Notice of Intent to Adopt Rules

A copy of the proposed rules may be obtained at http://rules.wyo.gov

Revised May 2018

1. General Information

a. Agency/Board Name* Wyoming 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 Lisa V. Hunt	f. Agency Liaison Telephone Number (307) 634-9636	
g. Agency Liaison Email Address lisa.hunt@wyo.gov		
h. Date of Public Notice 09/21/2018	i. Comment Period End Date 11/05/2018 at 05:00 pm	
j. Public Comment URL or Email Address: bop@wyo.gov		
k. Program Commissioner of Drugs and Substance Control		

* ☐ *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 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 rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?

☐ **No.** ☒ **Yes.** Please provide the Chapter Numbers and Years Enacted (eg: 2015 Session Laws Chapter 154): 2018 Session Laws Chapter 0096

3. Rule Type and Information

a. Provide the Chapter Number, Title, and Proposed Action for Each Chapter.

Please use the Additional Rule Information form for more than 10 chapters, and attach it to this certification.

Chapter Number:	Chapter Name:	
6	Issuing Filing and Filling of Prescriptions	☐ New ☒ Amended ☐ Repealed
7	Administrative Inspections	☐ New ☒ Amended ☐ Repealed
8	Prescription Drug Monitoring Program	☒ New ☒ Amended ☐ Repealed
		☐ New ☐ Amended ☐ Repealed
		☐ New ☐ Amended ☐ Repealed
		☐ New ☐ Amended ☐ Repealed
		☐ New ☐ Amended ☐ Repealed
		☐ New ☐ Amended ☐ Repealed
		☐ New ☐ Amended ☐ Repealed

4. Public Comments and Hearing Information

a. A public hearing on the proposed rules has been scheduled. ☒ **No.** ☐ **Yes. Please complete the boxes below.**

Date:	Time:	City:	Location:

b. What is the manner in which interested persons may present their views on the rulemaking action?

☒ By submitting written comments to the Agency at the physical and/or email address listed in Section 1 above.

☐ At the following URL: _____

A public hearing will be held if requested by 25 persons, a government subdivision, or by an association having not less than 25 members. Requests for a public hearing may be submitted:

☒ To the Agency at the physical and/or email address listed in Section 1 above.

☐ At the following URL: _____

c. Any person may urge the Agency not to adopt the rules and request the Agency to state its reasons for overruling the consideration urged against adoption. Requests for an agency response must be made prior to, or within thirty (30) days after adoption, of the rule, addressed to the Agency and Agency Liaison listed in Section 1 above.

5. Federal Law Requirements

a. These rules are created/amended/repealed to comply with federal law or regulatory requirements. ☐ **No.** ☒ **Yes. Please complete the boxes below.**

Applicable Federal Law or Regulation Citation: Title 21 CFR Food and Drugs Part 1300 to End

Indicate one (1):

☒ The proposed rules meet, but do not exceed, minimum federal requirements.

☐ The proposed rules exceed minimum federal requirements.

Any person wishing to object to the accuracy of any information provided by the Agency under this item should submit their objections prior to final adoption to:

☒ To the Agency at the physical and/or email address listed in Section 1 above.

☐ At the following URL: _____

6. State Statutory Requirements

a. Indicate one (1):

☒ The proposed rule change *MEETS* minimum substantive statutory requirements.

☐ The proposed rule change *EXCEEDS* minimum substantive statutory requirements. Please attach a statement explaining the reason that the rules exceed the requirements.

b. Indicate one (1):

☒ The Agency has complied with the requirements of W.S. 9-5-304. A copy of the assessment used to evaluate the proposed rules may be obtained:

☒ By contacting the Agency at the physical and/or email address listed in Section 1 above.

☐ At the following URL: _____

☐ Not Applicable.

7. Additional APA Provisions

a. Complete all that apply in regards to uniform rules:

☒ These rules are not impacted by the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j).

☐ The following chapters do not differ from the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j):

_____

(Provide chapter numbers)

☐ These chapters differ from the uniform rules identified in the Administrative Procedure Act, W.S. 16-3-103(j) (see Statement of Principal Reasons).

_____

(Provide chapter numbers)

b. Checklist

☒ The Statement of Principal Reasons is attached to this Notice 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.

☐ If applicable: In consultation with the Attorney General's Office, the Agency's Attorney General representative concurs that strike and underscore is not required as the proposed amendments are pervasive (Chapter 3, *Types of Rules Filings*, Section 1, Proposed Rules, of the Rules on Rules).

8. Authorization

a. I certify that the foregoing information is correct.

Printed Name of Authorized Individual	Lisa V. Hunt
Title of Authorized Individual	Executive Director
Date of Authorization	September 20, 2018

BOARD OF PHARMACY WYOMING

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Matthew R. Martineau, RPh, Inspector/Compliance Officer

Governor: Matthew H. Mead

WYOMING CONTROLLED SUBSTANCES ACT RULES AND REGULATIONS

STATEMENT OF PRINCIPAL REASONS FOR REVISIONS

September 2018

Revisions are proposed in Chapters 6, 7, and 8 of the Wyoming Controlled Substances Act Rules and Regulations and include reduction of the number, the length, and the complexity of rules and regulations whenever possible. These chapters have also been revised to correct spelling, grammar, and format including numbering and pagination. As required by WYO. STAT. ANN. § 16-3-103(a)(i)(G), these rules meet minimum substantive state statutory requirements.

