



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, Dept 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 08/05/2020	
i. Program Pharmacy, Board of - 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 **Enrolled Act No. 66, Sentate 2019** 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: 6	Chapter Name: Issuing Filing and Filling of Prescriptions	<input type="checkbox"/> New <input type="checkbox"/> Amended <input checked="" type="checkbox"/> Repealed
Amended Chapter Name (if applicable):		
Chapter Number: 10	Chapter Name: Issuing and Dispensing Prescriptions for Controlled Substances	<input checked="" type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
Amended Chapter Name (if applicable):		
Chapter Number:	Chapter Name:	<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed
Amended Chapter Name (if applicable):		
Chapter Number:	Chapter Name:	<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed
Amended Chapter Name (if applicable):		
Chapter Number:	Chapter Name:	<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> 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	August 6, 2020

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	



Bessie S. McGirr, RPh, President
Kerri Kilgore, RPh, Vice President
Brenda Upton, RPh, Secretary/Treasurer
Patrick Fitzgerald, APRN, Public Member
Jim Massengill, RPh, Member
Robert R. Prentice, MD, Member
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Governor: Mark Gordon

WYOMING CONTROLLED SUBSTANCES ACT RULES AND REGULATIONS

STATEMENT OF PRINCIPAL REASONS FOR REVISIONS

May 2020

The Board of Pharmacy is proposing to repeal Chapter 6 and create Chapter 10 of the Controlled Substances Act Rules and Regulations. This is being done to simplify, modernize, and reorganize the rules. Chapter 10 is also being created to provide exemptions to Wyoming Statute § 35-7-1030, which requires that all controlled substances be electronically prescribed.

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

Chapter 6. Issuing, Filing, and Filling of Prescriptions

) Chapter 6 is repealed.

Chapter 10. Issuing and Dispensing Prescriptions for Controlled Substances

) Chapter 10 is being created to simplify, modernize, and reorganize the information that was previously in Chapter 6.

) Chapter 10 also provides exemptions to the requirement that all controlled substances be electronically prescribed under Wyoming Statute § 35-7-1030 and Enrolled Act No. 66, Senate 2019, SF0047.



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SUMMARY OF COMMENTS RECEIVED REGARDING REVISIONS TO THE WYOMING CONTROLLED SUBSTANCES ACT RULES AND REGULATIONS CHAPTERS 6 AND 10.

Chapter 6. Issuing, Filing, and Filling of Prescriptions: The Board of Pharmacy is proposing to repeal Chapter 6 and create Chapter 10 of the Controlled Substances Act Rules and Regulations to simplify, modernize, and reorganize the rules. Chapter 10 is also being created to provide exemptions to Wyoming Statute § 35-7-1030, which requires that all controlled substances be electronically prescribed. No written or verbal public comments were received regarding the repeal of Chapter 6.

Chapter 10. Issuing and Dispensing Prescriptions for Controlled Substances: The Board received a total of four (4) comments during the public comment period. The Board did not receive a request to hold a public hearing on the proposed changes. One (1) comment from a Wyoming dentist opposed the statutory requirement that all controlled substances be electronically prescribed. Two (2) of the comments received were in support of the proposed changes, one (1) was neutral. These three comments provided information that included:

-) Language from the federal Controlled Substances Act, specifically 21 USC 829, 21 CFR 1306.13 and 1306.21;
-) Language from the SUPPORT for Patients and Communities Act; and
-) Language from the previous Chapter 6: Issuing, Filing, and Filling of Prescriptions

The Board met and discussed the public comments that were received. All comments received and the Board's responses are included in the final rules packet. The Board believes that there are two (2) changes that should be made based on the public comments received and that these changes are logical outgrowths from those comments. The proposed changes are:

Proposed Amendment #1:

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.

(v) If the pharmacist is unable to supply the full quantity prescribed, the remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

Chapter 6 had language that addressed the 72-hour period wherein a schedule II-controlled substance could be partially filled. The Board chose to leave that language out of Chapter 10 because they believed that the new language would cover the situations when a schedule II-controlled substance would need to be partially filled. Given the comments received the Board believes it needed to be included. The Board also believes this change should be made to align with the Federal Controlled Substances Act and that this change provides for situations when a pharmacy needs to partial fill a controlled substance prescription that was issued more than 30 days before the fill date.

