Certification Page
Regular and Emergency Rules

Revised June 2020

☐ **Emergency Rules** *(Complete Sections 1-3 and 5-6)* ■ **Regular Rules**

1. General Information

a. Agency/Board Name* Administration and Information, Dpt of/WY State Board of Pharmacy

b. Agency/Board Address 1712 Carey Avenue, Suite 200 | c. City Cheyenne | d. Zip Code 82002

e. Name of Agency Liaison Matthew R. Martineau | f. Agency Liaison Telephone Number (307)634-9636

g. Agency Liaison Email Address matt.martineau@wyo.gov | h. Adoption Date 3/15/2023

i. Program Commissioner of Drugs and Substances Control

Amended Program Name (*if applicable*):

* ☐ *By checking this box, the agency is indicating it is exempt from certain sections of the Administrative Procedure Act including public comment period requirements. Please contact the agency for details regarding these rules.*

2. Legislative Enactment

For purposes of this Section 2, "new" only applies to regular (non-emergency) rules promulgated in response to a Wyoming legislative enactment not previously addressed in whole or in part by prior rulemaking and does not include rules adopted in response to a federal mandate.

a. Are these non-emergency or regular rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?

■ **No.** ☐ **Yes.** If the rules are new, please provide the Legislative Chapter Numbers and Years Enacted (e.g. 2015 Session Laws Chapter 154):

3. Rule Type and Information

For purposes of this Section 3, "New" means an emergency or regular rule that has never been previously created.

a. Provide the Chapter Number, Title* and Proposed Action for Each Chapter. *Please use the "Additional Rule Information" form to identify additional rule chapters.*

Chapter Number:	Chapter Name:			
8	Prescription Drug Monitoring Program	☐ New	■ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
Chapter Number:	Chapter Name:			
10	Issuing and Dispesning Prescriptions for Controlled Substances	☐ New	■ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
Chapter Number:	Chapter Name:	☐ New	☐ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
Chapter Number:	Chapter Name:	☐ New	☐ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
Chapter Number:	Chapter Name:	☐ New	☐ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			
Chapter Number:	Chapter Name:	☐ New	☐ Amended	☐ Repealed
	Amended Chapter Name (*if applicable*):			

4. Public Notice of Intended Rulemaking

a. Notice was mailed 45 days in advance to all persons who made a timely request for advance notice. ☐ No. ☑ Yes. ☐ N/A

b. A public hearing was held on the proposed rules. ■ No. ☐ Yes. Please complete the boxes below.

Date:	Time:	City:	Location:

5. Checklist

a. ☑ For regular rules, the Statement of Principal Reasons is attached to this Certification and, in compliance with Tri-State Generation and Transmission Association, Inc. v. Environmental Quality Council, 590 P.2d 1324 (Wyo. 1979), includes a brief statement of the substance or terms of the rule and the basis and purpose of the rule

b. ☐ For emergency rules, the Memorandum to the Governor documenting the emergency, which requires promulgation of these rules without providing notice or an opportunity for a public hearing, is attached to this Certification.

6. Agency/Board Certification

The undersigned certifies that the foregoing information is correct. By electronically submitting the emergency or regular rules into the Wyoming Administrative Rules System, the undersigned acknowledges that the Registrar of Rules will review the rules as to form and, if approved, the electronic filing system will electronically notify the Governor's Office, Attorney General's Office, and Legislative Service Office of the approval and electronically provide them with a copy of the complete rule packet on the date approved by the Registrar of Rules. The complete rules packet includes this signed certification page; the Statement of Principal Reasons or, if emergency rules, the Memorandum to the Governor documenting the emergency; and a strike and underscore copy and clean copy of each chapter of rules.

Signature of Authorized Individual	
Printed Name of Signatory	Matthew R. Martineau
Signatory Title	Executive Director
Date of Signature	3/23/2023

7. Governor's Certification

I have reviewed these rules and determined that they:

1. Are within the scope of the statutory authority delegated to the adopting agency;
2. Appear to be within the scope of the legislative purpose of the statutory authority; and, if emergency rules,
3. Are necessary and that I concur in the finding that they are an emergency.

Therefore, I approve the same.

Governor's Signature	
Date of Signature	

WYOMING STATE BOARD OF PHARMACY

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Matthew R. Martineau, RPh, Executive Director

WYOMING CONTROLLED SUBSTANCES ACT RULES AND REGULATIONS

STATEMENT OF PRINCIPAL REASONS FOR REVISIONS

January 2023

The Board of Pharmacy proposes to amend Chapters 8 and 10 of the Wyoming Controlled Substances Act Rules and Regulations in order to modernize and simplify rules for reporting into and using the prescription drug monitoring program now that the Board has transitioned to the new Wyoming PMP AWARxE platform and to update the requirements for transferring controlled substance prescriptions pursuant to the revisions being done to the Wyoming Pharmacy Act Rules Chapter 2.

As required by Wyoming Statute § 16-3-103(a)(i)(G), these rules meet minimum substantive state statutory requirements.

Chapter 8: Prescription Drug Monitoring Program

- The rules for reporting into and using the prescription drug monitoring program are being modernized and simplified now that the Board has transitioned to the new Wyoming PMP AWARxE platform.

Chapter 10: Issuing and Dispensing Prescriptions for Controlled Substances

- Requirements for transferring prescriptions for controlled substances are being updated due to the revisions being done to Chapter 2: General Practice of Pharmacy Regulations.

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SUMMARY OF COMMENTS RECEIVED REGARDING REVISIONS TO THE WYOMING CONTROLLED SUBSTANCES ACT RULES AND REGULATIONS CHAPTERS 8 &10.