Some of the rules are proposed based on the 2018 Session of the Wyoming Legislature, specifically Enrolled Act No. 46, Senate, 2018.

Chapter 6: Issuing, Filing and Filling of Prescriptions

- Clarifying partial filling of prescriptions for Schedule II controlled substances.

Chapter 7: Administrative Inspections

- Updated incorporation by reference to Title 21 Chapter II Drug Enforcement Administration, Department of Justice Part § 1316 which describes administrative inspections.

Chapter 8: Prescription Drug Monitoring Program

- Clarified definitions.
- Adding the requirement for practitioners who are authorized to dispense any controlled substances in Schedules II through V to register in the Wyoming Online Prescription Database (WORx).
- Describing the requirement for reporting by practitioners who dispense prescriptions of controlled substances to the Wyoming program within twenty-four hours.
- Requiring the board to maintain the database records for five years and then archive de-identified records for research purposes.

ISSUING, FILING AND FILLING OF PRESCRIPTIONS

CHAPTER 6

Section 1. Authority

These rules are promulgated by the Wyoming Controlled Substances Act; W.S. § 35-7-1001 through 35-7-1060.

Section 2. Purpose.

To describe requirements for controlled substance prescriptions.

Section 3. Scope.

Applies to all registrants.

Section 4. Definitions.

(a) "Audit Trail" means a record showing who has accessed an information technology application and what operations the user performed during a given period.

(b) "Authentication" means verifying the identity of the user as a prerequisite to allow access to the information application.

(c) "Digital signature" means an electronic identifier that:

(i) Is intended by the party using it to have the same force and effect as a manual signature;

(ii) Is unique to the authorized signer;

(iii) Is capable of verification;

(iv) Is under the sole control of the authorized signer; and

(v) Is linked to the prescription in such a manner that, if the prescription information is changed, the signature is invalidated.

(d) "Drug order" means a lawful order from a practitioner for a drug for a specific patient, where a valid patient/practitioner relationship exists, that is communicated to a pharmacist in a licensed pharmacy.

(e) "Electronic prescription" means a prescription that is generated on an electronic application and transmitted as an electronic data file.

(f) “Electronic signature” means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person’s approval of the information contained in the message.

(g) “Electronic transmission” means transmission of the digital representation of information from one computer or other similar electronic device to another computer, which is authenticated by a digital signature.

(h) “Paper prescription” means a prescription created on approved security paper that includes a manual signature.

(i) “Readily retrievable” means that certain records are kept in such a manner that they can be separated out from all other records and produced for review within forty-eight (48) hours.

(j) “Registrant” means any person or entity licensed to prescribe or dispense controlled substances in the State.

(k) “Security” or “secure system” means a system which maintains the confidentiality and integrity of patient records being transmitted electronically.

Section 5. Persons Entitled to Issue Prescriptions.

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

Section 6. Purpose of Issue of Prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

Section 7. Manner of Issuance of Written, Typed or Computer Generated Prescriptions.

(a) All controlled substance prescriptions written by a Wyoming practitioner shall be issued on security paper, unless exempted under this Chapter for electronic transmission. Any controlled substance prescription written by a Wyoming practitioner issued on non-security paper may not be dispensed by a pharmacist.

(b) Any written, typed or computer generated prescription issued by a Wyoming practitioner for a Schedule II-V controlled substance except those issued as a medication order for administration in a long-term care facility or institutional facility shall meet the following requirements:

(i) Be printed on security paper, which includes the following features:

(A) If scanned or copied, “void” is displayed prominently throughout the front side of the document;

(B) Front side has erasure protection on green or blue background;

(C) Clear instructions printed on the paper indicating the front and back sides;

(D) Security warning list on the front or back;

(E) Quantity check-off boxes plus numeric forms of quantity values or alpha and numeric forms of quantity value (e.g. 20 and twenty); and

(F) Refill indicator (circle or check number of refills or “NR”) plus numeric form of refill values or alpha and numeric form of refill values.

(ii) All supplies of security paper shall be approved by the Board. Approval shall be based on the suppliers’ product meeting the requirements of this chapter. The Board shall make available a listing of all approved suppliers, which is updated at least annually.

(iii) All Board approved suppliers of security paper shall provide the Board written assurance that they will distribute prescription pads or paper only to practitioners duly authorized to prescribe controlled substances in Wyoming.

(c) All controlled substance paper prescriptions written by a Wyoming practitioner shall be manually signed in the same manner as the practitioner would sign a check or legal document. The use of electronic or digital signatures or signature stamps is not allowed, unless electronic prescriptions are used according to his chapter.

(d) Prescriptions may be prepared for dating and signature of the practitioner by an authorized agent of the practitioner and the use of preprinted prescriptions is allowed. Under no circumstances may stickers be utilized for information relating to drug, strength, quantity or directions.

(e) Prescriptions shall be dated as of, and signed on, the day when issued and shall bear the patient’s full name and address and the full name, address, telephone number and DEA registration number of the issuing practitioner. No postdating of controlled substance prescriptions is allowed.

(f) Prescriptions shall be written in ink, typed or electronically generated.

(g) The prescribing practitioner and dispensing pharmacist share the responsibility to assure compliance with this section.

(h) A refill request for a Schedule III-V controlled substance generated and faxed or requested electronically by the pharmacy to a practitioner for refill authorization need not be printed on security paper.

