

# Notice of Intent to Adopt Rules

# A copy of the proposed rules may be obtained at <a href="http://rules.wyo.gov">http://rules.wyo.gov</a>

Revised September 2016

1. General Informati	<u>tion</u>					
a. Agency/Board Name						
b. Agency/Board Address	6	c. City		d. Zip Code		
e. Name of Agency Liaison  f. Agency Liaison Telephon			Number			
g. Agency Liaison Email	Address					
h. Date of Public Notice		i. Comment Period End Date				
j. Public Comment URL o	or Email Address:					
k. Program						
	<u>tment</u> For purposes of this Section 2, "new" only applie whole or in part by prior rulemaking and does not include				ve enactment not	
-	s per the above description and the definition of "new" in		aorai manaa			
No.	/es. Please provide the Enrolled Act Numbers and Years	S Enacted:				
3. Rule Type and In	<u> </u>	, Endotod.				
a. Provide the Chapter N	umber, Title, and Proposed Action for Each Chapter.					
	Rule Information form for more than 10 chapters, and attach it	to this certification.	_			
Chapter Number:	Chapter Name:		New	Amended	Repealed	
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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:	
By sub	mitting written comr		e physical	on the rulemaking action? and/or email address listed in Secti	on 1 above.	
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:						
Requests for an age Section 1 above.	ency response must	be made prior to, or with			ruling the consideration urged against adoption. ddressed to the Agency and Agency Liaison listed in	
<u>5. Federal La</u>	<u>w Requireme</u>	<u>nts</u>				
a. These rules are o	reated/amended/rep	pealed to comply with fed	leral law o	r regulatory requirements. N	o. Yes. Please complete the boxes below.	
Applicable Fe	deral Law or Regula	ation Citation:				
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 Statu	itory Require	<u>ments</u>				
The pro		MEETS minimum substa			a statement explaining the reason that the rules	
b. Indicate one (1):  The Ag	jency has complied	with the requirements of	W.S. 9-5-3	304. A copy of the assessment used	to evaluate the proposed rules may be obtained:	
		ency at the physical and :		ddress listed in Section 1 above.		
☐ Not App	licable.					

7. Additional APA Provisions						
a. Complete all that apply in regards to uniform rules	5:					
☐ These rules are not impacted by the uni	form rules identified in the Administrative Procedure Act, W.S. 16-3-103(j).					
☐ The following chapters <u>do not</u> 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 r	ules identified in the Administrative Procedure Act, W.S. 16-3-103(j) (see Statement of Principal Reasons).					
	(Provide chapter numbers)					
Environmental Quality Council, 590 P.2d 132 rule.   If applicable: In consultation with the Attorney required as the proposed amendments are proposed.	need to this Notice and, in compliance with Tri-State Generation and Transmission Association, Inc. v. 4 (Wyo. 1979), includes a brief statement of the substance or terms of the rule and the basis and purpose of the y General's Office, the Agency's Attorney General representative concurs that strike and underscore is not ervasive (Chapter 3, <i>Types of Rules Filings</i> , Section 1, Proposed Rules, of the Rules on Rules).					
8. Authorization						
a. I certify that the foregoing information is corr	ect.					
Printed Name of Authorized Individual						
Title of Authorized Individual						
Date of Authorization						



# **Additional Rule Information**

Revised September 2016

1. General Information							
a. Agen	cy/Board Name						
b. Agency/Board Address		c. City		d. Zip	d. Zip Code		
e. Na Name of Agency Liaison		f. Agency Liaison Telephone Number					
g. Agen	cy Liaison Email Address		h. Adoption Date				
i. Progra	ım						
2. Rul	e Type and Information	<u>n, Cont.</u>					
a. Provid	de the Chapter Number, Title	, and Proposed Action for Each Chapter.					
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# **BOARD OF PHARMACY**



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# **WYOMING**

1712 Carey Avenue, Suite 200, Cheyenne, WY 82002 307-634-9636 Telephone 307-634-6335 Fax bop@wyo.gov electronic mailbox Mary K. Walker, RPh, Executive Director

Lisa V. Hunt, RPh, Inspector/Compliance Officer Henry A. (Hank) York, RPh, Inspector/Compliance Officer

Governor: Matthew H. Mead

#### WYOMING CONTROLLED SUBSTANCES ACT RULES AND REGULATIONS

## STATEMENT OF PRINCIPAL REASONS FOR REVISIONS

January 2017

Revisions are proposed in Chapters 4, 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 2015 Session of the Wyoming Legislature, specifically Enrolled Act No. 66, Senate, 2015, and Enrolled Act No. 49, Senate, 2015.

