STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING EMERGENCY RULES

The statement of scope for this rule, SS 044-23, was approved by the Governor on June 22, 2023, published in Register 811A2 on July 10, 2023, and approved by the Pharmacy Examining Board on September 5, 2023. This emergency rule was approved by the Governor on (date).

ORDER

An order of the Pharmacy Examining Board to create Phar 8.03 (3), amend Phar 8.04, and repeal and recreate Phar 8.07, relating to controlled substances requirements.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

The Pharmacy Examining Board finds that an emergency exists and that this rule is necessary for the immediate preservation of the public peace, health, safety, or welfare. A statement of facts constituting the emergency is: Clearinghouse Rule 21-071 went into effect on October 1, 2022. This rule repealed and recreated all of Wisconsin Administrative Code Chapter Phar 8. Upon receiving feedback and completing an additional review, the Pharmacy Examining Board has determined that additional changes are needed to Phar 8 to address areas where requirements are no longer in effect or do not match federal regulations. Emergency rules are needed to ensure that these requirements can be updated to protect patient safety and allow effective regulation of the profession until permanent rules can be promulgated.

ANALYSIS

Statutes interpreted: ss. 450.09, 450.11, and 961.31, Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (2), 450.02 (3) (a), (d), and (e)., 961.31, Stats.

Explanation of agency authority:
Section 15.08 (5) (b), Stats. states that "[t]he 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."

Section 450.02 (2), Stats. provides that the board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

Section 450.02 (3) (a), Stats. provides that the board "may promulgate rules [r]elating to the manufacture of drugs and the distribution and dispensing of prescription drugs."

Section 450.02 (3) (d), Stats. provides that the board "may promulgate rules [n]ecessary for the administration and enforcement of this chapter and ch. 961."

Section 450.02 (3) (e), Stats. provides that the board "may promulgate rules [e]stablishing minimum standards for the practice of pharmacy."

Section 961.31, Stats. providers that "[t]he pharmacy examining board may promulgate rules relating to the manufacture, distribution, and dispensing of controlled substances within this state."

Related statute or rule: Wisconsin Administrative Code ch. Phar 7

Plain language analysis: This rule project revises ch. Phar 8 to reduce regulatory burdens on pharmacies, while maintaining public safety. These revisions include the addition of language regarding changes to controlled substances prescriptions, amendments to remove language regarding suspicious controlled substances orders, and amendments to clarify that partial dispensing of controlled substances is allowed.

Summary of, and comparison with, existing or proposed federal regulation: The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

Comparison with rules in adjacent states:

Illinois: 225 Illinois Compiled Statutes 85 outlines Illinois' Pharmacy Practice Act. These statutes are further described in the Illinois Administrative Code Title 68 Part 1330. Included in both are requirements for pharmacy standards and pharmacy operation [225 Illinois Compiled Statutes 85, Illinois Administrative Code Title 68 Chapter VII Subchapter b Part 1330 Sections 1330.600 to 1330.800]. Illinois law also requires a pharmacist to report theft or loss of controlled substances to the board at the same time it is reported to the DEA [Illinois Administrative Code Title 68 Chapter VII Subchapter b Part 1330 Sections 1330.710].

In the Illinois Controlled Substances Act, partial filling of schedule III to V controlled substances is allowed within 6 months after the date the prescription was issued, as long as the total quantity dispensed does not exceed the total quantity prescribed and each partial fill is recorded in the same manner as a refill. Schedule II partial refills are allowed under certain circumstances. Those circumstances include if the pharmacist is unable to provide the full quantity of a prescription, then the remaining quantity may be filled within 72 hours. If the remaining quantity is not filled within 72 hours, the pharmacist shall notify the prescribing practitioner and a new prescription is required to dispense any further quantity of that medication. Other circumstances include requirements for partial filling of schedule II controlled substance prescriptions for patients in long term care facilities with a terminal illness [Illinois Administrative Code Title 77 Chapter XV Part 3100 Section 3100.420]. Illinois also allows certain changes to schedule II controlled substance prescriptions. Outside of the changing or adding the date, name of the patient, name of the prescriber or adding a signature, and the name of the drug, any other components of a schedule II controlled substance prescription may be changed after consultation with the prescriber [Illinois Administrative Code Title 77 Chapter XV Part 3100 Section 3100.400].