Chapter 8: Prescription Drug Monitoring Program – Five (5) commenters provided comments to the Board during the public comment period relevant to this chapter. Most of the comments requested that the Board remove the requirement that naloxone be reported into the Wyoming Prescription Drug Monitoring Program (PDMP). The commenters pointed to:

- Recent legislation (SF0007 – Definition of opiate antagonist) that broadened the definition of opiate antagonist to mean any device or medication approved by the United States food and drug administration for the treatment of an opiate-related overdose, and not just naloxone;
- An FDA advisory committee recommendation that naloxone should be made available over the counter; and
- That the requirement to report naloxone into the PDMP has created unnecessary barriers with the public health initiative to increase access to naloxone by:
    - making it difficult for healthcare systems to efficiently distribute naloxone to patients; and
    - stigma related to obtaining naloxone because of providers making assumptions about patients who have a naloxone prescription in the PDMP.

The Board agreed with the comments and reasoning provided and chose to amend the rules in response.

One (1) commenter pointed out that when the Board had decided to revise chapter 8, the Board had decided to remove the delegate limit. This revision was inadvertently missed when the chapter was moved forward for public comment. The commenter reminded the Board of their decision and their reasoning/discussion to remove the limit, i.e. to increase the use of the PDMP, to lead to better prescribing and dispensing practices by health care practitioners. **The Board agreed and chose to amend the rules in response.**

One of the commenters thought that a new subsection was unnecessary. The Board disagreed as those revisions were made to distinguish between the requirements for practitioners vs the requirements for dispensers. **The Board chose not to amend the rules in response to this comment.**

One of the commenters pointed out a discrepancy between the clean and strikethrough versions of the revisions that were posted. The strikethrough version correctly identified the revision and the clean version was duly corrected. This commenter also posed two questions to the Board. The Board chose not to amend the rules in response to these two questions.

Chapter 10: Issuing and Dispensing Prescriptions for Controlled Substances – One (1) commenter provided comments to the Board during the public comment period relevant to this chapter. The commenter asked whether "wet signed" should be defined in the chapter. Wet signed was determined to be a commonly understood definition when the chapter was created in 2020 and the Board has not received questions asking what is meant by "wet signed." **The Board chose not to amend the rules in response to this comment.**

The commenter pointed out that the wording of Chapter 10 Section 7(a)(ii) implied that patients must have both a state and federally issued identification when they presented a non-electronic controlled substance prescription or received any controlled substance prescription from a pharmacy. **The Board agreed and chose to amend the rules in response to this comment.**

Written Public Comments for Rules Packet 059.011023.Commissioner of Drugs and Substances Control – Chpts 8 & 10.			
No.	Comment	Agency Response	
		Yes – Amend Rules	No – Why?
1.	Hello, My name is [redacted] and I am writing in regards to proposed changes. I am a practicing pharmacist for a hospital pharmacy in [redacted] Wyoming. Controlled substance Chapter 8, new subsection 4(a) is unnecessary. 4(d) says all the same things but also explains the inpatient exclusion. Having the information in two places is confusing		Thank you for your comment.
2.	I am [redacted], [redacted], and would like to make comments on Chapters 2, 21, 8, and 10. Thank you. Chapter 8 [1]6(b): currently states "to may" -- should this be one or the other? [2]6(b)(iv): as in comment for Chapter 2, 15(c)(ii) -- can under contract be used for students? [3]9: should a statement on the board's use be included for statistical analysis? Chapter 10 [4]6(a)(ii): should wet signed be in the definitions? [5]7(a)(ii): for identification, should state "or" federal be allowed. "And" implies that both are needed.	[1]The strikethrough version of the chapter correctly reads (b) Pharmacists and practitioners shall register as users with Wyoming PMP AWARxE to ~~may~~ request patient profiles where a pharmacist/patient, practitioner/patient relationship exists. ~~from the Board provided the following conditions are met for faxed paper requests:~~ The clean version has been duly corrected. [5]The Board agrees and moves amending Chapter 10 Section 7(a)(ii) to: (ii) Identification may be verified by state ~~and~~ or federally issued identification.	[2,3,4] Thank you for your comments.
3.	To whom it may concern, This opinion is my own professional opinion and should not be construed to be representative of the organization that employs me. Reporting naloxone dispensing through the PDMP system creates unnecessary barriers in the public health initiative to increase naloxone in the community as a viable response to the opioid crisis.	The Board agrees and moves amending Chapter 8 Section 5(b) as follows: (b)Dispensers shall report the information required pursuant to this Chapter	

	Naloxone being reported to the PDMP system has also not provided any perceptible benefit and has increased regulatory burden and increased regulatory burden leads to increased cost to the healthcare system that is already operating in a challenging economic environment. It is in my own professional judgement that removing the requirement to report naloxone dispenses to the PDMP system will be beneficial to promote community wellbeing with no perceptible net negative effect. Thank you [redacted], RPh, PharmD	for the following non-controlled substances: (i) Gabapentin; (ii) Cyclobenzaprine.~~;~~ ~~and~~ ~~(iii) Naloxone.~~	

4.	On behalf of [redacted], I would like to provide public comment on the proposed rules revisions, specifically for Chapter 8. The prescribing and dispensing of naloxone is a critical part of the public health response to the opioid overdose epidemic. We have identified one substantial barrier that could be improved by rules revisions, which is the requirement to report to the PDMP for naloxone, a non-controlled substance. Please consider the following change:
	- Remove the requirement that naloxone be reported through the PDMP.
	  - Currently, naloxone can only be dispensed in the Emergency Department as the automated dispensing cabinet in that area is the only one set up to report to the PDMP, making it difficult to efficiently distribute to patients across the healthcare system.
	  - Stigma related to obtaining naloxone has occurred because of providers accessing the PDMP information. Community members have shared stories about providers making assumptions about them when they have identified a naloxone prescription in the PDMP. Friends, family, and other bystanders can save lives so it is essential that we reduce stigma associated with obtaining and carrying naloxone.
	  - The PDMP reporting requirement was initiated to optimize reporting and data collection around naloxone use. However, the unanticipated result of this requirement has been limited distribution and availability of naloxone in our community.
	