(i) The information sent by the practitioner to the pharmacy shall indicate who authorized the refill.

(j) A Schedule III-V controlled substance prescription faxed by the practitioner to the pharmacy need not be printed on security paper.

(k) An intern, resident, or foreign physician exempted from registration under Chapter 3 of these rules shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in Chapter 3 of these rules, in lieu of the registration number of the practitioner required by this section. Each prescription shall have the name of the intern, resident, or foreign physician stamped or printed on it, as well as the signature of the physician.

(l) An official exempted from registration under Chapter 3 of these rules shall include on all prescriptions issued by him, his branch of service or agency (e.g. “U.S. Army” or “Public Health Service”) and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number of a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.

Section 8. Persons Entitled to Fill Prescriptions.

A prescription for a controlled substance may only be filled by a pharmacist or intern or pharmacy technician or technician-in-training under direct supervision by a pharmacist, acting in the usual course of his/her professional practice or by a registered practitioner.

Section 9. Identification of a Patient.

(a) The pharmacist or employee under supervision must verify the identity of the person presenting a controlled substance prescription to the pharmacy for dispensing. This may be done by visual recognition. If identity is not established by visual recognition, a driver’s license or similar photo identification form is acceptable documentation. The following information shall be recorded on the paper prescription, if identification is utilized: name, type of identification, and identification number.

(b) The name of the person receiving the dispensed drug is to be recorded on the prescription document, patient profile, or signature log, if an agent and not the patient receives the drug.

(c) This Section shall not apply to pharmacies that mail prescriptions to their patients. A note shall be entered on the prescription or patient's profile with the name and address of where the medication was mailed. Additionally, the date of such mailing shall be entered.

Section 10. Dispensing of Narcotic Drugs for Maintenance Purposes.

The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs in the course of conducting a federally authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his professional practice or research."

Section 11. Prescription Formats.

(a) A pharmacist may dispense any prescription drug as follows:

(i) A written prescription signed by a practitioner or their agent;

(ii) A prescription transmitted by the practitioner or their agent to the pharmacy by electronic means; or

(iii) A verbal prescription made by an individual practitioner or their agent and promptly reduced to writing.

Section 12. Electronic Prescriptions.

(a) The practitioner may issue a prescription for a Schedule II, III, IV or V controlled substance electronically if an electronic prescription application is used that has been certified by a third party auditor to ensure that the electronic prescription application records, stores, and transmits the prescription accurately and consistently and that individual practitioner has obtained a two-factor authentication credential for signing.

(b) The electronic prescription application must transmit the electronic prescription as soon as possible after signature by the practitioner and the contents of the prescription must not be altered during transmission between the practitioner and pharmacy.

(c) The pharmacy receiving the electronic prescription must determine that third-party certification has found that the pharmacy application accurately and consistently imports, stores and displays the information required for the prescription including the number of refills and the practitioner's digital signature.

(d) An electronic prescription shall only be transmitted to the pharmacy of the patient's choice.

(e) The pharmacist is responsible for assuring the validity of the electronically transmitted prescription.

(f) A pharmacist or pharmacy shall not enter into any agreement to provide or receive a computer modem, personal digital assistant, facsimile machine, or any other electronic device which would adversely affect a patient's freedom to select the pharmacy of the patient's choice.

(g) A pharmacist or pharmacy shall not provide a computer or computer modem, personal digital assistant, facsimile machine or any other electronic device to a prescriber or health care facility for the purpose of providing an incentive to refer a patient to a particular pharmacy.

Section 13. Requirement of Prescription for Schedule II Substances.

(a) A pharmacist may dispense a controlled substance listed in Schedule II, only pursuant to a written or electronic prescription signed by the practitioner, except as provided in this section.

(b) A practitioner may administer or directly dispense a controlled substance listed in Schedule II without a prescription if it is dispensed in the course of his professional practice.

(c) In the case of an emergency situation, as defined in this section, a pharmacist may directly dispense a controlled substance listed in Schedule II upon receiving verbal authorization of 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 written or electronic prescription signed by the practitioner);

(ii) The emergency verbal prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in this chapter except for the signature of the practitioner;

(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) Within seven (7) calendar days after authorizing an emergency verbal prescription, the practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of this chapter, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the verbal order. The written prescription may be

delivered to the pharmacist in person or by mail. If delivered by mail, it must be postmarked within the seven (7) day period. 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 a written prescription

(d) A prescription for a Schedule II controlled substance shall be valid up to six (6) months from the date issued by the practitioner.

(e) A pharmacist shall cancel all written Schedule II controlled substance prescriptions when dispensed by dating and signing the face of the paper prescription. All electronic Schedule II controlled substance prescriptions shall be cancelled once dispensed.

(f) Information that can be changed on a Schedule II prescription shall meet the following requirements:

(i) After consultation/approval of the prescribing practitioner, the pharmacist is permitted to change the following:

(A) Drug strength;

(B) Drug quantity;

(C) Directions for use; or

(D) Dosage form.

(ii) The pharmacist is permitted to add or change the patient's address with proper verification without consulting the practitioner.

(iii) The practitioner's DEA registration number may be added to a prescription drug order after consulting the practitioner or verifying the number from another reliable source.

(iv) Required information may appear on the front or back of the paper prescription drug order. Computer generated modifications to the prescription drug order are allowed.