#### Chapter 4: Records and Inventories of Registrants

Allowing Pharmacies to maintain records of dispensed prescriptions in a separate written or electronic file in consecutive numbers or by date for Schedules II, III, IV, or V controlled substances.

### Chapter 6: Issuing, Filing and Filling of Prescriptions

- Allowing for electronic records.
- Clarifying partial filling of prescriptions for Schedule II controlled substances particularly for long term care facility residents.

#### Chapter 7: Administrative Inspections

- Incorporation by reference to Title 21 Chapter II Drug Enforcement Administration, Department of Justice Part § 1316 which describes administrative inspections.
- Describing the notice of inspection.

#### Chapter 8: Prescription Drug Monitoring Program

- Adding the requirement for pharmacies to report the method of payment for dispensed prescriptions of controlled substances.
- Describing the requirement for reporting dispensed prescriptions of controlled substances to the Wyoming program within twenty-four hours, rather than the previous requirement to report within seven days of dispensing.
- Describing the criteria for practitioners and pharmacists to appoint delegates to request patient reports from the program (WORx).
- Requiring records to be kept by the board for two years from the date of request for solicited and unsolicited patient reports.
- Adding non-controlled substance pharmaceuticals to the reporting requirement: gabapentin, cyclobenzaprine, naloxone.

#### RECORDS AND INVENTORIES OF REGISTRANTS

#### CHAPTER 4

#### **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 maintain the records and inventories and file reports as required by W.S. 35-7-1028.

### **Section 3.** Scope

Applies to all registrants.

**Section 4.** Records and Inventory Requirements Generally.

- (a) Each registered manufacturer, distributor, importer, and narcotic treatment program shall maintain inventories and records of controlled substances.
- (b) Each registered individual practitioner shall keep records with respect to controlled substances which he prescribes or administers. Said practitioner shall keep additional records of such substances which he dispenses.
- (c) Each registered pharmacy shall maintain records of controlled substances as follows:
- (i) Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate written or electronic prescription file in consecutive numbers or by date.
- (ii) Schedules III-V shall be maintained separately from all other records of the pharmacy and prescriptions for such substances shall be maintained in separate written or electronic prescription files for controlled substances in consecutive numbers or by date.
- (iii) All written or electronic invoices for controlled substances shall be dated and signed when received by the pharmacist in charge or his/her designated agent. Invoices shall be maintained on file for two years and readily available for inspection by the Board.
- (iv) All retail and institutional pharmacies shall maintain a perpetual inventory for all Schedule II controlled substances. This inventory shall be reconciled no less than once a quarter. Discrepancies discovered during reconciliation shall be reported to the Board within ten (10) calendar days of discovery. Only those discrepancies which are

considered a significant loss or gain shall be reported. For the purpose of this section, a significant loss or gain shall exist whenever the actual inventory differs from the recorded inventory by more than five percent (5%) for any drug product.

(d) All required records shall be kept by the registrant and be made available for at least two (2) years from the date of record.

#### **Section 5.** Inventory Requirements.

Every registrant required to keep records shall take a physical inventory count of controlled substances during the first seven (7) days of May of each year or other date approved by the Board.

- (a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.
- (b) A separate inventory shall be made by a registrant for each registered address. Each inventory shall be kept at the registered location for which it is taken.
- (c) A registrant may take an inventory either at the opening or close of business on the inventory date. The registrant shall indicate the time the inventory was taken on the inventory record.
  - (d) An inventory must be maintained in a legible written or printed form.
- (e) Each registered pharmacy shall forward one (1) copy of the annual inventory to the office of the Board of Pharmacy, including the name of the pharmacy, date and time the inventory was taken, and the signature of the responsible person(s).