	[redacted] recognizes the importance of partnerships in improving the health of individuals and the quality of life for our community, including preventing opioid overdoses. The evidence shows that when naloxone and overdose education are available, overdose deaths decrease. Please consider the changes above as we work together to expand naloxone access and help reduce the stigma of prescribing, dispensing, and carrying naloxone.
	
	Sincerely,
	[redacted]
		The Board agrees and moves amending Chapter 8 Section 5(b) as follows:
		
		(b)Dispensers shall report the information required pursuant to this Chapter for the following non-controlled substances:
		(i) Gabapentin;
		(ii) Cyclobenzaprine.~~;~~
		~~and~~
		~~(iii) Naloxone.~~	

5.	Dear Collogues at the Wyoming Board of Pharmacy, I am writing in regard to the recent rules revisions that were posted. [redacted] is overall pleased with the changes being proposed; however, we do have a few recommendations that we would like to bring to the Boards attention:	[1] The Board agrees and moves amending Chapter 8 Section 5(b) as follows:	

	1. This session, the Wyoming legislature passed and Governor Gordon signed SF0007 – Definition of opiate antagonist-amendment. This legislation amended the statutory definition of opiate antagonist in W.S. 35-4-902 to mean any device or medication approved by the United States food and drug administration for the treatment of an opiate-related overdose. An FDA advisory committee recently recommended that naloxone be available over the counter. Given these changes, naloxone would be the only opiate antagonist required to be reported into the WY PMP. Therefore, [redacted] believes the Board should amend WY CSA chapter 8 to no longer require naloxone to be reported into the WY PMP 2. During the Board's September 2022 meeting, the Board discussed updating the rules for delegates of providers that are registered to access the WY PMP. I believe that the Board had decided to remove the delegate limit. [redacted] believes this would be beneficial for several reasons; one of the most valuable reasons for the removal of the limit would be to increase the use of the WY PMP, which in turn would hopefully lead to better prescribing and dispensing practices. I appreciate the Boards consideration of these recommendations and look forward to the rules revisions being adopted. If [redacted] can be of any help, please feel free to reach out. Warmest Regards, [redacted]	(b)Dispensers shall report the information required pursuant to this Chapter for the following non-controlled substances: (i) Gabapentin; (ii) Cyclobenzaprine.~~;~~ ~~and~~ ~~(iii) Naloxone.~~ [2] The Board agrees and moves amending Chapter 8 Section 6 (b)(i) as follows: (b) Pharmacists and practitioners shall register as users with Wyoming PMP AWARxE to request patient profiles where a pharmacist/patient, practitioner/patient relationship exists. (i) Pharmacists or practitioners may appoint ~~up to two (2)~~ delegates to perform patient searches in Wyoming PMP AWARxE on their behalf.	

PRESCRIPTION DRUG MONITORING PROGRAM

CHAPTER 8

Section 1. Authority.

These regulations are promulgated as authorized by the Wyoming Controlled Substances Act; W.S. 35-7-1001 through -1101.

Section 2. Scope.

This Chapter applies to all Wyoming controlled substance registrants and dispensers licensed by the Board of Pharmacy

Section 3. Definitions.

(a) "Drug of Concern" means any non-controlled substance prescription medication that is required to be reported into the prescription tracking program by the Board of Pharmacy as authorized by W.S. §35-7-1060(b).

(b) "Inpatient" (for the purposes of this chapter) means:

(i) The patient is physically located in a hospital, long term care facility, or correctional facility; or

(ii) The practitioner or his agent is administering a controlled substance directly to the patient as part of a procedure, whether or not the patient is physically located in a facility.

Section 4. Registration Requirements.

(a) Practitioners shall register with the controlled substances prescription tracking program (Wyoming PMP AWARxE) if the practitioner is authorized to dispense any controlled substances in Schedules II through V.

(b) Practitioners shall register online at https://wyoming.pmpaware.net/; and

(c) Board staff shall approve the practitioner as a user after verifying the practitioner's registration.

(d) Each dispenser that dispenses a controlled substance listed in Schedule II, III, IV or V, or drug of concern to a person in this state who is not an inpatient shall register as a dispenser with the Wyoming PMP AWARxE program.

Section 5. Required Reporting.

(a) Dispensers shall transmit the following required information into the PMP Clearinghouse:

(i) Dispenser identification number;

(ii) Patient date of birth;

(iii) Patient gender;

(iv) Date prescription was dispensed;

(v) Prescription number;

(vi) Prescription is new or is a refill. If the prescription was a refill, the date of the original dispensing;

(vii) Quantity dispensed;

(viii) Date the prescription was issued by the prescriber;

(ix) Number of days supply dispensed;

(x) NDC code number for drug dispensed;

(xi) Prescriber identification number;

(xii) Patient last name;

(xiii) Patient first name;

(xiv) If patient is an animal, the animal's name, species and the owner's last name;

(xv) Patient street address;

(xvi) Patient zip code; and

(xvii) Method of third-party liability and/or payment.

