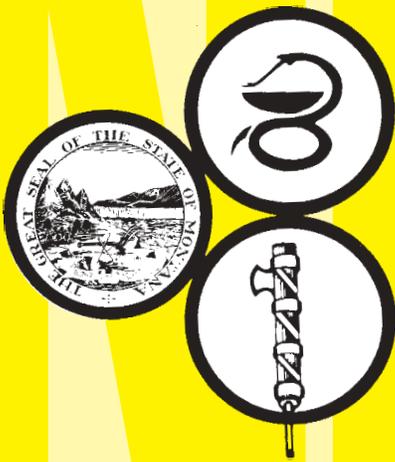


April 2002



Montana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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The passage of HB279 brought many positive changes to the practice of pharmacy in Montana:

- ◆ *Electronic transmission of prescriptions directly from prescriber to pharmacy is now possible (8.40.416).*
- ◆ *In an emergency, a pharmacy may transfer up to a seven-day supply of a non-controlled substance to a second pharmacy for dispensing without voiding the original prescription.*
- ◆ *Pharmacies accessing a common electronic database are no longer required to transfer prescriptions between themselves for dispensing purposes pursuant to changes in 8.40.408A. Note that pharmacies sharing a common electronic database must have the ability to allow their patients to "opt out" of sharing their prescription information with other pharmacies. It is of interest that California, one of the earliest states to require an "opt out" is now in the process of requiring a more stringent "opt in," in which a patient must request that prescription information be shared among other pharmacies accessing the database.*

These and other rule changes can be found at: www.discoveringmontana.com/dli/bsd/license/bsd_boards/.

New law books will be sent to all Montana pharmacies later this spring. Pharmacists wishing to have a personal copy can download them from the above Web site or contact the Board office at 406/841-2356.

8.40.416 Transmission of Prescriptions by Electronic Means

- (4) Prescriptions may be transmitted electronically directly from an authorized prescriber or his/her authorized agent to the pharmacy of the patient's choice without intervention by a third party, providing the following requirements are met:
- (a) Both prescriber and pharmacist must have a secure (encrypted or encoded) system for electronic transmission from computer to computer;
 - (b) The receiving electronic device shall be located within the pharmacy department to ensure security and confidentiality;
 - (c) An electronically transmitted prescription shall contain all information required by state and federal law, including the date and time of transmission, the

prescriber's telephone number for verbal confirmation and the name of the prescriber's agent transmitting the order, if other than the prescriber.

- (d) The prescriber's electronic signature or other secure (encrypted or encoded) method of validation shall be provided with the electronically transmitted order. Faxed prescription orders shall contain the identifying number of the sending fax machine.
 - (e) A printed, non-fading copy of an electronically transcribed prescription will be maintained in the pharmacy for a period of two years.
 - (f) The prescription shall be marked "electronically transmitted prescription."
 - (g) The electronic transmission shall maintain patient confidentiality.
 - (h) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice.
 - (i) The pharmacist is responsible for assuring the validity of the electronically transmitted prescription.
- (5) Two or more pharmacies sharing common electronic files to maintain dispensing information are not required to transfer prescription information between these pharmacies, providing all common electronic files maintain complete and accurate records of each prescription and refill dispensed, and the total number of refills authorized is not exceeded.
- (a) Any pharmacy sharing a common electronic file for prescription records post the following notice in readily readable form in a conspicuous place within the pharmacy:
This pharmacy maintains its prescription information in a secure electronic file that is shared by the following pharmacies: (list names of pharmacies which share the prescription information). If refills are authorized, your prescriptions may be refilled at any of the above locations. If you do not want your prescriptions to be maintained in this way, please notify the pharmacist at the time of filling.
 - (b) Pharmacies sharing common electronic files will have policies and procedures in place for handling these exceptions.

8.40.408A Transfer of Prescriptions

- (1) unchanged
- (2) unchanged
- (3) Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the common prescription file provided, however, that any such common file shall contain complete records of each prescription drug order and refill dispensed and further, that a hard copy record of each prescription drug order transferred or accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription drug order or to which the prescription drug order is transferred.
 - (a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:

Notice to Consumers

This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies: (list names of pharmacies which share the prescription information). By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained this way, please notify the pharmacist-in-charge.

- (b) Whenever a consumer objects to prescription records being made accessible to other pharmacies through the use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy except as provided in (1), (2), and (4) of this rule. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form, which reads substantially as follows: "I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file." The pharmacist shall date and co-sign the form and shall deliver a copy to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.
- (4) In an emergency, a pharmacy may transfer original prescription drug order information for a non-controlled substance to a second pharmacy for the purpose of dispensing up to seven days supply without voiding the original prescription drug order.
- (3) and (4) remain the same but is renumbered (5) and (6).

Collaborative practice was a prominent feature of HB279 and is now allowed in roughly 36 states. Its availability will enable Montana pharmacists and prescribers to provide better and more coordinated care for their patients. Note that the requirements of item (1) will be satisfied in institutions having a pharmacy and therapeutics committee when the patient signs treatment consent forms upon admission.