#### **Section 6.** Drug Enforcement Administration (DEA) Order Form 222.

The order forms may be obtained only by those persons registered to handle controlled substances in Schedules I and II.

- (a) An order form may be executed only by or on behalf of the registrant named thereon and only if his registration is current.
- (b) Order forms issued by the DEA will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and the schedules of the registrant. This information cannot be altered or changed in any manner.
- (c) Order forms shall be prepared using a typewriter, pen or the electronic equivalent.
- (d) A registrant may authorize another individual to obtain and execute an order form on his behalf by executing a power of attorney. The power of attorney shall be filed with

and retained for the same period as any order form bearing the signature of the grantor. The power of attorney shall be available for inspection.

- (e) The purchaser registrant shall submit Copy 1 and Copy 2 of the order form to the supplier and retain Copy 3 with his own records. The supplier shall enter the suppliers DEA registration number, number of packages shipped, and the date shipped on Copies 1 and 2. If the supplier is another local registrant (not a registrant manufacturer or distributor), Copy 2 may be forwarded directly to the DEA Regional Office or the office of the Board of Pharmacy.
- (f) The purchaser registrant shall record on Copy 3 of the order form the number of containers received on each item of the order form and the date received.
- (g) Order forms and attached corresponding invoices shall be maintained separately from all other records of the registrant for a period of two years. Order forms shall be available for inspection during that time.
  - (h) The Controlled Substance Ordering System (CSOS) is authorized.

## **Section 7.** Methamphetamine Precursor Records.

- (a) The retail sale of non-liquid methamphetamine precursor drugs or liquid products with ephedrine or pseudoephedrine as the sole active ingredient shall be limited to amounts as specified in W.S. § 35-7-1059.
- (b) The seller shall maintain a written or electronic list of such sales (logbook) as described in W.S. § 35-7-1059.
  - (c) The sale shall be documented as follows:
- (i) The prospective purchaser shall present photo identification in accordance with W.S. § 31-7-111 and W.S. § 8-7-101.
- (ii) The prospective purchaser shall sign the logbook and enter in the logbook his or her name, address and the date and time of the sale.
- (iii) The seller shall determine that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct.
- (iv) The seller shall enter into the logbook the name of the product and the quantity sold.
- (d) The logbook shall contain a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under 18 U.S.C. § 1001 and such notice must specify the maximum fine (\$250,000.00) and term of imprisonment (5 years).

#### RECORDS AND INVENTORIES OF REGISTRANTS

#### **CHAPTER 4**

#### **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 maintain the records and inventories and file reports as required by W.S. 35-7-1028.

Section 3. Scope

Applies to all registrants.

**Section 4.** Records and Inventory Requirements Generally.

Each registrant shall maintain the records and inventories and shall file reports as required by the Act (W.S. § 35-7-1028); the Federal Act and CFR.

- (a) Each registered manufacturer, distributor, importer, and narcotic treatment program shall maintain inventories and records of controlled substances as outlined in Chapter II Code of Federal Regulations (1304.01 forward).
- (b) Each registered individual practitioner shall keep records with respect to narcotic and non-narcotic controlled substances—II-V which he prescribes or administers. Said practitioner shall keep additional records of such substances which he dispenses, whether he charges his patients either separately or together with charges for other professional services.
- (c) Each registered pharmacy shall maintain inventories and records of controlled substances as follows:
- (i) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate written or electronic prescription file in consecutive numbers or by date.
- (ii) Inventories and records of all controlled substances listed in Schedules III-V shall be maintained separately from all other records of the pharmacy and prescriptions for such substances shall be maintained in separate written or electronic prescription files for controlled substances in consecutive numbers or by date.