(b) Dispensers shall report the information required pursuant to this Chapter for the following non-controlled substances:

(i) Gabapentin; and

(ii) Cyclobenzaprine.

(c) The dispenser shall ensure that, not later than the close of business on the business day immediately following the day the controlled substance, or drug of concern, was dispensed, the information required pursuant to this Chapter is reported into the PMP Clearinghouse.

(d) When a dispenser does not have any dispensations to report, the dispenser shall submit a "zero report" into the PMP Clearinghouse.

(e) Exemptions from reporting include certain inpatient health care settings.

(f) Each dispenser shall ensure that information reported to the PMP Clearinghouse is correct and shall submit corrections when necessary.

(g) Each dispenser shall reverse information for any prescription that was not dispensed.

Section 6. Solicited Patient Profiles.

(a) Occupational licensing boards in Wyoming that regulate practitioners who are authorized to dispense any controlled substances in Schedules II through V or other drugs of concern, may register with Wyoming PMP AWARxE to request licensee profiles from the Board as it relates to their investigation regarding their licensees' practice.

(b) Pharmacists and practitioners shall register as users with Wyoming PMP AWARxE to request patient profiles where a pharmacist/patient, practitioner/patient relationship exists.

(i) Pharmacists or practitioners may appoint delegates to perform patient searches in Wyoming PMP AWARxE on their behalf.

(ii) The pharmacist or practitioner shall be responsible for the actions of their appointed delegates; and

(iii) The pharmacist or practitioner shall terminate the delegate's access in Wyoming PMP AWARxE when the appointment has ended.

(iv) A pharmacist appointed delegate must be a pharmacy technician, pharmacy technician in training, or pharmacy intern, licensed by the Board, who is employed at the pharmacy where the pharmacist is employed.

(v) All practitioners, pharmacists, and delegates shall attest that inappropriate access or disclosure of this information is a violation of Wyoming Law and may result in disciplinary action and/or revocation of access privileges to Wyoming PMP AWARxE.

(vi) The Board staff shall discontinue access to any user whose license, DEA registration or WY Controlled Substance Registration has lapsed or been revoked or suspended.

(vii) The Board staff shall discontinue access to any user who fails to follow these regulations.

(c) Patients, or in the case of a minor, the minor's parent or guardian may request a copy of the patient's profile from the Board office provided:

(i) The requestor shall complete a notarized form provided by the Board; and

(ii) The notarized form may be faxed, emailed, or mailed to the Board office.

(d) Local, State, or Federal law enforcement may register with Wyoming PMP AWARxE to request information that is contained in the PMP as it relates to investigations regarding violations of the Wyoming Controlled Substances Act or the Federal Controlled Substances Act. Requests must contain:

(i) The purpose of the request, the date range requested, and the specific reasons for this request including investigation number, if applicable, must be included; and

(ii) A copy of the warrant or subpoena related to their investigation is uploaded into Wyoming PMP AWARxE as part of their request.

(e) A patient may authorize the release of their Wyoming PMP AWARxE profile to third party provided:

(i) The patient shall complete a notarized form provided by the Board; and

(ii) The notarized form may be faxed, emailed, or mailed to the Board office.

Section 7. Unsolicited Patient Profiles.

Board staff may generate patient profiles based on information showing use of controlled substances, within established parameters. Profiles generated will be emailed to each pharmacy and practitioner where the patient was seen. A letter of explanation will accompany each profile.

Section 8. Reports.

(a) Board staff shall maintain a register for solicited patient profile requests for five (5) years from the date of the request. The register shall include:

(i) Date request received;

(ii) Name of patient, patient's date of birth;

(iii) Name, title, business, and address of the requestor; and

(iv) Date profile was provided to the requestor.

(b) The Board shall maintain a register for five (5) years for any unsolicited patient profile generated by the Board. The register shall include:

(i) Date generated;

(ii) Criteria used for profile generation; and

(iii) The pharmacies and practitioners that the unsolicited report was provided too.

(c) The Board shall maintain the database records for five (5) years and then archive de-identified records for research purposes.

Section 9. Statistical Profiles.

The Board may generate statistical profiles upon request, provided no patient/practitioner/pharmacy specific information is included. The Board shall charge a fee of $500.00 per profile to any non-governmental agency.

PRESCRIPTION DRUG MONITORING PROGRAM

CHAPTER 8

Section 1. Authority.

~~(a)~~ These regulations are promulgated as authorized by the Wyoming Controlled Substances Act; W.S. 35-7-1001 through -1101.

~~**Section 2**. Purpose.~~

~~To describe procedures for the Prescription Drug Monitoring Program (WORx).~~

~~**Section 3**~~**Section 2**. Scope.

~~Applies~~ This Chapter applies to all Wyoming controlled substance registrants and dispensers licensed by the Board of Pharmacy

~~**Section 4**~~**Section 3**. Definitions.

~~(a) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:~~

~~(i) A practitioner (or by his authorized agent); or~~

~~(ii) The patient or research subject at the direction of the practitioner.~~

~~(b) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery;~~

~~(c) "Dispenser" means a practitioner who dispenses, or his authorized agent;~~

~~(d) "Inpatient" (for the purposes of this chapter) means:~~

~~(i) The patient is physically located in a hospital, long term care facility, or correctional facility; or~~

~~(ii) The practitioner or his agent is administering a controlled substance directly to the patient as part of a procedure, whether or not the patient is physically located in a facility.~~

(a) "Drug of Concern" means any non-controlled substance prescription medication that is required to be reported into the prescription tracking program by the Board of Pharmacy as authorized by W.S. §35-7-1060(b).