(v) Any change made by the pharmacist shall be documented and shall include the date, name of person consulted, and initials of the pharmacist.

(vi) A pharmacist shall not change the patient's name, controlled substance prescribed (except for generic substitution permitted by state law), date issued, or the prescriber's signature.

(g) For the purposes of authorizing a verbal prescription of a controlled substance listed in Schedule II, the term "emergency situation" means those situations in which the prescribing practitioner determines:

(i) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user;

(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 a written or electronic prescription to be presented to the person dispensing the substance prior to dispensing.

(h) A Schedule II controlled substance prescription may be faxed if it meets the criteria as specified in this chapter and Wyoming Pharmacy Act, Chapter 2, General Practice of Pharmacy Regulations.

Section 14. Refilling Prescriptions – Schedule II.

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

Section 15. Issuance of Multiple Prescriptions – Schedule II.

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

(a) Each separate prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(b) Each individual prescription is dated with the date it was prescribed and contains all other information required by this Chapter;

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

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

Section 16. Partial Filling of a Prescription – Schedule II.

(a) A prescription for a controlled substance in schedule II may be partially filled if:

(i) The partial fill is requested by the patient or the practitioner;

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

(iii) Remaining portions of a partially filled prescription shall be filled not later than 30 days after the date on which the prescription is written.

(b) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written, electronic or emergency verbal prescription and he makes a notation of the quantity supplied on the face of the paper prescription, and a written record of the emergency verbal prescription. The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling. If the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall notify the practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

(c) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities including individual dosage units.

(i) If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription.

(ii) The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient."

(iii) For each partial filling, the dispensing pharmacist shall record on an appropriate record, uniformly maintained and readily retrievable:

(A) The date of the partial filling;

(B) Quantity dispensed;

(C) Remaining quantity authorized to be dispensed; and

(D) Identification of the dispensing pharmacist.

(iv) The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed.

(v) Schedule II prescriptions dispensed in partial fillings shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuation of the medication.

(d) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system

Section 17. Labeling of Substances – Schedule II.

The pharmacist filling a written, electronic, or emergency verbal prescription for a controlled substance listed in Schedule II shall affix to the package a label showing the date of the filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

Section 18. Filling of Prescription – Schedule II.

All written or electronic prescriptions and written records of emergency verbal prescription shall be kept in accordance with requirements of Chapter 4 of these rules.

Section 19. Requirement of Prescription for Schedule III and IV Substances.

(a) A pharmacist may dispense a controlled substance listed in Schedule III or IV, only pursuant to either a written or electronic prescription signed by a prescribing practitioner or a verbal prescription made by a prescribing practitioner and promptly reduced to writing or electronic record. The prescription may be faxed. All Schedule III or IV prescriptions must contain the information required in this chapter.

(b) A practitioner may administer or dispense a controlled substance listed in Schedules III or IV in the course of his professional practice without a prescription.

(c) An institutional practitioner or his authorized agent may administer or dispense directly (but not prescribe) controlled substances listed in Schedules III or IV pursuant to a paper prescription signed by a prescribing practitioner or his authorized agent, or pursuant to a verbal prescription made by a prescribing practitioner and promptly reduced to writing by the pharmacist (containing all information required in this Chapter, except for the signature of the prescribing practitioner), or pursuant to an order for medication made by a practitioner or his authorized agent which is dispensed for immediate administration to the intended ultimate user.

Section 20. Refilling of Prescription – Schedules III and IV.

(a) No prescription for a controlled substance listed in Schedules III or IV shall be filled or refilled more than six (6) months after the date on which such prescription was issued.

(b) No prescription authorized to be refilled may be refilled more than five (5) times.

(c) Each refilling of a prescription shall be documented on a readily retrievable record, which indicates the date and name of the dispensing pharmacist and is initialed and dated by the pharmacist. The amount dispensed shall be stated on the record.

(d) Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription.

Section 21. Partial Filling of Prescriptions – Schedules III and IV.

The partial filling of a prescription for a controlled substance listed in Schedules III or IV is permissible, provided that:

(a) Each partial filling is recorded in the same manner as a refilling;

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

(c) No dispensing occurs after six (6) months after the date on which the prescription was issued.

Section 22. Labeling of Substances – Schedules III and IV.

The pharmacist filling a prescription for a controlled substance listed in Schedules III or IV shall affix to the package a label showing the pharmacy name and address, the serial number and date of the filling, the name of the patient, the name of the practitioner issuing the prescription, directions for use, and cautionary statements, if any, as required by law.

Section 23. Filing Prescriptions – Schedules III and IV.

All prescription records for controlled substances listed in Schedules III and IV shall be kept in accordance with Chapter 4 of these rules.

Section 24. Requirements of Prescription for Schedule V Substances.

(a) A pharmacist may dispense a controlled substance listed in Schedule V pursuant to a prescription as required for controlled substances listed in Schedules III and IV in this chapter. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing practitioner on the prescription; if no authorization is given, the prescription shall not be filled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with this chapter and file the prescription in accordance with this chapter.

(b) A practitioner may administer or dispense a controlled substance listed in Schedule V in the course of his professional practice without a prescription.

ADMINISTRATIVE INSPECTIONS

CHAPTER 7

Section 1. Authority.

These rules are pursuant to Title 21 Code of Federal Regulations and by the Wyoming Controlled Substances Act W.S. § 35-7-1001 through -1101.

Section 2. Scope.

