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

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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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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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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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

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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