(b) "Inpatient" (for the purposes of this chapter) means:

(i) The patient is physically located in a hospital, long term care facility, or correctional facility; or

(ii) The practitioner or his agent is administering a controlled substance directly to the patient as part of a procedure, whether or not the patient is physically located in a facility.

~~(c) "Practitioner" means:~~

~~(i) A physician, dentist, veterinarian, podiatrist, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state; and~~

~~(ii) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state.~~

~~(f) WORx" means the Wyoming online controlled substance prescription database.~~

~~Section 5~~ Section 4. Registration Requirements.

(a) Practitioners shall ~~be registered in~~ register with the controlled substances prescription tracking program (Wyoming PMP AWARxE) if the practitioner is authorized to dispense any controlled substances in Schedules II through V.

(b) Practitioners shall register online at ~~worxpdmp.com~~ https://wyoming.pmpaware.net/; and

(c) Board staff shall ~~enroll~~ approve the practitioner as a user after verifying the practitioner's registration.

(d) Each dispenser that dispenses a controlled substance listed in Schedule II, III, IV or V, or drug of concern to a person in this state who is not an inpatient shall register as a dispenser with the Wyoming PMP AWARxE program.

~~Section 6~~ Section 5. ~~Transmission of information regarding dispensing of controlled substances to certain persons.~~ Required Reporting.

(a) ~~Each resident/nonresident retail pharmacy that dispenses a controlled substance listed in Schedule II, III, IV or V to a person in this state who is not an inpatient transmit to the Board or its agent the following required information:~~ Dispensers shall transmit the following required information into the PMP Clearinghouse:

(i) Dispenser identification number;

(ii) Patient date of birth;

(iii) Patient gender;

(iv) Date prescription was ~~filled~~ dispensed;

(v) Prescription number;

(vi) Prescription is new or is a refill. If the prescription was a refill, the date of the original dispensing;

(vii) Quantity dispensed;

(viii) Date the prescription was issued by the prescriber;

(ix) Number of days supply dispensed;

(x) NDC code number for drug dispensed;

(xi) Prescriber identification number;

(xii) Patient last name;

(xiii) Patient first name;

(xiv) If patient is an animal, the animal's name, species and the owner's last name;

(xv) Patient street address;

(xvi) Patient zip code; and

(xvii) Method of third-party liability and/or payment.

(b) Dispensers shall report the information required pursuant to this Chapter for the following non-controlled substances:

(i) Gabapentin; and

(ii) Cyclobenzaprine.

~~(b)~~(c) The ~~resident/nonresident retail pharmacy or practitioner~~ dispenser shall ensure that, not later than the close of business on the business day immediately following the day the controlled substance, or drug of concern, was dispensed, the information required pursuant to this Chapter is reported into the PMP Clearinghouse. ~~transmitted to the Board or its agent by one of the following methods:~~

~~(i) Computer modem that can transmit information at the rate of 2400 baud or more;~~

~~(ii) Computer disk;~~

~~(iii) Cassette containing magnetic tape, which is ¼ of an inch wide and is used to transmit information between computerized systems; or~~

~~(iv) Paper printout.~~

(d) When a dispenser does not have any dispensations to report, the dispenser shall submit a "zero report" into the PMP Clearinghouse.

~~(c)~~(e) Exemptions from reporting include certain inpatient health care settings.

(f) Each dispenser shall ensure that information reported to the PMP Clearinghouse is correct and shall submit corrections when necessary.

(g) Each dispenser shall reverse information for any prescription that was not dispensed.

~~Section 7~~ Section 6. Solicited Patient Profiles.

(a) Occupational licensing boards in Wyoming that regulate practitioners who are authorized to dispense any controlled substances in Schedules II through V or other drugs of concern, may register with Wyoming PMP AWARxE to request licensee profiles from the Board as it relates to their investigation regarding their licensees' practice. ~~provided the following are met:~~

~~(i) All requests shall be on a form provided by the Board and include the name and license number of the licensee;~~

~~(ii) The purpose of the request, the date range requested, and the specific reasons for this request;~~

~~(iii) The signature and mailing address of the authorized agent for the occupational licensing board;~~

~~(iv) The request shall be mailed, emailed or faxed to the Board's office;~~

~~(v) No licensee profile will be generated by the Board until the request is received. All profiles generated by the Board will be sent to the occupational licensing board and marked "confidential, to be opened by addressee only;" and~~

~~(vi) A lengthy profile may be converted to a spreadsheet and provided electronically to an occupational licensing board.~~

(b) Pharmacists and practitioners shall register as users with Wyoming PMP AWARxE to ~~may~~ request patient profiles where a pharmacist/patient, practitioner/patient relationship exists. ~~from the Board provided the following conditions are met for faxed paper requests:~~

(i) Pharmacists or practitioners may appoint delegates to perform patient searches in Wyoming PMP AWARxE on their behalf.

(ii) The pharmacist or practitioner shall be responsible for the actions of their appointed delegates; and

(iii) The pharmacist or practitioner shall terminate the delegate's access in Wyoming PMP AWARxE when the appointment has ended.

(iv) A pharmacist appointed delegate must be a pharmacy technician, pharmacy technician in training, or pharmacy intern, licensed by the Board, who is employed at the pharmacy where the pharmacist is employed.

(v) All practitioners, pharmacists, and delegates shall attest that inappropriate access or disclosure of this information is a violation of Wyoming Law and may result in disciplinary action and/or revocation of access privileges to Wyoming PMP AWARxE.

