

Board of Pharmacy Update

Presented by Starla Blank, PharmD, BCPS

Learning Objectives

- ▶ Given a citation from Montana law, identify if it is a rule or a statute
- ▶ List a proposed change to pharmacy rules approved by the Board in October 2017
- ▶ List the critical steps in the rule making process

Board of Pharmacy

- ▶ 7 members appointed by the governor
 - ▶ 5 year term, may be reappointed for a 2nd 5 year term
 - ▶ Apply on-line to be considered
 - ▶ Letter of interest and resume/CV
- ▶ Pharmacist members
 - ▶ Tony King
 - ▶ Paul Brand
 - ▶ Mike Bertanolli
 - ▶ Starla Blank
- ▶ Technician member
 - ▶ Rebecca Matovich
- ▶ Public members
 - ▶ Marian Jensen
 - ▶ Charmell Owens

Licensing Statistics September 2017

- ▶ Individuals
 - ▶ Pharmacists: 2,034
 - ▶ Interns: 359
 - ▶ Certified Techs: 1,244
 - ▶ Tech-in-Training : 351
 - ▶ Dangerous Drug Researchers: 13
 - ▶ Clinical Pharmacist Practitioners: 22
- ▶ Facilities
 - ▶ Community: 264
 - ▶ Telepharmacy 17
 - ▶ Institutional: 97
 - ▶ Mail Order: 661
 - ▶ Limited Services: 5
 - ▶ OP Surgical Centers: 19
 - ▶ Wholesalers: 1,367
 - ▶ In state: 102

Adjusted Fee Schedule Effective October 2017

License Type	Fee
Pharmacist renewal	\$65 (\$110)
Technician renewal	\$30 (\$50)
Clinical Pharmacist Practitioner application	\$25 (\$25)
Clinical Pharmacist Practitioner renewal	\$25 (\$25)
Pharmacy renewal	\$150
Technician Utilization Plan renewal	\$75
Dispenser of Dangerous Drugs renewal	\$75

Legislative and Rule Making Process

- ▶ Statutes = laws = Montana Code Annotated (MCA)
- ▶ New statutes or changes to existing statutes (amendments) must be passed by the legislature
- ▶ Rule making authority is delegated to Boards in statute. Rules also = law
- ▶ Rules may be proposed, adopted, and amended by Boards without the legislature
- ▶ Administrative Rules of Montana (ARM)

Rule Making Process

- ▶ New rule or change to an existing rule proposed
- ▶ Rule proposal approved by the Board
- ▶ Rule notice published
- ▶ Public comment period – minimum of 28 days allowed
- ▶ Rule hearing – minimum of 20 days between notice and hearing
- ▶ Board responds to comments
- ▶ Rules may be revised by Board based on comments
- ▶ Rule adoption notice published – maximum 6 months between rule notice and adoption

Changes to Rules or Statutes

- ▶ Changes to existing rules or statutes are indicated with a strike through for text to be removed and with an underline for new text
- ▶ Example:
 - ▶ ~~This indicates text to be removed~~
 - ▶ This indicates new text to be added

Clinical Pharmacist Practitioner

- ▶ Effective July 1, 2017 Montana Medicaid covers Collaborative Practice Drug Therapy Management provided by a Clinical Pharmacist Practitioner (CPP).
- ▶ Requirements
 - ▶ CPP must meet the requirements outlined in ARM 24.174.526
 - ▶ CPP must manage a member's drug therapy by providing face-to-face, direct care
 - ▶ CPP must provide care through employment or contract within a physical practice of a medical practitioner or facility.
- ▶ Enrollment
 - ▶ CPP must enroll with Montana Medicaid utilizing the full Medicaid provider enrollment application as a rendering only provider
- ▶ Blue Cross Blue Shield of Montana is also covering services provided by a CPP

Clinical Pharmacist Practitioner Medicaid Fee Schedule

Code	Description	Rate
99605	initial 15 minutes, new patient	\$58.45
99606	initial 15 minutes, established patient	\$39.75
99607	each additional 15 minutes	\$16.04

Clinical Pharmacist Practitioner

- ▶ ARM 24.174.526 REQUIREMENTS TO BECOME A CLINICAL PHARMACIST PRACTITIONER
- ▶ Active MT RPh license, application, fee
- ▶ 5 years of clinical experience OR residency and 2 years of clinical experience
- ▶ BPS certified or other nationally recognized certification
- ▶ Collaborative practice agreement
- ▶ Approval of Boards of Pharmacy and Medical Examiners
- ▶ Endorsement on Pharmacist License (CPP)