- (iii) All <u>written or electronic</u> invoices for controlled substances shall be dated and signed when received by the pharmacist in charge or his/her designated agent. Invoices shall be maintained on file for two years and readily available for inspection by the Board.
- (iv) All retail and institutional pharmacies shall maintain a perpetual inventory for all Schedule II controlled substances. This inventory shall be reconciled no less than once a quarter. Discrepancies discovered during reconciliation shall be reported to the Board within ten (10) calendar days of discovery. Only those discrepancies which are considered a significant loss or gain shall be reported. For the purpose of this section, a significant loss or gain shall exist whenever the actual inventory differs from the recorded inventory by more than five percent (5%) for any drug product.
- (d) Every inventory and other records required to be kept All required records shall be kept by the registrant and be made available for at least two (2) years from the date of such inventory or record.

### **Section 5.** Inventory Requirements.

Every person registrant required to keep records shall take an physical inventory count of all stocks of controlled substances during the first seven (7) days of May of each year or other date approved by the Board.

- (a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.
- (b) A separate inventory shall be made by a registrant for each registered address. Each inventory shall be kept at the registered location for which it is taken.
- (c) A registrant may take an inventory either as of at the opening of business or as of the or close of business on the inventory date. The registrant shall indicate the time the inventory was taken on the inventory record.
- (d) An inventory must be maintained in a legible written, typewritten, or printed form.
- (e) Each registered pharmacy shall forward one (1) copy of the annual inventory to the office of the Board of Pharmacy, including the name of the pharmacy, date and time (beginning of business or close of business) the inventory was taken, and the signature of the responsible person(s).

## Section 6. Order Forms. Drug Enforcement Administration (DEA) Order Form 222.

<u>The</u> Oorder forms may be obtained only by those persons registered to handle controlled substances in Schedules I and II.

- (a) An order form may be executed only by or on behalf of the registrant named thereon and only if his registration is current.
- (b) Order forms issued by <u>the</u> DEA will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and the schedules of the registrant. This information cannot be altered or changed in any manner.
- (c) Order forms shall be prepared by use of using a typewriter, pen or indelible pencil the electronic equivalent.
- (d) A registrant may authorize another individual to obtain and execute <u>an</u> order form on his behalf by executing a power of attorney. The power of attorney shall be filed with and retained for the same period as any order form bearing the signature of the <u>attorney</u> grantor. The power of attorney shall be available for inspection.
- (e) The purchaser registrant shall submit Copy 1 and Copy 2 of the DEA order form 222 to the supplier and retain Copy 3 with his own records. The supplier shall enter the suppliers DEA registration number, number of packages shipped, and the date shipped on Copies 1 and 2. If the supplier is another local registrant (not a registrant manufacturer or distributor), Copy 2 may be forwarded directly to the DEA Regional Office or the office of the Board of Pharmacy.
- (f) The purchaser registrant shall record on Copy 3 of the order form the number of containers received on each item of the order form and the date received.
- (g) Order forms—<u>must</u> <u>and attached corresponding invoices</u> shall be maintained separately from all other records of the registrant for a period of two years. Order forms—<u>must shall</u> be available for inspection during that time.
- (h) The use of electronic 222 forms issued by the Drug Enforcement Administration The Controlled Substance Ordering System (CSOS) is authorized.

# **Section 7.** Methamphetamine Precursor Records.

- (a) The retail sale of non-liquid methamphetamine precursor drugs or liquid products with ephedrine or pseudoephedrine as the sole active ingredient shall be limited to those amounts as described specified in W.S. § 35-7-1059.
- (b) The seller shall maintain a written or electronic list of such sales (logbook) as described in W.S. § 35-7-1059.
  - (c) The sale shall be documented as follows:
- (i) The prospective purchaser shall present an photo identification card that provides a photograph and is issued by a state or the federal government, an alien registration

receipt card, a foreign passport, or an employment authorization document which contains a photograph in accordance with W.S. § 31-7-111 and W.S. § 8-7-101.

- (ii) The prospective purchaser <u>must shall</u> sign the logbook and enter in the logbook his or her name, address and the date and time of the sale.
- (iii) The seller must shall determine that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct.
- (iv) The seller must shall enter into the logbook the name of the product and the quantity sold.
- (d) The logbook must shall contain a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under 18 U.S.C. § 1001 and such notice must specify the maximum fine (\$250,000.00) and term of imprisonment (5 years).

