BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the adoption of NEW RULE I pertaining to pharmacist prescribing	)))	NOTICE OF ADOPTION

TO: All Concerned Persons

1. On November 3, 2023, the Board of Pharmacy (board) published MAR Notice No. 24-174-80 regarding the public hearing on the proposed adoption of the above-stated rule, at page 1471 of the 2023 Montana Administrative Register, Issue No. 21.

2. On November 28, 2023, a public hearing was held on the proposed adoption of the above-stated rule via the videoconference and telephonic platform. Comments were received by the deadline.

3. The board has thoroughly considered the comments received. A summary of the comments and the board responses are as follows:

Comment 1: Several commenters thanked the board for proposing clear and concise rules.

Response 1: The board appreciates all comments received during the rulemaking process.

Comment 2: One commenter opposed the proposal, stating that telehealth is a better idea to make physicians more available to patients.

Response 2: The 2023 Legislature passed Senate Bill (SB) 112, extending limited prescribing authority to pharmacists. The board is therefore exercising its rulemaking authority to set standards for patient care, evaluation, recordkeeping, and provider notification required of pharmacists prescribing under SB 112's authority.

Comment 3: Several commenters opposed the rule, stating the rule as drafted lacks specificity needed to ensure a clear standard of practice.

Response 3: The board believes that allowing for pharmacists to use flexibility to exercise their professional judgment in treating patients is better for patient care than requiring every patient be treated pursuant to a specific protocol that may not fit that patient's needs.

Comment 4: Numerous commenters opposed the proposal, stating that pharmacists are not trained in diagnosis of diseases or patient-centered medical decision making,

and that extending general prescribing authority to pharmacists is a patient safety issue.

Response 4: The board disagrees with the commenters, and notes that the 2023 Legislature passed SB 112, extending limited prescribing authority to pharmacists. The board is therefore exercising its rulemaking authority to set standards for patient care, evaluation, recordkeeping, and provider notification required of pharmacists prescribing under SB 112's authority.

Comment 5: One commenter noted that pharmacy school does not prepare pharmacists to give physical or mental examinations or diagnose patients.

Response 5: SB 112 allows for independent prescribing by pharmacists in specific situations but requires that a pharmacist recognize the limits of the pharmacist's knowledge and experience and consult with and refer to other health care providers as appropriate.

Comment 6: Commenters suggested that patients should be made aware that pharmacists do not have the same level of training as other medical professionals, including that pharmacists do not have the ability to diagnose a medical condition.

Response 6: See Response 5.

Comment 7: Numerous commenters suggested the pharmacist be required to communicate their credentials to the patient and if the pharmacist holds a doctorate degree, to clearly state they are not a medical doctor.

Response 7: See Response 5.

Comment 8: One commenter believed it is not responsible or ethical to allow pharmacists to prescribe medication without the oversight of a physician, PA, or nurse practitioner.

Response 8: See Response 5.

Comment 9: Several commenters noted that conditions which are "minor" and "self-limiting" do not require prescription medication, and suggested the board amend the rules to suggest patients consider rest and over-the-counter medications.

Response 9: See Response 5.

Comment 10: Several commenters requested defining the term "patient emergencies" in the rules.

Response 10: The board considered defining the term, and determined that a definition would be too limiting, since "emergency" is particular to each patient. Pharmacists choosing to prescribe under SB 112's authority are expected to use

independent clinical judgment in assessing patients and comply with the requirements of SB 112 and corresponding rules.

Comment 11: Numerous commenters suggested the board add a section specifying what medications a pharmacist may prescribe in a patient emergency.

Response 11: See Response 10.

Comment 12: One commenter suggested that limiting refilling of prescriptions in "emergency" situations with proper physician notification would be appropriate.

Response 12: Emergency refills are addressed in ARM 24.174.836. This new rule addresses pharmacists' independent prescribing authority, as allowed by the Legislature in passing SB 112. Pharmacists must document the justification for the patient care they provide and comply with the requirements of SB 112 and corresponding rules.

Comment 13: Numerous commenters suggested the board add a section specifying conditions that are "minor."

Response 13: The board considered defining the term, and determined that a definition would be too limiting, since "minor" is particular to each patient. Pharmacists choosing to prescribe under SB 112's authority are expected to use independent clinical judgment in assessing patients. Patient care is unique to each patient, and adding the commenter's specific language would potentially limit the pharmacist's exercise of judgment and interfere with patient care.