~~(i) All paper requests must be submitted on a form provided by the Board and must be mailed or faxed;~~

~~(ii) All paper requests must be signed with a manual or electronic signature by the pharmacist or practitioner requesting the information and include the business name/address of the pharmacist or practitioner;~~

~~(iii) All paper requests must include the DEA registration number for the pharmacy or practitioner;~~

~~(iv) All paper requests shall include the patient's name, date of birth and address;~~

~~(v) All paper requests shall include a statement indicating a pharmacist/patient, or practitioner/patient relationship exists; and~~

(vi) All profiles generated by the Board shall be faxed, emailed or mailed to the pharmacist or practitioner at their business address, and if mailed marked "confidential, to be opened by addressee only."

(c) Pharmacists, practitioners and their respective appointed delegates may request patient profiles from the Board provided the following conditions are met for electronic requests:

(i) The pharmacist or practitioner or their appointed delegate registers for access to the online system (WORx) using the online registration;

(ii) All practitioner or pharmacist registrations shall attest that a pharmacist/patient, practitioner/patient relationship exists;

(iii) All practitioner or pharmacist registrations shall attest that inappropriate access or disclosure of this information is a violation of Wyoming Law and may result in disciplinary action and/or revocation of database access privileges.

(iv) The Board staff verifies current licensure, current WY Controlled Substance Registration and DEA number of the pharmacy or practitioner;

(v) The Board staff activates the online access to enroll the practitioner/pharmacist;

(iv) The practitioner or pharmacist-in-charge (PIC) determines the competency of their appointed delegates before allowing registration in WORx;

(v) Practitioner appointed delegates shall be authorized agents of the practitioner:

(A) A delegate registered under one practitioner may perform searches on behalf of other practitioners;

(B) Each registered practitioner may appoint up to two (2) delegates;

(C) The practitioner shall be responsible for the actions of their appointed delegates; and

(D) The practitioner shall terminate the delegate's access in the WORx system when the appointment has ended.

(vi) A PIC may appoint up to two (2) delegates per employed pharmacist, who are licensed pharmacy technicians or licensed pharmacy interns employed at the pharmacy:

(A) A delegate registered under one PIC may perform searches on behalf of other pharmacists;

~~(B) If the PIC changes at the pharmacy, the Board shall be notified and delegates re-appointed in the same time frame as the controlled substance inventory is completed for a change in PIC;~~

~~(C) The PIC shall be responsible for the actions of their appointed delegates; and~~

~~(D) The PIC shall terminate the delegate's access in the WORx system when the appointment has ended.~~

~~(d)~~(vi) The Board staff shall discontinue access to any ~~pharmacist or practitioner or their appointed delegate~~ user whose license, DEA registration or WY Controlled Substance Registration has lapsed or been revoked or suspended.

~~(e)~~(vii) The Board staff shall discontinue access to any ~~pharmacist or practitioner or their appointed delegate~~ user who fails to follow these regulations.

~~(f)~~(c) Patients, ~~their authorized agent,~~ or in the case of a minor, the minor's parent or guardian may request a copy of the patient's profile from the Board office provided:

(i) ~~All requests shall be made in person at the Board office. The patient requesting the profile or the authorized agent of the patient or parents or guardians of minors requesting a profile must have proof of identification acceptable to Board staff; and~~ The requestor shall complete a notarized form provided by the Board; and

(ii) ~~Any person making a request for a profile shall complete a form provided by the Board. Any profile generated by Board staff will be available at the Board office the same day of the request.~~ The notarized form may be faxed, emailed, or mailed to the Board office.

~~(g) Other entities as authorized in W.S. § 35-7-1060 may request a copy of the patient's profile from the Board office provided the following are met:~~

~~(i) All requests must be submitted on a form provided by the Board and must be mailed or faxed to the Board office;~~

~~(ii) All requests must be signed by the requestor and include the business name and address;~~

~~(iii) The purpose of the request, the date range requested, and the specific reasons for this request including investigation number, if applicable, must be included; and~~

~~(iv) The requirements identified in W.S. § 35-7-1060 (c)(ii) or (iv) must be met before the patient's profile is provided to the requestor or a copy of the patient's signed consent~~

~~specifically stating permission for the requestor to access and review the profile must be provided by the requestor.~~

(d) Local, State, or Federal law enforcement may register with Wyoming PMP AWARxE to request information that is contained in the PMP as it relates to investigations regarding violations of the Wyoming Controlled Substances Act or the Federal Controlled Substances Act. Requests must contain:

(i) The purpose of the request, the date range requested, and the specific reasons for this request including investigation number, if applicable, must be included; and

(ii) A copy of the warrant or subpoena related to their investigation is uploaded into Wyoming PMP AWARxE as part of their request.

(e) A patient may authorize the release of their Wyoming PMP AWARxE profile to third party provided:

(i) The patient shall complete a notarized form provided by the Board; and

(ii) The notarized form may be faxed, emailed, or mailed to the Board office.

~~**Section 8**~~ **Section 7**. Unsolicited Patient Profiles.

Board staff may generate patient profiles based on information showing use of controlled substances, within established parameters. Profiles generated will be ~~mailed~~ emailed to each pharmacy and practitioner where the patient was seen. A letter of explanation will accompany each profile.

~~**Section 9**~~ **Section 8**. Reports.

(a) Board staff shall maintain a register for solicited patient profile requests for ~~two (2)~~ five (5) years from the date of the request. The register shall include:

(i) Date request received;

(ii) Name of patient, patient's date of birth ~~or the name of the practitioner and practitioner's DEA registration number~~;

(iii) Name, title, business, and address of the requestor; and

(iv) Date profile was provided to the requestor.