#### 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.
- (I) 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) 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.

- (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 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.
- (c) 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.

#### ISSUING, FILING AND FILLING OF PRESCRIPTIONS

#### **CHAPTER 6**

# Section 1. Scope of Chapter 6. Authority

Rules governing the issuance, filling and filing of prescriptions pursuant to These rules are promulgated by the Wyoming Controlled Substances Act; W.S. § 35-7-1001 through 35-7-10602.

## 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 allowing 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.: and
  - (vi) Conforms to Wyoming State Statute and Board Rules and Regulations.
- (d) "Drug order" means a written or electronic order issued by an authorized practitioner, or a verbal order promptly reduced to writing, for the compounding and dispensing of a drug to be administered to patients within a facility 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, or transmission of the electronic representation of information from one computer or other similar electronic device to a fax machine, which is authenticated by an electronic signature.
- (h) "Paper prescription" means a prescription created on <u>approved security</u> paper <del>or computer generated to be printed or transmitted via facsimile</del> 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 (48 hrs).
- (j) <u>"Registrant" means any person or entity licensed to prescribe or dispense</u> controlled substances in the State.
- (k) "Security" or "secure system" means a system to which maintains the confidentiality and integrity of patient records which are being transmitted electronically.

## **Section 5.** Persons Entitled to Issue Prescriptions.

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

### **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) Effective January 1, 2007, <u>aAll</u> 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) Shall bBe 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) <u>Front side has erasure protection on green or blue background is utilized on the front side;</u>
- (C) Clear instructions printed on the paper indicating the front and back sides;
  - (D) Security warning list on the front or back of the blank;
- (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 must shall be approved by the Board. Approval will 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 <u>paper</u> 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 <u>are is</u> 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 patient name, 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 are 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 <u>or</u> <u>requested electronically</u> by the pharmacy to a practitioner for refill authorization need not be printed on security paper.
- (i) A refill request for a Schedule III-V controlled substance generated electronically and transmitted electronically by the pharmacy to a practitioner 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.
- (I) 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 considered acceptable documentation. The following information must shall be recorded on the reverse of 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.** Electronic Prescription Formats Transmission.

- (a) A pharmacist may dispense directly any legend prescription drug which requires a prescription to dispense only pursuant to the following 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) An oral A verbal prescription made by an individual practitioner or their agent and promptly reduced to hard copy writingby the pharmacist or pharmacy intern containing all information required.
- **Section 12.** Electronic <u>pPrescriptions.</u> for controlled substances shall include the requirements listed in 21 CFR § 1311 including:

- (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 electronically transmitted prescription shall only be transmitted only 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 directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to a written or electronic prescription signed by the prescribing individual practitioner, except as provided in this section.
- (b) A practitioner may administer or <u>directly</u> dispense <u>directly</u> a controlled substance listed in Schedule II <u>without a prescription if it is dispensed</u> in the course of his professional practice <u>without a prescription</u>.
- (c) In the case of an emergency situation, as defined in this section, a pharmacist may <u>directly</u> dispense a controlled substance listed in Schedule II upon receiving <u>oral verbal</u> authorization of a <u>prescribing</u> practitioner, provided that:

- (i) The quantity prescribed and dispensed is shall be limited to the amount necessary adequate 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 prescribing practitioner);
- (ii) The emergency <u>oral verbal</u> 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 <u>prescribing</u> practitioner;
- (iii) If the prescribing practitioner is not known to the pharmacist, he must the pharmacist shall make a reasonable effort to determine that the oral verbal authorization came from a registered practitioner, which may include a call back to the prescribing individual practitioner using his phone number as listed in the telephone director and/or other good faith efforts to ensure his identity; and
- (iv) Within seven (7) <u>calendar</u> days after authorizing an emergency <u>oral verbal</u> prescription, the <u>prescribing</u> 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 <u>oral verbal</u> order. The written prescription may be delivered to the pharmacist in person or by mail., <u>but if If</u> delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the <u>oral verbal</u> emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the <u>Board DEA</u> if the <u>prescribing individual practitioner</u> fails to deliver a written prescription. <u>to him. Failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing practitioner.</u>
- (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 <u>paper</u> 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 prescribing practitioner.
- (iii) The prescribing practitioner's DEA registration number may be added to a prescription drug order after consulting the prescribing practitioner or verifying the number from another reliable source.
- (iv) Required information may appear on the front or back of the <u>paper</u> prescription drug order. <u>and eComputer generated data on modifications to</u> the prescription drug order <u>satisfies these requirements are allowed</u>.
- (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 is not permitted to 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 an oral a verbal prescription of a controlled substance listed in Schedule II of the Controlled Substance Act, 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 under Schedule II of the Act; and
- (iii) That 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; Issuance of Multiple Prescriptions.

