and not receive the important patient consultation information contained in proposed Phar 7.08 (1) (a), (b), (c), (d), (e), (f) and (g) all on their own. In addition, so many patients are currently required to receive their prescriptions via mail order despite their need to receive consultation, adherence education, and have direct access to a pharmacist. Often, patients and former patients of mine will desperately contact me with questions about medications they received from mail order pharmacies or with emergencies that mail order pharmacies are unable or unwilling to address. I am asked to spend time away from my business and am asked to provide consultation on medications that I did not dispense. I question the judgement of pharmacists/pharmacies that conclude in their professional judgment that a patient should not receive consultation on new medications they are receiving.

It is my opinion that all pharmacies providing medications to patients in Wisconsin should have the same responsibility to provide medication services including the consultation necessary to use those medications safely and with effect. When pharmacists that have gone through the process of obtaining Wisconsin licensure and are dispensing prescriptions face to face to patients are held to a higher standard than mail order pharmacies, it impacts my ability to function as a small business in Wisconsin that also has patient safety and outcomes as a primary goal.

I also believe that the delivery service at most community pharmacies far exceeds the patient safety standards than that of receiving a prescription in the mail with no consultation or assessment. Many delivery drivers function as community health workers and provide feedback to the pharmacist that ensures patient understanding as well as patient safety and wellbeing.

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

Sincerely,

Abbigail Linde, PharmD

Henes, Sharon - DSPS

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

Dear PEB,

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

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

Thank you.

--

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

3900 Erie St

Racine, WI 53402

Pharmacy Examining Board

1400 E Washington Ave,

Madison, WI 53703

Dear Members of the Pharmacy Examining Board:

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

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

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

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

Sincerely,

Jeremy Laffin, RPh

Owner Wautoma Hometown Pharmacy

Manager Racine Hometown Pharmacy

Henes, Sharon - DSPS

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

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

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

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

Thank you,

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

HOMETOWN PHARMACY

Pharmacy Examining Board

Dear Members of the Pharmacy Examining Board:

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

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

> ***Proposed* Phar 7.08 Patient consultation. (1)** Patient consultation shall include all of the following:
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Any exemption to Phar 7 which allows patients to get their original fill by mail order, where no consultation exists, simply puts patient's safety and health at risk. We are very concerned about a

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

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

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

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

Sincerely,

Dan Strause, President
Hometown Pharmacies of Wisconsin

To: Sharon Henes
Administrative Rules Coordinator

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

Under 7.02

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

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

Under 7.03

Add is the patient compliant on refills.

Under 7.04 (3) (d,4)

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

Under 7.05 (2) (b)

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

Under 7.08

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

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

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

Under 7.085 (4)

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

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

Under 7.13 (c)

State registry for vaccines is required.

Under 7.14

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

Submitted by:

Kenneth R. Schaefer
Retired Pharmacist

149330 Mountain Lane
Wausau, Wisconsin 54401

Phone: 715-848-8748

EIA Process

An agency shall prepare an economic impact analysis for a proposed rule before submitting the proposed rule to the legislative council staff under s. 227.15. [s. 227.137 (2), Stats.]

An economic impact analysis of a proposed rule shall contain information on the economic effect of the proposed rule on specific businesses, business sectors, public utility ratepayers, local governmental units, and the state's economy as a whole. When preparing the analysis, the agency shall solicit information and advice from businesses, associations representing businesses, local governmental units, and individuals that may be affected by the proposed rule. The agency shall prepare the economic impact analysis in coordination with local governmental units that may be affected by the proposed rule. The agency may request information that is reasonably necessary for the preparation of an economic impact analysis from other businesses, associations, local governmental units, and individuals and from other agencies. [s. 227.137 (3), Stats.]

In preparing an EIA, the agency shall solicit information and advice from business, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule by making information about the rule available and requesting comments.

- Information including the proposed rule language shall be made available by posting on the agency website and the Wisconsin administrative rules website, submitting the information to the Governor's Office of Regulatory Compliance, and by emailing individuals who have requested to receive information and other persons identified by the agency as potentially interested parties.
- The agency shall accept comments for a period of at least 14 calendar days if the statement of scope indicates that the draft rule will have no or minimal economic impact locally or statewide.

After soliciting information and advice from businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule, the agency shall make a determination in the EIA as required, in consultation with those businesses, business sectors, associations representing businesses, local governmental units, and individuals as to whether the proposed rule would adversely affect in a material way the economy, a sector of the economy, productivity, jobs, or the overall economic competitiveness of this state in the following manner:

- The agency shall compile a list of affected persons and economic concerns identified in the comments solicited by the agency.
- The agency shall contact those affected persons to discuss economic concerns and give consideration to those concerns in its EIA determination.
- The agency shall document in the EIA the affected persons who were consulted and whether the agency's determination is disputed by any of the affected persons.

If the agency finds that a proposed rule will not have an economic impact after a review of comments submitted in response to the agency's solicitation, it may complete the EIA without additional coordination with local governmental units or consultation with other affected parties. The agency shall detail in the EIA the information supporting the conclusion that the proposed rule will not have an economic impact.

If the final EIA indicates that a total of $20,000,000 or more in implementation and compliance costs are reasonably expected to be incurred or passed along to businesses, local governmental units and individuals as a result of the proposed rule, the Department of Administration shall review the rule and issue a report. Any cost savings identified in the analysis of actual and quantifiable benefits shall not reduce the total estimated implementation and compliance costs for purposes of determining whether the Department of Administration shall issue a report. [Walker Executive Order #50]

If an economic impact analysis regarding a proposed rule indicates that a total of $20,000,000 or more in implementation and compliance costs are reasonably expected to be incurred by or passed along to businesses, local governmental units ,and individuals as a result of the proposed rule, the department of administration shall review the proposed rule and issue a report. [s. 227.137 (8), Stats.]

If an agency makes modifications to a proposed rule following the agency public hearing, the agency shall review the rule to determine whether the economic impact of the proposed rule is significantly changed. A significant change includes an increase or decrease of at least 10% or $50,000, whichever is greater, in the estimated compliance costs reasonably expected to be incurred by a majority of the business, business sector, local governmental units, or individuals that may be affected by the proposed rule or a significant change in the persons affected by the proposed rule. [Walker Executive Order #50]