Applies to all registrants.

Section 3. Inspections.

(a) In carrying out their functions under the Act, the Board, and the Commissioner of Drugs and Substances Control and their duly authorized agents are authorized in accordance with W.S. § 35-7-1024 to enter controlled premises and conduct administrative inspections thereof.

(b) Inspections shall be done in accordance with Title 21 Code of Federal Regulations process:

(c) Incorporation by Reference:

(i) Title 21 Chapter II Drug Enforcement Administration, Department of Justice, Part § 1316.01 to 1316.13 as of July 17, 2015.

(ii) The incorporated rule does not include any later amendments or editions;

(iii) The incorporated rule is maintained at the Wyoming State Board of Pharmacy, 1712 Carey Avenue, Suite 200, Cheyenne, WY 82002 and is available for public inspection and copying at cost at the same location.

(iv) The incorporated rule is maintained at https://www.deadiversion.usdoj.gov/21cfr/cfr/2116cfrt.htm.

Section 4. Notice of Inspection.

The notice of inspection form shall contain:

(a) The name and title of the owner, operator, or agent in charge of the controlled premises;

(b) The controlled premises name;

(c) The address of the controlled premises to be inspected;

(d) The date and time of the inspection;

(e) A statement that a notice of inspection is given pursuant to W.S. § 35-7-1024;

(f) A reproduction of the pertinent parts of W.S. § 35-7-1024; and

(g) The signature of the authorized agent.

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. Scope.

Applies to all registrants.

Section 4. 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.

(e) "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. Registration Requirements.

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

(b) Practitioners shall register online at worxpdmp.com; and

(c) Board staff shall enroll the practitioner after verifying the registration.

Section 6. Transmission of information regarding dispensing of controlled substances to certain persons.

(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 shall transmit to the Board or its agent the following required information:

(i) Dispenser identification number;

(ii) Patient date of birth;

(iii) Patient gender;

(iv) Date prescription was filled;

(v) Prescription number;

(vi) Prescription is new or is a refill;

(vii) Quantity dispensed;

(viii) Date prescription issued by 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, name and species;

(xv) Patient street address;

(xvi) Patient zip code; and

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

(b) The resident/nonresident retail pharmacy or practitioner dispenser shall ensure that, not later than close of business on the business day immediately following the day the controlled substance was dispensed, the information required pursuant to this Chapter is 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.

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

Section 7. Solicited Patient Profiles.

(a) Occupational licensing boards may request licensee profiles from the Board 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 may request patient profiles from the Board provided the following conditions are met for faxed paper requests:

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

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

(f) 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

(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.

(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.

Section 8. 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 to each pharmacy and practitioner where the patient was seen. A letter of explanation will accompany each profile.

Section 9. Reports.

(a) Board staff shall maintain a register for solicited patient profile requests for two (2) 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) 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.

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

Section 8. 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.

Section 9. 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, FILING AND FILLING OF PRESCRIPTIONS

CHAPTER 6

Section 1. Authority

These rules are promulgated by the Wyoming Controlled Substances Act; W.S. § 35-7-1001 through 35-7-1060.

Section 2. Purpose.

To describe requirements for controlled substance prescriptions.

Section 3. Scope.

Applies to all registrants.

Section 4. Definitions.

(a) "Audit Trail" means a record showing who has accessed an information technology application and what operations the user performed during a given period.

(b) "Authentication" means verifying the identity of the user as a prerequisite to allow access to the information application.

(c) "Digital signature" means an electronic identifier that:

(i) Is intended by the party using it to have the same force and effect as a manual signature;

(ii) Is unique to the authorized signer;

(iii) Is capable of verification;

(iv) Is under the sole control of the authorized signer; and

(v) Is linked to the prescription in such a manner that, if the prescription information is changed, the signature is invalidated.

(d) "Drug order" means a lawful order from a practitioner for a drug for a specific patient, where a valid patient/practitioner relationship exists, that is communicated to a pharmacist in a licensed pharmacy.

(e) "Electronic prescription" means a prescription that is generated on an electronic application and transmitted as an electronic data file.

(f) “Electronic signature” means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person’s approval of the information contained in the message.

(g) “Electronic transmission” means transmission of the digital representation of information from one computer or other similar electronic device to another computer, which is authenticated by a digital signature.

(h) “Paper prescription” means a prescription created on approved security paper that includes a manual signature.

(i) “Readily retrievable” means that certain records are kept in such a manner that they can be separated out from all other records and produced for review within forty-eight (48) hours.

(j) “Registrant” means any person or entity licensed to prescribe or dispense controlled substances in the State.

(k) “Security” or “secure system” means a system which maintains the confidentiality and integrity of patient records being transmitted electronically.

Section 5. Persons Entitled to Issue Prescriptions.

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

Section 6. Purpose of Issue of Prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

Section 7. Manner of Issuance of Written, Typed or Computer Generated Prescriptions.

(a) All controlled substance prescriptions written by a Wyoming practitioner shall be issued on security paper, unless exempted under this Chapter for electronic transmission. Any controlled substance prescription written by a Wyoming practitioner issued on non-security paper may not be dispensed by a pharmacist.