CPP Rule Change Approved by Board of Pharmacy October 2017

- Action Item: Amend**
- 24.174.526. REQUIREMENTS TO BECOME A CLINICAL PHARMACIST PRACTITIONER**
- (1) An applicant for a clinical pharmacist practitioner registration shall:
- (a) submit an application on a form prescribed by the board;
 - (b) pay a registration fee as prescribed by the board;
 - (c) hold an active, unrestricted Montana pharmacist license;
 - (d) have completed **five years of the years of** clinical practice experience **that meet the requirements for Board of Pharmacy Specialists (BPS) certification or other equivalent national certification or have completed a pharmacy residency two years clinical practice experience** and hold one of the following active certifications:
 - (i) BPS certification; or
 - (ii) nationally recognized certification **equivalent to BPS** in an area of practice as approved by the board and Board of Medical Examiners (BME);
 - (e) submit a signed collaborative practice agreement to the board that includes a description of the type of supervision the collaborating **physician/practitioner** will exercise over the clinical pharmacist practitioner;
 - (f) following approval of the board, submit the application and collaborative practice agreement to the BME for approval; and
 - (g) appear before the board and/or BME if requested.
- (2) Within ten days of discontinuing work under an approved collaborative drug therapy agreement, the pharmacist shall notify the board and the clinical pharmacist practitioner's registration shall be inactive, until such time as a new application is approved.

AUTH: 37-7-201, MCA
RMP: 37-7-201, 37-7-306, MCA

Rule Making Process

- ▶ New rule or change to an existing rule proposed
- ▶ Rule proposal approved by the Board of Pharmacy ←
- ▶ Rule proposal will be presented to the Board of Medical Examiners on November 17, 2017
- ▶ Rule notice published – Target December 2017
- ▶ Public comment period – minimum of 28 days
 - ▶ Comments must be in writing
 - ▶ Comments may support, oppose, or offer suggestions for changes

Rule Making Process

- ▶ Rule hearing – minimum of 20 days between notice and hearing
 - ▶ Comments supporting, opposing, or offering suggestions for changes may be done in person at hearing
- ▶ Board responds to comments
 - ▶ Rules may be revised by Board based on comments
 - ▶ Minor revisions vs. major revisions
- ▶ Rule adoption notice published – maximum 6 months between rule notice and adoption

CPP Rule Change Timeline

- ▶ Proposed rule change approved by Board of Pharmacy October 2017
- ▶ Proposed rule change to be presented to Board of Medical Examiners for approval 11/17/17
- ▶ Rule notice published December 2017
- ▶ Public comment and hearing January 2017
- ▶ Board response January 2018
- ▶ Notice of adoption March 2018

Questions and Discussion



MT PDR Rule Change Next Day Reporting

Action Item: Amend

24.174.1704. REQUIREMENTS FOR SUBMITTING PRESCRIPTION REGISTRY INFORMATION TO THE BOARD. (1) All prescription drug order information for controlled substances shall be submitted to the board pursuant to this subchapter.

(2) A pharmacy shall submit all prescription drug order information for a controlled substance to the board no later than **eight days close of the next business day** after the date of dispensing the controlled substance.

(3) If a pharmacy that dispenses controlled substances has not dispensed any controlled substances during a calendar month, the pharmacy shall verify that no controlled substances were dispensed for that month by submitting a "zero report" to the board. A "zero report" is due on or before the fifth day of the next month.

(4) A pharmacy that does not dispense controlled substances shall notify the board by submitting an appropriate board-approved form attesting that the pharmacy does not dispense controlled substances.

(5) The form submitted by a pharmacy that does not dispense controlled substances shall be maintained on file with the board and at the pharmacy's location.

(6) If a pharmacy does dispense a controlled substance, it shall then comply with the reporting requirements of this rule.

(7) **For the purposes of establishing a data history at the initiation of the prescription drug registry, each certified pharmacy and out-of-state mail service pharmacy shall submit a one-time batch submission of controlled substances dispensed to Montana patients from July 1, 2011 forward to the date the registry is operational.**

(8) In the event that a pharmacy cannot submit the required information as described in this rule, the pharmacy must timely report that fact to the board on or before the date the submission is due. The board office may grant an extension, at their discretion, when a pharmacy notifies the board that they are unable to submit their report.

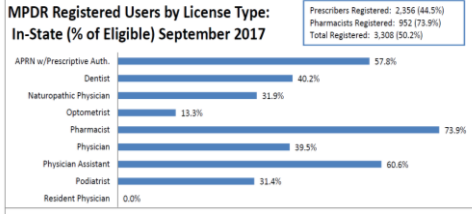
(9) It is the responsibility of the submitting pharmacy to address any errors or questions about information that the pharmacy has submitted to the prescription drug registry and resubmit corrected data no later than **eight days close of the next business day** after the date of the original submission.