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 <a href="#cchapter"><u>Cchapter</u></a>;
- (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) 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 oral 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 oral verbal prescription. The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling.; however, ilf the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall notify the prescribing practitioner. No further quantity may be supplied beyond seventy-two (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 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) <u>Identification of the dispensing pharmacist.</u>
- (iv) The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed.
- (v) <u>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.</u>
- (c) <u>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</u>

## **Section 17.** Labeling of Substances – Schedule II.

The pharmacist filling a written, electronic, or emergency oral 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 oral verbal prescription shall be kept in accordance with requirements of Chapter 4 of these regulations 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, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to either a written or electronic prescription signed by a prescribing practitioner or an oral a verbal prescription made by a prescribing practitioner and promptly reduced to writing or electronic record. by the pharmacist containing all information required in this chapter, except for the signature of the prescribing practitioner, or an electronically transmitted prescription provided it meets all requirements in Chapter 2 of the Board's Rules and federal law, or a faxed prescription provided it meets all requirements in Chapter 2 of the Board's rules. 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 written paper prescription signed by a prescribing practitioner or his authorized agent, or pursuant to an oral a verbal prescription made by a prescribing practitioner and promptly reduced to writing by the pharmacist (containing all information required in this Chapter—6, 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 such 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, such as medication record, which indicates the date, quantity, and name of the dispensing pharmacist for each prescription and is initialed, and dated by the pharmacist are of the date of dispensing, and shall state 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 initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use, and cautionary statements, if any, contained in such prescription as required by law.

## **Section 23.** Filing Prescriptions – Schedules III and IV.

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

## **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 may 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 subject to this chapter.

#### 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:
  - (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 <a href="http://www.deadiversion.usdoj.gov/">http://www.deadiversion.usdoj.gov/</a> under Resources, Title 21 Code of Federal Regulations, Part § 1316 Subpart A-Administrative Inspections.

## **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.

#### ADMINISTRATIVE INSPECTIONS

### CHAPTER 7

# Section 1. <u>Authority.</u>

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. Procedures.

Procedures regarding administrative inspections and warrants pursuant to Section 30 and 46 of the Act (Sections 302 and 502 of the Federal Act) are governed generally by those sections and specifically by the sections of this Chapter.

## **Section 3.** Authority to Make Inspections.

In carrying out their functions under the Act, the Board, and the Commissioner, and their duly authorized agents are authorized in accordance with Section 46 of the Act (Section 502 of the Federal Act) to enter controlled premises and conduct administrative inspections thereof, for the purpose of:

- (a) <u>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.</u>
- (b) <u>Inspections shall be done in accordance with Title 21 Code of Federal</u> Regulations:
  - (c) Incorporation by Reference:
- (i) <u>Title 21 Chapter II Drug Enforcement Administration, Department of</u> 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 <a href="http://www.deadiversion.usdoj.gov/">http://www.deadiversion.usdoj.gov/</a> under Resources, Title 21 Code of Federal Regulations, Part § 1316 Subpart A-Administrative Inspections.
- (d) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and regulations promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to Chapter 4 of these regulations, prescription and distribution records required to be kept pursuant to Chapter 6 of these regulations; shipping records identifying the name of each carrier used, and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage.
- (e) Inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finishe3d and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to this Act;'
- (f) Making a physical inventory of all controlled substances on hand at the premises;
- (g) Collecting samples of controlled substances or precursors (in the event any samples are collected during an inspection, the authorized agent shall issue a receipt for such samples) to the owner, operator, or agent in charge of the premises;
- (h) Checking of records and information on distribution of controlled substances by the registrant as they relate to total distribution of the registrant (i.e., has the distribution in controlled substances increased markedly within the past year, and if so, why?); and
- (i) Except as provided in Section 3, all other things therein (including records, files, papers, processes controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the regulations thereunder.