(b) The Board shall maintain a register for ~~two (2)~~ five (5) years for any unsolicited patient profile generated by the Board. The register shall include:

(i) Date generated;

(ii) Criteria used for profile generation; and

(iii) ~~Number of profiles/cover letters mailed~~ The pharmacies and practitioners that the unsolicited report was provided too.

(c) The Board shall maintain the database records for five (5) years and then archive de-identified records for research purposes.

~~Section 10~~Section 9. Statistical Profiles.

The Board may generate statistical profiles upon request, provided no patient/practitioner/pharmacy specific information is included. The Board shall charge a fee of ~~$25.00 per profile generated for any government agency and~~ $500.00 per profile ~~for all others~~ to any non-governmental agency.

~~**Section 11**. Reporting of Non-Controlled Prescription Drugs.~~

~~If formally requested by the Board, resident and nonresident retail pharmacies and practitioner dispensers shall ensure that, not later than the close of business on the business day immediately following the day the non-controlled substance was dispensed, the information required pursuant to this Chapter is transmitted to the Board or its agent. As of July 1, 2017, the Board requires the reporting of:~~

~~(a) Gabapentin;~~

~~(b) Cyclobenzaprine; and~~

~~(c) Naloxone.~~

Issuing and Dispensing Prescriptions for Controlled Substances

Chapter 10

Section 1. Authority.

These rules are promulgated as authorized by the Wyoming Controlled Substances Act; W.S. § 35-7-1001 through 35-7-1063.

Section 2. Definitions.

(a) "Electronic prescription" means the computer to computer transmission of prescription data that meets the federal requirements for electronically prescribed controlled substances (EPCS).

(b) "Security paper" means standardized paper used for issuing controlled substance prescriptions to help prevent tampering, counterfeiting, and fraudulent use of controlled substances.

Section 3. General Requirements for all Controlled Substance Prescriptions.

(a) A controlled substance prescription shall be issued only by a practitioner who is either registered or exempted from registration.

(b) A practitioner, other than a pharmacy, may directly dispense controlled substances to a patient.

(c) In order for a controlled substance prescription to be effective it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice. The responsibility for the proper prescribing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

(d) An individual practitioner may issue multiple controlled substance prescriptions authorizing the patient to receive a total of up to a ninety (90) day supply of a Schedule II controlled substance provided the following conditions are met:

(i) Each individual prescription shall be dated with the date it was issued;

(ii) The practitioner provides instructions on each prescription indicating the earliest date on which a pharmacy may dispense each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately); and

(iii) The practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

(iv) Practitioners shall not issue multiple prescriptions to circumvent the seven (7) day prescribing limits outlined in W.S. 35-7-1030(e).

(e) Practitioners shall not issue controlled substance prescriptions to an individual practitioner for the purpose of general dispensing to patients.

(f) All controlled substance prescriptions shall contain the following:

(i) The patient's full name and address;

(ii) Name and strength of the drug;

(iii) Quantity to be dispensed;

(iv) Directions for using the drug;

(v) Date issued by the practitioner; and

(vi) The practitioner's full name, address, telephone number, and DEA registration.

Section 4. Issuing Electronic Controlled Substance Prescriptions.

(a) The practitioner's electronic prescription system and the receiving pharmacy's dispensing system shall comply with federal law and regulation for electronic prescriptions of controlled substances.

(b) Practitioners and practitioner's agents shall transmit EPCS to the pharmacy of the patient's choice.

Section 5. Exemptions to Electronic Prescribing Requirement.

(a) A practitioner may authorize a verbal controlled substance prescription in the case of an emergency situation. Emergency situations are those situations in which the prescribing practitioner determines:

(i) That immediate administration of the controlled substance is necessary for the proper treatment of the patient;

(ii) No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance; and

(iii) It is not reasonably possible for the prescribing practitioner to provide an electronic prescription to be transmitted to the pharmacy prior to dispensing.

(b) In the case of an emergency situation, a pharmacist may directly dispense a controlled substance upon receiving verbal authorization from a practitioner, provided that:

(i) The quantity prescribed and dispensed shall be limited to the amount necessary to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a valid controlled substance prescription from the practitioner);

(ii) The emergency verbal prescription shall be immediately reduced to writing by the pharmacist and shall contain all of the information required of a valid prescription;

(iii) If the practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the verbal authorization came from a registered practitioner; and

(iv) The practitioner shall cause a valid controlled substance prescription for the emergency quantity prescribed to be transmitted to the dispensing pharmacy. This valid controlled substance prescription shall include "Authorization for Emergency Dispensing" and the date of the verbal order. Upon receipt, the dispensing pharmacist shall attach this prescription to the verbal emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the DEA if the practitioner fails to deliver the electronic prescription as required by federal regulation.

(c) A controlled substance prescription may be issued on security paper or faxed to a pharmacy when

(i) The patient resides in a nursing home, long-term care facility, correctional facility, or jail;

(ii) The patient is terminally ill. The prescription shall have written on its face "terminally ill," "hospice," or "palliative care;"

(iii) The prescription is to be filled at a pharmacy outside of Wyoming or at a pharmacy within federal jurisdiction. The practitioner shall write on the face of the prescription "Not to be dispensed in Wyoming" or indicate that the prescription shall be dispensed at a pharmacy within a federal jurisdiction

(iv) The prescription is issued by a licensed veterinarian;

(v) The prescription is issued by a practitioner working at a federal facility;

(vi) The prescription is for a compounded preparation containing two or more components; or

(vii) The prescription is for a Schedule II controlled substance that is to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion.