Proposed Amendment #2:

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 ~~and~~ or federally issued identification.

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

(iv) The recorded information shall be readily retrievable.

The Board believes this change should be made to clarify the record keeping and identification requirements. The Board also noted in their discussion that in (ii) it should be "or", not "and." The Board did not intend to require individuals presenting non-electronic prescriptions to have to provide both a federal and state identification.

Public Hearing Comments		
No.	Comments	Agency Response
		Yes – Amend Rules
1	<p>Members of the Wyoming Board of Pharmacy,</p> <p>Recently a Public Notice in the Casper Star Tribune caught my eye. The Pharmacy Board is providing notice that the Board is considering changes to the Controlled Substance prescribing Rules.</p> <p>Specifically to provide an exemption to the Rules which require that all prescriptions for Controlled Substances to be “electronically prescribed”. I am strongly opposed to being forced to use a computer to provide a Controlled Substance prescription for my patients. Having to interrupt the flow of patient care to access whatever web site and try to remember my access secrets is very disruptive and intrusive to my practice. I strongly encourage the Board of Pharmacy to exempt Controlled Substance prescriptions from the requirement of electronic transmission and remain with the current written prescriptions for Controlled Substances. There may be offices which will readily adapt to the electronic prescribing but each office should be provided the opportunity to choose a method.</p> <p>Thank you for your consideration.</p> <p>Sincerely, Sean F. Ellis, DDS</p>	<p>W. S. § 35-7-1030 and Enrolled Act No. 66, Senate 2019, SF0047 requires that controlled substances be electronically prescribed. It does not give the Board broad authority to negate that requirement.</p>
2	<p>On behalf of all pharmacies owned and operated by Walgreen Co. in the state of Wyoming, I would like to thank the Board for the opportunity to comment on Chapter 10, Issuing and Dispensing Prescriptions for Controlled Substances.</p> <p><u>Section 5. Exemptions to Electronic Prescribing Requirement.</u></p> <p>As currently drafted, Section 5 would require pharmacists to validate that certain exceptions to electronic prescribing exist. Requiring the pharmacist to confirm such exceptions if not already noted on the prescription may delay patient care if the pharmacist is unable to reach the prescriber. Walgreens respectfully requests the amendment as set forth below to explicitly state that pharmacists are not required to validate these prescriber exceptions.</p> <p><u>Section 5. Exemptions to Electronic Prescribing Requirement.</u></p> <p><u>(d) A pharmacist who receives a non-electronic prescription for a controlled substance is not required to verify that one of the exceptions set forth in Chapter 10, Section 5 applies and may dispense such controlled substance pursuant to such prescription and applicable law.</u></p> <p><u>Section 6. Additional Requirements for Non-Electronic Prescriptions for Controlled Substances.</u></p>	<p>The proposed chapter does not explicitly require pharmacists to verify an exception exists when they have received a paper prescription for a controlled substance. Explicitly exempting them from having to do any verification invalidates the corresponding responsibility that rests with the Pharmacist who fills the prescription.</p>

Current section 6 requires all non-electronic controlled substance prescriptions to have a wet signature. Federal regulations in 21 CFR 1306.21(A) specifically states that facsimile of a signed paper prescription is permissible. Walgreens respectfully requests clarification that facsimile of a signed paper prescription is not excluded or to include the below language:

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, **including a facsimile of a signed paper prescription**, 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.

21 CFR 1306.21 Requirement of prescription

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to either a paper prescription signed by a practitioner, **a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent** to the pharmacy, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in 1306.05, except for the signature of the practitioner

Section 9. Partial Filling of Controlled Substances.