Comment 14: Several commenters noted that the rule proposal states "any pharmacist" may independently prescribe, but that the bill states the section does not apply to a pharmacist within a collaborative pharmacy practice agreement, and that appears to be a conflict.

Response 14: Pharmacists working under the authority of collaborative pharmacy practice agreements, including clinical pharmacist practitioners, can still choose to prescribe independently pursuant to SB 112's authority. Testimony at the legislature included the difference between a clinical pharmacist practitioner, pharmacists working under collaborative agreements, and this independent authority. Pharmacists working in any of those three roles are required to document patient assessments and justification for the care provided.

Comment 15: Several commenters suggested that the rule provides confusion among pharmacists working under a collaborative practice agreement.

Response 15: See Response 14.

Comment 16: Numerous commenters suggested the board delete (1) of the rule as duplicative of statute, or in the alternative, strike the word "any" as confusing to

pharmacists in collaborative agreements or pharmacists whose license does not allow them to prescribe.

Response 16: See Response 14. Pharmacists whose licenses have been restricted from practice are governed by the restriction in the disciplinary action, and use of the term "any" in this section does not override a disciplinary action.

Comment 17: Numerous commenters suggested amending (2) to include obtaining all necessary information for appropriate clinical decision making.

Response 17: The board believes that "adequate information" and "all pertinent information" serve the same purpose, and that the pharmacist will exercise independent clinical judgment in determining whether they have gathered information sufficient to make an appropriate clinical decision.

Comment 18: Numerous commenters suggested that the board amend the new rule to include patient inclusion and exclusion criteria, and explicit medical referral criteria.

Response 18: Patient care is unique to each patient, and including the specifics requested by the commenter would potentially limit the pharmacist's exercise of judgment and interfere with patient care. SB 112 requires that a pharmacist recognize the limits of the pharmacist's knowledge and experience and consult with and refer to other health care providers as appropriate.

Comment 19: Numerous commenters suggested the board amend the unprofessional conduct rule to include failure to implement or produce the pharmacist's patient assessment.

Response 19: This rule requires that documentation be made available to the board upon request, and the board already has unprofessional conduct rules requiring pharmacists to follow laws governing pharmacy and to respond to requests from the board. The board believes this to be sufficient to address the commenters' concerns.

Comment 20: Numerous commenters suggested the board amend (3) to require the follow up care plan adhere to clinical guidelines and a requirement that the follow up care plan be implemented.

Response 20: The board believes the rule is sufficient to require implementation of the follow up care plan based on the standard of care model and the patient assessment being based on current clinical guidelines, best practice standards, or evidence-based research findings, as applicable.

Comment 21: Numerous commenters suggested that the board amend (4) to require effective communication methods and confirmation of receipt when a follow up care plan involves a named provider or a patient emergency.

Response 21: No other professionals are held to this standard. The rules are designed to hold pharmacists to the standard of care model, and pharmacists use various forms of communication as part of their standard of care. The board believes further notification requirements suggested by the commenter to be unnecessary.

Comment 22: One commenter stated the board should set a three-business day requirement for notifying a provider, or in the event of a patient emergency, 24 hours.

Response 22: Pharmacists choosing to prescribe under SB 112's authority are expected to use independent clinical judgment, including what is a reasonable time for provider notification.

Comment 23: Several commenters requested that prescribing pharmacists be held to the same standards of documentation as all other medical professionals.

Response 23: Medical record keeping of medical records are understood to be part of the standard of care of each profession. The board has complied with the statutory requirements as set forth in SB 112.

Comment 24: One commenter requested the board address whether every clinical laboratory improvement amendment (CLIA) waived test is allowed, even if the condition is not minor or self-limiting.

Response 24: The commenter is requesting a statutory interpretation, which is outside the scope of this rulemaking project. The commenter is welcome to use 2-4-501, MCA, to seek a formal ruling from the agency on the statutory interpretation.

4. The board has adopted NEW RULE I (24.174.505) as proposed.

BOARD OF PHARMACY
JEFF NIKOLAISEN, PHARMACIST,
PRESIDENT

/s/ DARCEE L. MOE
Darcee L. Moe
Rule Reviewer

/s/ SARAH SWANSON
Sarah Swanson, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State December 12, 2023.