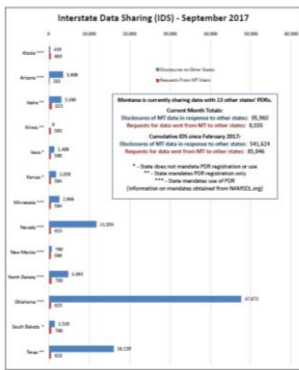
ALTH: 37-7-1512, MCA
BMP: 37-7-1503, 37-7-1512, MCA

MT PDR Statistics September 2017

Category	Sept 2017	Since 2012
Prescriptions in database		11,567,273
Patients in database		1,015,198
Registered users	44	3,898
Active delegate relationships	24	977 since 2016
Patient history searches	24,699	856,140
Law enforcement subpoenas	23	1,055
Board investigator or compliance requests	2	101
Individual requests	1	19

MT PDR Statistics





Naloxone Laws 2017 Legislature

- ▶ **HB 333, Help Save Lives from Overdose Act**
 - ▶ Defines "eligible recipient" and provides authority for facilities such as police/fire departments, crime lab, investigators to be identified as a patient for the purpose of obtaining a prescription for naloxone
 - ▶ Allows a state-wide standing order through DPHHS in addition to private collaborative practice agreements for pharmacists to dispense naloxone
 - ▶ Naloxone remains an prescription product. It is NOT available OTC

Naloxone Laws 2017 Legislature

- ▶ HB 323, Authorize Emergency Use of Opioid Antagonists in a School Setting
 - ▶ Identifies the school as a patient for the purpose of obtaining a naloxone prescription.

Prescription Drug Registry 2017 Legislature

- ▶ SB 56, Revise Sunset Dates Related to Funding of the MPDR
- ▶ Extends authority for the Board to collect a \$30 MPDR fee from licensees authorized to prescribe or dispense controlled substances until June 30, 2019.
- ▶ Fee are collected at the time of license renewal for all affected licensees.

Immunization Laws 2017 Legislature

- ▶ HB 177, Revise Administration of Immunizations
 - ▶ Clarifies the list of immunizations that pharmacists can independently prescribe and administer without a collaborative practice agreement.
 - ▶ Allows for any pneumococcal vaccine
 - ▶ Previously limited to pneumococcal 23 valent vaccine

Pharmacy Benefit Manager (PBM) Laws - 2017 Legislature

- ▶ HB 276, Revise Reimbursement for Pharmacies
 - ▶ Montana Pharmacy Association bill that directs PBMs to provide greater price transparency when claims are reimbursed at less than the acquisition cost of a drug
 - ▶ Effective date: January 1, 2018

Biosimilars 2017 Legislature

- ▶ HB 233, Drug Product Selection Act for Biosimilars
 - ▶ Provides definitions for biologic interchangeable products as approved by the FDA
 - ▶ Includes post-dispensing communication requirements

Montana Professional Assistance Program (MPAP)

- ▶ Board of Pharmacy has hired a new contractor to provide assistance to pharmacists and technicians
- ▶ MPAP is also the contractor for the Boards of Medicine, Dentistry, and Nursing
- ▶ Phone: 406-245-4300
- ▶ <https://www.montanaprofessionalassistance.com>

Montana Professional Assistance Program



MONTANA PROFESSIONAL ASSISTANCE PROGRAM

Phone: 406.245.4300
Fax: 406.245.4432
3333 2nd Ave. N., Ste 100,
Billings, MT 59103
Toll Free: 1-800-697-9349
mapa@mapa.net

MEMBER:

- American Opt
- Aetna
- Blue Cross
- Blue Cross of Montana
- Blue Cross of North Carolina
- Blue Cross of South Carolina
- Blue Cross of Tennessee
- Blue Cross of Virginia
- Blue Cross of West Virginia
- Blue Cross of Wyoming
- Blue Cross of the Pacific
- Blue Cross of the South
- Blue Cross of the South East
- Blue Cross of the South West
- Blue Cross of the West
- Blue Cross of the West Coast
- Blue Cross of the West North Central
- Blue Cross of the West South Central
- Blue Cross of the West South West
- Blue Cross of the West South Central
- Blue Cross of the West South West
- Blue Cross of the West South Central
- Blue Cross of the West South West

Click here to view:
[Cross-Tag](#)

How often have you heard this statement from a patient: "Help Me, I'm In Pain!" But who hears your cry for help? As a professional care giver you are accustomed to pushing yourself beyond your physical and mental capacities with long hours, aberrant sleep and eating habits and working in a state of sustained stress. Constant fatigue, becomes routine, but be aware, this type of behavior may lead to chemical dependency, depression or other forms of illness which can profoundly affect your professional and personal life.

Copyright 2008, Montana Professional Assistance Program. All Rights Reserved.

Questions