(b) Any written, typed or computer generated prescription issued by a Wyoming practitioner for a Schedule II-V controlled substance except those issued as a medication order for administration in a long-term care facility or institutional facility shall meet the following requirements:

(i) Be printed on security paper, which includes the following features:

(A) If scanned or copied, “void” is displayed prominently throughout the front side of the document;

(B) Front side has erasure protection on green or blue background;

(C) Clear instructions printed on the paper indicating the front and back sides;

(D) Security warning list on the front or back;

(E) Quantity check-off boxes plus numeric forms of quantity values or alpha and numeric forms of quantity value (e.g. 20 and twenty); and

(F) Refill indicator (circle or check number of refills or “NR”) plus numeric form of refill values or alpha and numeric form of refill values.

(ii) All supplies of security paper shall be approved by the Board. Approval shall be based on the suppliers’ product meeting the requirements of this chapter. The Board shall make available a listing of all approved suppliers, which is updated at least annually.

(iii) All Board approved suppliers of security paper shall provide the Board written assurance that they will distribute prescription pads or paper only to practitioners duly authorized to prescribe controlled substances in Wyoming.

(c) All controlled substance paper prescriptions written by a Wyoming practitioner shall be manually signed in the same manner as the practitioner would sign a check or legal document. The use of electronic or digital signatures or signature stamps is not allowed, unless electronic prescriptions are used according to his chapter.

(d) Prescriptions may be prepared for dating and signature of the practitioner by an authorized agent of the practitioner and the use of preprinted prescriptions is allowed. Under no circumstances may stickers be utilized for information relating to drug, strength, quantity or directions.

(e) Prescriptions shall be dated as of, and signed on, the day when issued and shall bear the patient’s full name and address and the full name, address, telephone number and DEA registration number of the issuing practitioner. No postdating of controlled substance prescriptions is allowed.

(f) Prescriptions shall be written in ink, typed or electronically generated.

(g) The prescribing practitioner and dispensing pharmacist share the responsibility to assure compliance with this section.

(h) A refill request for a Schedule III-V controlled substance generated and faxed or requested electronically by the pharmacy to a practitioner for refill authorization need not be printed on security paper.

(i) The information sent by the practitioner to the pharmacy shall indicate who authorized the refill.

(j) A Schedule III-V controlled substance prescription faxed by the practitioner to the pharmacy need not be printed on security paper.

(k) An intern, resident, or foreign physician exempted from registration under Chapter 3 of these rules shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in Chapter 3 of these rules, in lieu of the registration number of the practitioner required by this section. Each prescription shall have the name of the intern, resident, or foreign physician stamped or printed on it, as well as the signature of the physician.

(l) An official exempted from registration under Chapter 3 of these rules shall include on all prescriptions issued by him, his branch of service or agency (e.g. “U.S. Army” or “Public Health Service”) and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number of a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.

Section 8. Persons Entitled to Fill Prescriptions.

A prescription for a controlled substance may only be filled by a pharmacist or intern or pharmacy technician or technician-in-training under direct supervision by a pharmacist, acting in the usual course of his/her professional practice or by a registered practitioner.

Section 9. Identification of a Patient.

(a) The pharmacist or employee under supervision must verify the identity of the person presenting a controlled substance prescription to the pharmacy for dispensing. This may be done by visual recognition. If identity is not established by visual recognition, a driver’s license or similar photo identification form is acceptable documentation. The following information shall be recorded on the paper prescription, if identification is utilized: name, type of identification, and identification number.

(b) The name of the person receiving the dispensed drug is to be recorded on the prescription document, patient profile, or signature log, if an agent and not the patient receives the drug.

(c) This Section shall not apply to pharmacies that mail prescriptions to their patients. A note shall be entered on the prescription or patient's profile with the name and address of where the medication was mailed. Additionally, the date of such mailing shall be entered.

Section 10. Dispensing of Narcotic Drugs for Maintenance Purposes.

The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs in the course of conducting a federally authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his professional practice or research."

Section 11. Prescription Formats.

(a) A pharmacist may dispense any prescription drug as follows:

(i) A written prescription signed by a practitioner or their agent;

(ii) A prescription transmitted by the practitioner or their agent to the pharmacy by electronic means; or

(iii) A verbal prescription made by an individual practitioner or their agent and promptly reduced to writing.

Section 12. Electronic Prescriptions.

(a) The practitioner may issue a prescription for a Schedule II, III, IV or V controlled substance electronically if an electronic prescription application is used that has been certified by a third party auditor to ensure that the electronic prescription application records, stores, and transmits the prescription accurately and consistently and that individual practitioner has obtained a two-factor authentication credential for signing.

(b) The electronic prescription application must transmit the electronic prescription as soon as possible after signature by the practitioner and the contents of the prescription must not be altered during transmission between the practitioner and pharmacy.

(c) The pharmacy receiving the electronic prescription must determine that third-party certification has found that the pharmacy application accurately and consistently imports, stores and displays the information required for the prescription including the number of refills and the practitioner's digital signature.

(d) An electronic prescription shall only be transmitted to the pharmacy of the patient's choice.

(e) The pharmacist is responsible for assuring the validity of the electronically transmitted prescription.

(f) A pharmacist or pharmacy shall not enter into any agreement to provide or receive a computer modem, personal digital assistant, facsimile machine, or any other electronic device which would adversely affect a patient's freedom to select the pharmacy of the patient's choice.

(g) A pharmacist or pharmacy shall not provide a computer or computer modem, personal digital assistant, facsimile machine or any other electronic device to a prescriber or health care facility for the purpose of providing an incentive to refer a patient to a particular pharmacy.