Current Wyoming 9(a)(i-iv) does not align with the Federal requirements in 1306.13 & 21 USC 829. Instead of separating the two situations when a partial fill may occur, due to insufficient stock or based on a Patient/Prescriber request, it appears that the Board has attempted to merge both situations. The timeline to dispense the remainder will vary based on the situation. For insufficient stock, the remainder must be filled within 72 hours (unless hospice or LTC, then it is 60 days). For patient/prescriber requests, the remainder must be filled within 30 days. There is no section here that limits pharmacies to 72 hours, which may create confusion between the Federal requirements and state requirements when a pharmacist fills due to insufficient stock. Walgreens respectfully requests the amendment to section 9 as follows:

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**

W. S. § 35-7-1030 and Enrolled Act No. 66, Senate 2019, SF0047 requires that controlled substances be electronically prescribed. Prescriptions for controlled substances may be faxed to a pharmacy as described in the proposed chapter 10 Section 5 (c).

The Board believes this to be a logical

~~(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.~~

~~(a) A Schedule II controlled substance prescription may be partially filled if in accordance with 21 CFR 1306.13 and 21 USC 829.~~

21 CFR 1306.13 Partial filling of prescriptions

(a) 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 or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(b) 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 to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

21 USC 829

(f) Partial fills of schedule II controlled substances

(1) Partial fills. A prescription for a controlled substance in schedule II may be partially filled if

(A) it is not prohibited by State law;

(B) the prescription is written and filled in accordance with this subchapter, regulations prescribed by the Attorney General, and State law;

outgrowth from the public comment. Please see Proposed Amendment #1 at the end of this summary.

	<p>(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and (D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.</p> <p>(2) Remaining portions</p> <p>(A) In general. Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II-</p> <ul style="list-style-type: none"> (i) may be filled; and (ii) shall be filled not later than 30 days after the date on which the prescription is written. <p>(B) Emergency situations. In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in schedule II-</p> <ul style="list-style-type: none"> (i) may be filled; and (ii) shall be filled not later than 72 hours after the prescription is issued. <p>Thank you again for the opportunity to provide comments on Chapter 10, as proposed. If the Board would like additional information, please feel free to contact me.</p> <p>Sincerely, Lorri Walmsley, R.Ph.</p>		
3	<p>I am writing to you in my capacity as Advisor of Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in Wyoming through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the proposed rules Chapter 10 controlled substance regulations. We would also like to thank the Board for their vigilance to continuously improve the laws and regulations that guide pharmacists, pharmacy interns, and pharmacy technicians serving Wyoming patients.</p> <p>CVS Health supports the Board proposing to streamline and modernize chapter 10 rules related to the dispensing of controlled substance prescriptions. Generally, states do not place the burden upon the pharmacist to determine whether or not the controlled substance prescription correctly falls under an exception to the requirements to electronically prescribe. We request the Board amend Section 5 to make it clear a pharmacist may dispense an oral, written, and faxed controlled substance prescriptions according to Wyoming laws and rules, without verifying if the prescriber correctly chose a proper exception to the mode of prescription transmission. Arkansas, California, Iowa, Kansas, Kentucky, Missouri, Nevada, New York, South Carolina, Tennessee, and Virginia, are just some of the states that have imposed electronic prescribing requirements on prescribers but have continued to allow pharmacists to dispense all otherwise lawful prescriptions, regardless of format.</p> <p>During COVID-19, our patients have increasingly requested and utilized home delivery of prescription medications to avoid unnecessary pharmacy visits for refills or new prescriptions. One</p>		

regulatory restriction that has proven to be challenging is requiring patient identification and identification documentation on the delivery of controlled substance prescriptions. Identification requirements are further complicated when a pharmacy contracts with a third party logistics delivery service. We request the Board amend Section 7 to allow for pharmacies to establish patient identity through adjudication with the patient's prescription benefit plan.

CVS Health appreciates the opportunity to submit comments for the Board's review. We have provided suggested rule language in the appendix. Please contact me directly at 734-735-6251 if you have any questions.

Sincerely,
Tim Frost, PharmD
Advisor, Pharmacy Regulatory Affairs
CVS Health

Appendix

Suggested Rule Language:

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. The practitioner shall write on the face of the prescription "Not to be dispensed in Wyoming;"

(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."

(d) A pharmacist or pharmacy who receives a written, oral, or faxed prescription for a controlled substance shall not be required to verify that the prescription properly falls under one of the exceptions from the requirement to electronically prescribe. Pharmacists may continue to dispense medications from otherwise valid written, oral, or fax prescriptions that are consistent with current laws and administrative regulations.