Iowa: The Iowa Pharmacy Board requires pharmacist to report theft or loss of controlled substances to the Iowa Board if there is reason to believe that the theft was committed by a pharmacy board licensee, otherwise it is sufficient to report the theft to the DEA [657 Iowa Administrative Code Chapter 10 Section 10.21]. Iowa allows the partial filling of schedule II controlled substance prescriptions if there is an insufficient supply on hand for the pharmacist, for a long-term care or terminally patient, or a patient or prescriber request [657 Iowa Administrative Code Chapter 10 Section 10.27]. Changes to schedule II controlled substances are allowed after consultation with the prescriber or prescriber's agent in the areas of drug strength, dosage form, drug quantity, directions for use, date the prescription was issued, or the prescriber's address or DEA registration number. The pharmacist is not allowed to change the patient's name, the controlled substance prescribed except for generic substitution, or the name or signature of the prescriber [657 Iowa Administrative Code Chapter Section 10.30].

Michigan: Michigan requires theft or diversion of a controlled substance to be reported to the Michigan Department of Licensing and Regulatory Affairs within 15 days of completion of an investigation regarding a suspected theft or significant loss of a controlled substance, whether or not it is also reported to the DEA [Michigan Administrative Rules R 338.3141]. Michigan allows partial dispensing of schedule II controlled substances when the pharmacist is unable to supply the full quantity, at the request of the patient or prescriber, or for a patient in a long-term care facility or one who has a terminal illness. When the pharmacist is unable to supply the full quantity of a schedule II controlled substance prescription, the remaining quantity must be dispensed within 72 hours. If the remaining quantity is not dispensed within 72 hours, the pharmacist is required to notify the prescriber and a new prescription is required to dispense any further quantity. When a patient or prescriber requests a partial refill of a schedule II controlled substance prescription, the remaining portion may be dispensed within 30 days after the date of the on which the prescription was written. When the

schedule II controlled substance prescription is for a patient in a long-term care facility or for one with a terminal illness, individual dosage units may be dispensed and the prescription is valid for 60 days from the issue date. Partial filling of schedule III to V controlled substances prescriptions is also allowed as long as each partial fill is recorded as the same manner as a refill, the total quantity dispensed is not more than the total prescribed, and no dispensing can occur after 6 months for the date the prescription was issued [Michigan Administrative Rules R 338.3166]. Michigan Administrative Rules do not appear to mention requirements for changes to controlled substance prescriptions.

Minnesota: Minnesota allows the partial filling of schedule II controlled substances for patients in long term care facilities or those that are terminally ill [Minnesota Administrative Code Section 6800.4300]. Pharmacists, drug wholesalers, drug manufacturers, and controlled substance researchers must report loss or theft of controlled substances to the DEA immediately [Minnesota Administrative Code Section 6800.4800]. Minnesota Administrative Rules do not appear to mention requirements for changes to controlled substance prescriptions.

Summary of factual data and analytical methodologies: The Pharmacy Examining Board completed a comprehensive review of ch. Phar 8, Requirements for Controlled Substances, in order to identify and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices. The board also evaluated ch. Phar 8 for ways to reduce the regulatory impact on pharmacies without negatively impacting public safety.

Fiscal Estimate: The Fiscal Estimate will be attached upon completion.

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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-2112.

Agency contact person:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 8.03 (3) is created to read:

Phar 8.03 (3) Pharmacists are to use professional judgement to contact prescribers for changes to controlled substances prescriptions as needed and in accordance with federal law and s. Phar 7.02 (5).

SECTION 2. Phar 8.04 is amended to read:

Phar 8.04 Notification of ~~suspicious orders for and~~ theft or loss of controlled substances. A pharmacy or pharmacist shall notify the board of a ~~suspicious order or series of orders for controlled substances or the~~ theft or loss of controlled substances on the same day notification is required to be provided to the drug enforcement administration. Notification to the board shall include all of the information required to be provided in the notification to the drug enforcement administration.

SECTION 3. Phar 8.07 is repealed and recreated to read:

Phar 8.07 Partial Dispensing. Partial dispensing of controlled substances is allowed in accordance with federal law.

SECTION 4. This emergency rule shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)

Dated 5/10/2024 Agency John Waitekamp

Chairperson
Pharmacy Examining Board