New Rule I Collaborative Practice Agreement Requirements

- (1) Prior to initially engaging in collaborative practice, a pharmacist must provide the Board with an executed written and electronic copy of the collaborative practice agreement.
- (2) The collaborative practice agreement must include:
 - (a) the identification and signature of individual practitioner(s) or a facility's chief of staff or their designee authorized to prescribe drugs and responsible for the delegation of drug therapy management;
 - (b) the identification and signature of individual pharmacist(s) authorized to dispense drugs and engage in drug therapy management;
 - (c) the types of drug therapy management decisions that the pharmacist is allowed to make which may include:
 - (i) a specific description of the types of diseases and drugs involved, and the type of drug therapy management allowed in each case, and
 - (ii) a specific description of the procedures and methods, decision criteria, and plan the pharmacist is to follow.
 - (d) a detailed description of the procedures and patient activities the pharmacist is to follow in the course of the protocol, including the method for documenting decisions made and a plan or mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. Documentation shall be recorded within 24 hours following each intervention and may be recorded on the patient medication record, patient medical chart, or a separate log book. Documentation of drug therapy management must be kept as part of the patient's permanent record and shall be considered confidential information;
 - (e) a method by which adverse events shall be reported to the practitioner;
 - (f) a method for the practitioner to monitor clinical outcomes and intercede when necessary;
 - (g) a provision that allows the practitioner to override protocol agreements when necessary;
 - (h) a provision that allows either party to cancel the agreement by written notification;
 - (i) the effective date of the protocol. The duration of each protocol shall not exceed one year;
 - (j) the annual date by which review, renewal, and revision, if necessary, will be accomplished;
 - (k) the addresses where records of collaborative practice are maintained; and
- (1) the process for obtaining the patient's written consent to the collaborative practice agreement.
- (3) Patient records shall be maintained by the pharmacist for a minimum of seven years and may be maintained in an automated system pursuant to ARM 8.40.503(3).

HB279 Allowed for Registration of Pharmacy Technicians

Technicians presently working within the state must now be registered in order to continue to practice, or they will risk a citation. Instructions and forms can be found on the Board's Web site.

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* In addition, technician duties were added and clarified. Technicians may briefly act as agents in charge of the pharmacy in the temporary absence of a pharmacist, but no judgmental tasks are allowed.

* A store-specific variance in pharmacist/technician ratio may now be obtained with Board approval, but only if the increased ratio allows new clinical duties to be performed by the pharmacist.

8.40.1304 Tasks and Functions of Pharmacy Technician – New Additions

- ◆ answer the telephone, properly identify themselves as a technician, accept verbal orders for **refill** prescriptions from medical practitioners or their designated agents and issue refill requests to the prescriber;
- ◆ a pharmacy technician may act as agent in charge of the pharmacy to assure its integrity when a registered pharmacist is not physically present, but may not perform any duties, which require the exercise of the pharmacist's independent professional judgment. **The technician may not be left in charge for more than 30 minutes.**

8.40.1308 Ratio of Pharmacy Technicians to Supervising Pharmacists

- (4) All registered pharmacists in good standing in the state of Montana may supervise more than one registered pharmacy technician provided, in their professional judgment:
- (a) a request for a ratio other than those previously defined must first be approved by the Board;
 - (b) the policy and procedures of the certified pharmacy must allow for safe and accurate filling and labeling of prescriptions;
 - (c) the policy and procedures shall be reviewed annually. All affected supervising pharmacists and pharmacy technicians must be familiar with the contents and any changes made must be reported to the Board;
 - (d) a copy of the policy and procedures must be available for inspection by the Board compliance officer.

Pharmacists may now administer vaccines to persons 18 years of age or older, pursuant to an established protocol.

New Rule III Administration of Vaccines by Pharmacists

- (1) A pharmacist may administer vaccines to persons 18 years of age or older provided that:
- (a) the pharmacist has successfully completed an accredited course of training provided by the Centers for Disease (CDC) Control, the American Council on Pharmaceutical Education, or other authority approved by the Board;
 - (b) the pharmacist holds a current basic cardiopulmonary resuscitation certification issued by the American Heart Association, the American Red Cross or other recognized provider;
 - (c) the vaccines are administered in accordance with an established protocol that includes emergency measures; and
 - (d) the pharmacist has a current copy of the Centers for Disease Control reference "Epidemiology and Prevention of Vaccine-Preventable Diseases.