Section 13. Requirement of Prescription for Schedule II Substances.

(a) A pharmacist may dispense a controlled substance listed in Schedule II, only pursuant to a written or electronic prescription signed by the practitioner, except as provided in this section.

(b) A practitioner may administer or directly dispense a controlled substance listed in Schedule II without a prescription if it is dispensed in the course of his professional practice.

(c) In the case of an emergency situation, as defined in this section, a pharmacist may directly dispense a controlled substance listed in Schedule II upon receiving verbal authorization of 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 written or electronic prescription signed by the practitioner);

(ii) The emergency verbal prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in this chapter except for the signature of the practitioner;

(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) Within seven (7) calendar days after authorizing an emergency verbal prescription, the practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of this chapter, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the verbal order. The written prescription may be

delivered to the pharmacist in person or by mail. If delivered by mail, it must be postmarked within the seven (7) day period. 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 a written prescription

(d) A prescription for a Schedule II controlled substance shall be valid up to six (6) months from the date issued by the practitioner.

(e) A pharmacist shall cancel all written Schedule II controlled substance prescriptions when dispensed by dating and signing the face of the paper prescription. All electronic Schedule II controlled substance prescriptions shall be cancelled once dispensed.

(f) Information that can be changed on a Schedule II prescription shall meet the following requirements:

(i) After consultation/approval of the prescribing practitioner, the pharmacist is permitted to change the following:

(A) Drug strength;

(B) Drug quantity;

(C) Directions for use; or

(D) Dosage form.

(ii) The pharmacist is permitted to add or change the patient's address with proper verification without consulting the practitioner.

(iii) The practitioner's DEA registration number may be added to a prescription drug order after consulting the practitioner or verifying the number from another reliable source.

(iv) Required information may appear on the front or back of the paper prescription drug order. Computer generated modifications to the prescription drug order are allowed.

(v) Any change made by the pharmacist shall be documented and shall include the date, name of person consulted, and initials of the pharmacist.

(vi) A pharmacist shall not change the patient's name, controlled substance prescribed (except for generic substitution permitted by state law), date issued, or the prescriber's signature.

(g) For the purposes of authorizing a verbal prescription of a controlled substance listed in Schedule II, the term "emergency situation" means those situations in which the prescribing practitioner determines:

(i) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user;

(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 a written or electronic prescription to be presented to the person dispensing the substance prior to dispensing.

(h) A Schedule II controlled substance prescription may be faxed if it meets the criteria as specified in this chapter and Wyoming Pharmacy Act, Chapter 2, General Practice of Pharmacy Regulations.

Section 14. Refilling Prescriptions – Schedule II.

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

Section 15. Issuance of Multiple Prescriptions – Schedule II.

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

(a) Each separate prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(b) Each individual prescription is dated with the date it was prescribed and contains all other information required by this Chapter;

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

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

Section 16. Partial Filling of a Prescription – Schedule II.

(a) A prescription for a controlled substance in schedule II may be partially filled if:

(i) The partial fill is requested by the patient or the practitioner;

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

(iii) Remaining portions of a partially filled prescription shall be filled not later than 30 days after the date on which the prescription is written.

(b) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written, electronic or emergency verbal prescription and he makes a notation of the quantity supplied on the face of the paper prescription, and a written record of the emergency verbal prescription. The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling. If the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall notify the practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

(c) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities including individual dosage units.

(i) If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription.

(ii) The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient."

(iii) For each partial filling, the dispensing pharmacist shall record on an appropriate record, uniformly maintained and readily retrievable:

(A) The date of the partial filling;

(B) Quantity dispensed;

(C) Remaining quantity authorized to be dispensed; and

(D) Identification of the dispensing pharmacist.

(iv) The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed.

(v) Schedule II prescriptions dispensed in partial fillings shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuation of the medication.

(d) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system

Section 17. Labeling of Substances – Schedule II.

The pharmacist filling a written, electronic, or emergency verbal prescription for a controlled substance listed in Schedule II shall affix to the package a label showing the date of the filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

Section 18. Filling of Prescription – Schedule II.

All written or electronic prescriptions and written records of emergency verbal prescription shall be kept in accordance with requirements of Chapter 4 of these rules.

Section 19. Requirement of Prescription for Schedule III and IV Substances.

(a) A pharmacist may dispense a controlled substance listed in Schedule III or IV, only pursuant to either a written or electronic prescription signed by a prescribing practitioner or a verbal prescription made by a prescribing practitioner and promptly reduced to writing or electronic record. The prescription may be faxed. All Schedule III or IV prescriptions must contain the information required in this chapter.

(b) A practitioner may administer or dispense a controlled substance listed in Schedules III or IV in the course of his professional practice without a prescription.

(c) An institutional practitioner or his authorized agent may administer or dispense directly (but not prescribe) controlled substances listed in Schedules III or IV pursuant to a paper prescription signed by a prescribing practitioner or his authorized agent, or pursuant to a verbal prescription made by a prescribing practitioner and promptly reduced to writing by the pharmacist (containing all information required in this Chapter, except for the signature of the prescribing practitioner), or pursuant to an order for medication made by a practitioner or his authorized agent which is dispensed for immediate administration to the intended ultimate user.

Section 20. Refilling of Prescription – Schedules III and IV.

(a) No prescription for a controlled substance listed in Schedules III or IV shall be filled or refilled more than six (6) months after the date on which such prescription was issued.