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 done by adjudication with the patient's prescription benefit plan.

(iii) ~~(iii)~~ Identification may be verified by state and federally issued identification.

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

(B) ~~(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;

The proposed chapter does not explicitly require pharmacists to verify an exception exists when they have received a paper prescription for a controlled substance. Explicitly exempting them from having to do any verification invalidates the corresponding responsibility that rests with the Pharmacist who fills the prescription.

The Board does not believe that identity can properly be established through adjudication with the patient's prescription benefit plan.

	<p><u>(v) Date to be dispensed;</u> <u>(vi) The patient’s address with proper verification without consulting the practitioner.</u> <u>(vii) The practitioner’s DEA registration, address, or telephone number after verifying the information from another reliable source.</u></p> <p><u>(e) A pharmacist shall not change the following on a controlled substance prescription:</u> <u>(i) Patient’s name;</u> <u>(ii) Controlled substance prescribed;</u> <u>(iii) Date issued; or</u> <u>(iv) The prescribing practitioner.</u></p> <p><u>(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.</u> <u>(i) Pharmacists may make computer generated modifications to the controlled substance prescription.</u> <u>(ii) Any changes or additions made by the pharmacist may appear on the front or back of the non-electronic controlled substance prescription.</u></p> <p><u>(g) Pharmacies shall label dispensed controlled substance prescriptions according to the requirements in the Wyoming Pharmacy Act Rules Chapter 2.</u> <u>(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.</u></p>		
4	<p>On behalf of our members operating chain pharmacies in the state of Wyoming, the National Association of Chain Drug Stores (NACDS) is writing to provide feedback on the proposed changes to the Wyoming Controlled Substances Act Rules and Regulations as authorized by the Wyoming Controlled Substances Act, W.S. § 35-7-1001 through 35-7-1060.</p> <p>NACDS strongly supports electronic prescribing for controlled substances (EPCS) and appreciates the Board’s implementing the requirements of Wyoming Statute § 35-7-1030 [Enrolled Act No. 66, Senate 2019, SF0047], which mandates EPCS beginning January 1, 2021.</p> <p>We have carefully reviewed the proposed changes, which include repealing Chapter 6 and the creation of Chapter 10 of the Wyoming Controlled Substances Act Rules and Regulations. As proposed these regulatory changes appear to generally provide appropriate guidance for the implementation of EPCS in 2021. However, we would like to suggest three amendments to the proposed regulations for controlled substances as outlined in Chapter 10.</p> <p>Section 7 of proposed Chapter 10 lists requirements for the dispensing of controlled substance prescriptions. The following text had been in section 8 of the repealed Chapter 6 and would seem to fit appropriately Section 7 of Chapter 10 regarding the general conditions for dispensing controlled substances.</p> <p><u>A prescription for a controlled substance may only be filled or dispensed by a pharmacist or intern or pharmacy technician, or technician in training under direct supervision by a</u></p>		<p>The Board believes this to be sufficiently clear and commonly understood and was therefore not included as the Board attempts to clarify and modernize the chapter.</p>

pharmacist, acting in the usual course of his/her professional practice or by a registered practitioner.

Also, NACDS suggests a clarification to the proposed Chapter 10, section 9 to ensure that it aligns with federal statutory section 21 USC 829(f)(2)(A). Our suggested amendment is intended to avoid potential confusion about when the 30-day clock begins for dispensing the remaining portions of a partially filled Schedule II controlled substance prescription. We propose to clarify that the 30-day clock begins with the date on which the prescription is issued, as indicated by 21 USC 829(f)(A). Our proposed addition is below in **bold, underlined language**

Proposed Chapter 10, 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 **after the date on which the prescription is issued**, or sixty (60) days for terminally ill or long term care facility patients, after the date on which the prescription is issued.