- (2) The pharmacist must give the appropriate vaccine information statement to the patient or the patient's legal representative with each dose of vaccine covered by these forms and counsel the patient accordingly.
- (3) The pharmacist must maintain written policies and procedures for disposal of used or contaminated supplies.
- (4) The pharmacist must report any adverse events to the primary care provider identified by the patient and to the Centers for Disease Control.
- (5) A pharmacist administering any vaccine shall maintain the following information in the patient's medical records for a period of at least three years:
 - (a) the name, address, allergies, and date of birth of the patient;
 - (b) the date of administration;
 - (c) the name, manufacturer, dose, lot number, and expiration date of the vaccine;
 - (d) the vaccine information statement provided;
 - (e) the site and route of administration;
 - (f) the name and address of the patient's primary health care provider;
 - (g) the date on which the vaccination information was reported to the patient's primary health care provider under the provisions of the national vaccine injury compensation program;
 - (h) the name of the administering pharmacist; and
 - (i) any adverse events encountered.
- (6) The authority of a pharmacist to administer immunizations may not be delegated.
- (7) The pharmacist must provide a certified true copy of the certificate to the Board for endorsement on their pharmacist license.

Public Hearings

The Board will hold public hearings on mandatory pharmacist meal/rest break regulations (below) this spring, as well as the acceptance of continuing medical education for continuing education credit. New institutional regulations are nearing hearing stage as well, and will be on the Board Web site shortly. Your comments are encouraged.

Pharmacist Meal/Rest Breaks (Proposed Rule)

1. In any pharmacy staffed by a single pharmacist, the pharmacist shall take a meal/rest break for a period of up to 30 minutes per shift without closing the pharmacy and removing support personnel, provided the pharmacist reasonably believes that the security of prescription drugs will be maintained in the pharmacist's absence.
2. The time of closure and re-opening will be conspicuously posted in clear view of patients approaching the prescription area and will be consistently scheduled.
3. In the pharmacist's absence a sign indicating that no pharmacist is on duty will be conspicuously displayed in clear view of patients approaching the prescription area.
4. The pharmacist will remain on the premises if the prescription area is to remain open, and be available for emergencies.
5. When authorized by the pharmacist, only registered technicians directly involved in the process of filling prescriptions may remain in the prescription department to perform non-discretionary duties as delineated by the pharmacist.

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6. Upon returning, the pharmacist will review any work performed in the pharmacist's absence.
7. In the pharmacist's absence there shall be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor shall counseling be provided.
8. At the discretion of the pharmacist, previously checked medication refills may be handed to patients or their agents by registered technicians in the pharmacist's absence, and the technicians must offer the patient counseling by the pharmacist. If the patient desires counseling, the patient may wait for the pharmacist to return or may leave a telephone number for the pharmacist to call upon returning.
9. Telephoned new prescriptions will not be accepted by support personnel in the pharmacist's absence.
10. New hard copy prescriptions may be accepted and processed by registered technicians in the pharmacist's absence. These prescriptions may not be dispensed until the pharmacist has performed drug utilization review and completed the final check.
11. If two or more pharmacists are on duty the pharmacists will stagger their breaks so that the prescription department is not left without a pharmacist on duty.
12. The pharmacist-in-charge shall develop written policies and procedures for operation of the prescription department in the temporary absence of the pharmacist.

Responsibilities of a Pharmacist-in-Charge.

You have just been asked to sign on as pharmacist-in-charge of the pharmacy where you work. Congratulations! You will have the undying gratitude of your employer and the possibility of a small raise, with no real additional responsibilities. How hard can it be, right? If you answered in the affirmative, be grateful this is not the *Gong Show*! As pharmacist-in-charge, you are legally responsible for the operation of the pharmacy and must make certain that pharmacy activities are conducted in accordance with the law. You will be held accountable if the controlled substance count is off, if your technician oversteps his/her authority or if prescriptions are illegally filled or refilled within your pharmacy. Being pharmacist-in-charge demands more of you than merely a signature on a piece of

paper. It is an important position. Make certain that you understand the breadth of your responsibilities before you accept it.

Counseling Areas

Are you in compliance? July 1, 2003, will mark an important step forward in pharmacy practice in Montana. A private counseling area will be required in all pharmacies. The counseling area does not have to be a separate room, but it must offer visual and auditory privacy. Whether it is two or three soundproof walls or simply a few sheets of plywood, it will not be possible to obtain a new pharmacy license, or renew one, without it.

Most pharmacists take their counseling responsibilities seriously. They talk with their patients about what medications are used for, how to take them, precautions, adverse reactions, and storage considerations. Even though we have given patients a chance to ask questions, they may not feel free to ask them if the next patient is standing nearby. Unanswered questions can lead to incorrect use or noncompliance.

Many Montana pharmacies, even some that have been recently remodeled, have woefully inadequate counseling areas. The patients trusting their prescriptions to these pharmacies are the ultimate losers. The Board encourages you to remedy these inadequate situations now, rather than waiting until the last minute. Your patients should expect private, effective counseling. Beginning July 1, 2003, the Board will expect that as well.

Next Board Meeting

The Montana Board of Pharmacy will hold its next meeting May 1-2 in Great Falls in conjunction with the Montana Pharmacists Association convention May 3-5, 2002, at the Best Western Heritage Inn. You are invited to join us.

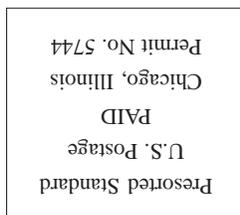
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The *Montana Board of Pharmacy News* is published by the Montana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc. to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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