(viii) The practitioner's electronic prescribing system is not functioning. The practitioner shall not prescribe for more than a thirty (30) day supply and shall write on the face of the prescription "E-Prescribing System Not Functioning."

Section 6. Additional Requirements for Non-Electronic Prescriptions for Controlled Substances.

(a) All non-electronic controlled substance prescriptions shall meet the following requirements;

(i) The controlled substance prescription shall be issued on security paper. Any controlled substance prescription issued by a Wyoming practitioner that is on non-security paper shall not be dispensed by a pharmacist.

(ii) All non-electronic controlled substance prescriptions issued by a practitioner shall be wet signed.

(iii) All non-electronic controlled substance prescriptions shall be dated and signed with the date they are issued to the patient.

(b) Non-electronic controlled substance prescriptions shall not contain stickers.

(c) Non-electronic controlled substance prescriptions shall not be written in pencil.

Section 7. Dispensing Controlled Substance Prescriptions.

(a) The pharmacist or employee under supervision shall verify the identity of the person who presents a non-electronic controlled substance prescription or receives any controlled substance prescription.

(i) Identification may be done by visual recognition.

(ii) Identification may be verified by state or federally issued identification.

(iii) The pharmacist or employee shall record the individual's name, identification, and identification number.

(iv) The recorded information shall be readily retrievable.

(b) If a controlled substance prescription is mailed to a patient, the pharmacist or employee shall record the name, address, and date the prescription was mailed. This information shall be readily retrievable.

(c) No controlled substance prescription shall be valid more than six (6) months after the date it was issued by the practitioner.

(d) The pharmacist, after consultation/approval of the prescribing practitioner, may change or add the following on a controlled substance prescription:

(i) Drug strength;

(ii) Drug quantity;

(iii) Directions for use;

(iv) Dosage form;

(v) Date to be dispensed;

(vi) The patient's address with proper verification without consulting the practitioner.

(vii) The practitioner's DEA registration, address, or telephone number after verifying the information from another reliable source.

(e) A pharmacist shall not change the following on a controlled substance prescription:

(i) Patient's name;

(ii) Controlled substance prescribed;

(iii) Date issued; or

(iv) The prescribing practitioner.

(f) A pharmacist shall document any change or addition made to a controlled substance prescription. The documentation shall include the date, name of person consulted, and initials of the pharmacist making the change.

(i) Pharmacists may make computer generated modifications to the controlled substance prescription.

(ii) Any changes or additions made by the pharmacist may appear on the front or back of the non-electronic controlled substance prescription.

(g) Pharmacies shall label dispensed controlled substance prescriptions according to the requirements in the Wyoming Pharmacy Act Rules Chapter 2.

(h) The pharmacist shall make a reasonable effort to determine that controlled substance prescriptions from out of state practitioners came from a registered practitioner before dispensing the controlled substance.

Section 8. Refilling Prescriptions for Controlled Substances.

(a) A Schedule II controlled substance prescription shall not be refilled.

(b) No Schedule III, IV, or V-controlled substance shall have more than five (5) refills authorized.

(c) The pharmacy shall document each refill of Schedule III, IV, and V-controlled substance prescriptions. The documentation shall be readily retrievable and shall include the date, quantity dispensed, and the name of the dispensing pharmacist.

Section 9. Partial Filling of Controlled Substances.

(a) A Schedule II controlled substance prescription may be partially filled if:

(i) The patient or practitioner requests a partial fill; or

(ii) The pharmacist is unable to supply the full quantity prescribed; and

(iii) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

(iv) The remaining portions of the partially filled Schedule II controlled substance prescription is dispensed no later than thirty (30) days, or sixty (60) days for terminally ill or long term care facility patients, after the date on which the prescription is issued.

(b) For each partial filling of a Schedule II controlled substance the dispensing pharmacist shall record:

(i) The date of the partial filling;

(ii) Quantity dispensed;

(iii) Remaining quantity authorized to be dispensed; and

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(c) Schedule III, IV, and V controlled substance prescriptions may be partially filled, provided that:

(i) Each partial filling is recorded in the same manner as a refilled Schedule III, IV, or V controlled substance prescription;

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(d) Pharmacists and practitioners shall not partially fill opioids or combinations of opioids to circumvent the seven (7) day prescribing limits outlined in W.S. 35-7-1030(e).

Section 10. Transferring Controlled Substance Prescription Orders Between Pharmacies.

(a) The transfer of a controlled substance prescription shall be communicated directly between two licensed pharmacists;

(b) The information required to be communicated and recorded for the transfer of non-controlled substance prescriptions between pharmacies in Chapter 2 of the Wyoming Pharmacy Act Rules shall also be communicated and recorded for the transfer of controlled substance prescriptions with the addition that

(i) The DEA registration number of the transferring pharmacy shall be provided to and recorded by the receiving pharmacist and

(ii) The DEA registration number of the receiving pharmacy shall be provided to and recorded by the transferring pharmacist.

(c) A Schedule II controlled substance prescription shall not be transferred, with the exception that an unfilled original EPCS may be transferred from one pharmacy to another pharmacy one time.

(d) Unfilled non-electronic Schedule III, IV, and V controlled substance prescriptions shall not be transferred.

(e) A Schedule III, IV, or V controlled substance prescription may be transferred only one time. Pharmacies sharing a real-time, online database may transfer up to the maximum refills permitted by law and the practitioner's authorization.

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Chapter 10

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