Finally, with respect to proposed Section 7, we ask that the Board retain clarifying language from current Chapter 6, Section 9 that speaks to verifying the identity of a person who presents a non-electronic controlled substance prescription or receives any controlled substance prescription. Presently, the language of Chapter 6, Section 9 is clear that documentation is required only when identify verification does not occur via visual recognition. To retain this clarification, we suggest the following amendment to proposed Chapter 10, Section 7. Our proposed addition is below in **bold, underlined language**:

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 and federally issued identification.
- (iii) **If identification is verified by state or federally issued identification**, the pharmacist or employee shall record the individual's name, identification, and identification number.
- (iv) The recorded information shall be readily retrievable.

NACDS thanks the Wyoming Board of Pharmacy for considering our suggested amendments to the content of proposed Chapter 10 of the Wyoming Controlled Substances Act Rules and Regulations. We urge you to adopt the proposed regulations with our suggested amendments. If you have any

The Board believes the wording to be sufficiently clear as written in the proposed chapter.

The Board believes this to be a logical outgrowth from the public comment. Please see Proposed Amendment #2 at the end of this summary.

The Board also notes in (ii) that it should be "or" (also in amendment# 2).

questions, please do not hesitate to contact NACDS' Lis Houchen at lhouchen@nacds.org or 360-480-6990.

Sincerely,
Steven C. Anderson, FASAE, CAE, IOM President and Chief Executive Officer

Proposed Amendment #1:

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.

(v) If the pharmacist is unable to supply the full quantity prescribed, the remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

Proposed Amendment #2:

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 ~~and~~ or federally issued identification.

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

(iv) The recorded information shall be readily retrievable.

Chapter 6

Issuing, Filing and Filling of Prescriptions

This chapter is repealed.

Chapter 10

Issuing and Dispensing Prescriptions for Controlled Substances

Section 1. Authority.

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

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 and dispensing 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. The practitioner shall write on the face of the prescription "Not to be dispensed in Wyoming;"

(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, or if visually identified, the individual's name

(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;

(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; and

(v) If the pharmacist is unable to supply the full quantity prescribed, the remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(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
- (iv) Identification of the dispensing pharmacist.

(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;

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

(iii) The prescription is not dispensed after six (6) months from the date that the prescription was issued.

(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 of Controlled Substances.

(a) 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.

(b) Schedule III, IV, and V controlled substance prescriptions shall be transferred in accordance with Chapter 2 of the Wyoming Pharmacy Act Rules, this includes unfilled original Schedule III, IV, and V EPCS. Unfilled non-electronic Schedule III, IV, and V controlled substance prescriptions shall not be transferred.

Chapter 6

Issuing, Filing and Filling of Prescriptions

~~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 feature:~~

~~_____ (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 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 issues 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 office 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 for 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 the 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 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 the 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 and 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, excepts as provided in this section.

(b) A practitioner may administer or directly dispense a controlled substance listed in Schedule II without a prescription if 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 additions 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 has 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 prescriptions 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 reasonable 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 prescriptions, 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 prescriptions, 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 documentation a terminal illness may be filled in partial quantities including individual dosage units.

_____ (i) _____ If there is any questions 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 maintains 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 the 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 prescriptions made by a prescribing practitioner and promptly reduced to writing or electronic records. The prescription may be faxed. All Schedule II 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 II or IV may only be authorized by a prescribing practitioner through issuance of a new prescription.~~

~~Section 21. Partial Filling of Prescriptions – Scheduled 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 – Scheduled 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 state 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 – Scheduled 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 Scheduled 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 prescriptions 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.~~

Chapter 10

Issuing and Dispensing Prescriptions for Controlled Substances

Section 1. Authority.

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

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 and dispensing 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. The practitioner shall write on the face of the prescription "Not to be dispensed in Wyoming;"

(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, or if visually identified, the individual's name

_____ (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;

(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; and

(v) If the pharmacist is unable to supply the full quantity prescribed, the remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(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

(iv) Identification of the dispensing pharmacist.

(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;

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

(iii) The prescription is not dispensed after six (6) months from the date that the prescription was issued.

(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 of Controlled Substances.

(a) 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.

(b) Schedule III, IV, and V controlled substance prescriptions shall be transferred in accordance with Chapter 2 of the Wyoming Pharmacy Act Rules, this includes unfilled original Schedule III, IV, and V EPCS. Unfilled non-electronic Schedule III, IV, and V controlled substance prescriptions shall not be transferred.