(b) No prescription authorized to be refilled may be refilled more than five (5) times.

(c) Each refilling of a prescription shall be documented on a readily retrievable record, which indicates the date and name of the dispensing pharmacist and is initialed and dated by the pharmacist. The amount dispensed shall be stated on the record.

(d) Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription.

Section 21. Partial Filling of Prescriptions – Schedules III and IV.

The partial filling of a prescription for a controlled substance listed in Schedules III or IV is permissible, provided that:

(a) Each partial filling is recorded in the same manner as a refilling;

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

(c) No dispensing occurs after six (6) months after the date on which the prescription was issued.

Section 22. Labeling of Substances – Schedules III and IV.

The pharmacist filling a prescription for a controlled substance listed in Schedules III or IV shall affix to the package a label showing the pharmacy name and address, the serial number and date of the filling, the name of the patient, the name of the practitioner issuing the prescription, directions for use, and cautionary statements, if any, as required by law.

Section 23. Filing Prescriptions – Schedules III and IV.

All prescription records for controlled substances listed in Schedules III and IV shall be kept in accordance with Chapter 4 of these rules.

Section 24. Requirements of Prescription for Schedule V Substances.

(a) A pharmacist may dispense a controlled substance listed in Schedule V pursuant to a prescription as required for controlled substances listed in Schedules III and IV in this chapter. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing practitioner on the prescription; if no authorization is given, the prescription shall not be filled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with this chapter and file the prescription in accordance with this chapter.

(b) A practitioner may administer or dispense a controlled substance listed in Schedule V in the course of his professional practice without a prescription.

ADMINISTRATIVE INSPECTIONS

CHAPTER 7

Section 1. Authority.

These rules are pursuant to Title 21 Code of Federal Regulations and by the Wyoming Controlled Substances Act W.S. § 35-7-1001 through -1101.

Section 2. Scope.

Applies to all registrants.

Section 3. Inspections.

(a) In carrying out their functions under the Act, the Board, and the Commissioner of Drugs and Substances Control and their duly authorized agents are authorized in accordance with W.S. § 35-7-1024 to enter controlled premises and conduct administrative inspections thereof.

(b) Inspections shall be done in accordance with Title 21 Code of Federal Regulations process:

(c) Incorporation by Reference:

(i) Title 21 Chapter II Drug Enforcement Administration, Department of Justice, Part § 1316.01 to 1316.13 as of July 17, 2015.

(ii) The incorporated rule does not include any later amendments or editions;

(iii) The incorporated rule is maintained at the Wyoming State Board of Pharmacy, 1712 Carey Avenue, Suite 200, Cheyenne, WY 82002 and is available for public inspection and copying at cost at the same location.

(iv) The incorporated rule is maintained at ~~http://www.deadiversion.usdoj.gov/ under Resources, Title 21 Code of Federal Regulations, Part § 1316 Subpart A-Administrative Inspections~~ https://www.deadiversion.usdoj.gov/21cfr/cfr/2116cfrt.htm.

Section 4. Notice of Inspection.

The notice of inspection form shall contain:

(a) The name and title of the owner, operator, or agent in charge of the controlled premises;

(b) The controlled premises name;

(c) The address of the controlled premises to be inspected;

(d) The date and time of the inspection;

(e) A statement that a notice of inspection is given pursuant to W.S. § 35-7-1024;

(f) A reproduction of the pertinent parts of W.S. § 35-7-1024; and

(g) The signature of the authorized agent.

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. Scope.

Applies to all registrants.

Section 4. 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.

(e) "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. Registration Requirements.

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

(b) Practitioners shall register online at worxpdmp.com; and

(c) Board staff shall enroll the practitioner after verifying the registration.

Section 6. Transmission of information regarding dispensing of controlled substances to certain persons.

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

(i) Dispenser identification number;

(ii) Patient date of birth;

(iii) Patient gender;

(iv) Date prescription was filled;

(v) Prescription number;

(vi) Prescription is new or is a refill;

(vii) Quantity dispensed;

(viii) Date prescription issued by prescriber;

(ix) Number of ~~D~~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, name and species;

(xv) Patient street address;

(xvi) Patient zip code; and

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

(b) ~~If the retail pharmacy does not dispense more than twenty-five (25) controlled substance prescriptions per month to patients residing in this State, the retail pharmacy may request a waiver from the Board~~.

(c) The resident/nonresident retail pharmacy or practitioner dispenser shall ensure that, not later than close of business on the business day immediately following the day the controlled substance was dispensed, the information required pursuant to this Chapter is 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) Exemptions from reporting include certain inpatient health care settings.

Section 7. Solicited Patient Profiles.

(a) Occupational licensing boards may request licensee profiles from the Board 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 ~~are under no obligation to, but~~ may request patient profiles from the Board provided the following conditions are met for faxed paper requests:

(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 ~~are under no obligation to, but~~ 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) The Board staff shall discontinue access to any pharmacist or practitioner or their appointed delegate whose license, DEA registration or WY Controlled Substance Registration has lapsed or been revoked or suspended.

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

(f) 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

(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.

(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.

Section 8. 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 to each pharmacy and practitioner where the patient was seen. A letter of explanation will accompany each profile.

Section 9. Reports.

(a) Board staff shall maintain a register for solicited patient profile requests for two (2) 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) 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.

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

Section 10. 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.

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.