### Section 4. Exclusion from Inspection.

Unless the owner, operator or agent in charge of the controlled premises so consents in writing, no inspection authorized by these regulations shall extend to:

- (a) Financial data;
- (b) Sales data other than shipping data; or
- (c) Pricing data.

### Section 5. Entry.

An inspection shall be carried out by an authorized agent. Any such authorized agent, upon (a) stating his purpose, and (b) presenting to the owner, operator, or agent in charge of the premises to be inspected (1) appropriate credentials, and (2) written notice of his inspection authority under Section 5 of these regulations, and (c) receiving informed consent under Section 7 or through the use of administrative warrant issued under Sections 8 through 13 shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

## **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 Section 46 of the Act (Section 502 of the Federal Act) W.S. § 35-7-1024;
- (f) A reproduction of the pertinent parts of W.S. § 35-7-1024 Section 46 of the Act (Section 502 of the Federal Act); and
  - (g) The signature of the authorized agent.

### Section 5. Requirement for Administrative Inspection Warrant; Exceptions.

In all cases where an inspection is contemplated, an Administrative Inspection Warrant is required pursuant to Section 46 of the Act (Section 502 of the Federal Act), except that such warrant shall not be required for establishments applying for initial registration under the Act, for the inspection of books and records pursuant to an administrative subpoena issued in accordance with the Wyoming Administrative Procedures Act, Section 16-3-107, nor for entries in administrative inspections (including seizures of property):

- (a) With the consent of the owner, operator, or agent in charge of the controlled premises as set forth in Section 7;
  - (b) In situations presenting imminent danger to health or safety;
- (c) In situations involving inspection of conveyances where there is reasonable cause to obtain a warrant;

- (d) In any other exceptional or emergency circumstance or time or opportunity to apply for a warrant is lacking; or (e) In any other situations where a warrant is not constitutionally required. **Section 6.** Consent to Inspection. (a) — An Administrative Inspection Warrant shall not be required if informed consent is obtained from the owner, operator, or agent in charge of the controlled premises to be inspected. (b) — Whenever possible, informed consent shall consist of a written statement signed by the owner, operator, or agent in charge of the premises to be inspected and witnessed by two persons. The written consent shall contain the following information: That he (the owner, operator, or agent in charge of the premises) has been informed of his constitutional right not to have an administrative inspection made without an Administrative Inspection Warrant; (ii) That he has a right to refuse to consent to such an inspection; (iii) That anything of an incriminating nature which may be found may be seized and used against him in a criminal prosecution; (iv) That he has been presented with a notice of inspection as set forth in Section 5: (v) That the consent given by him is voluntary and without threats of any kind; and (vi) That he may withdraw his consent at any time during the course of inspection. The written consent shall be produced in duplicate and be distributed as follows: (A) The original will be retained by the authorized agent; (B) The duplicate will be given to the person inspected. **Section 7.** Application for Administrative Inspection Warrant. —An Administrative Inspection Warrant application shall be submitted to any
- District Court Judge or District Court Commissioner and shall contain the following information:
  - (i) The name and address of the controlled premises to be inspected;
- (ii) A statement of statutory authority for the Administrative Inspection Warrant, and that the fact that the particular inspection in question is designe3d to ensure compliance with the Act and the regulations promulgated thereunder;

(iii) A statement relating to the nature and extent of the administrative inspection, including, where necessary, a request to seize specified items and/or to collect samples of finished or unfinished controlled substances;

- (iv) A statement that the establishment either:
  - (A) Has not been previously inspected, or
  - (B) Was last inspected on a particular date.
- (b) The application shall be submitted under oath to an appropriate judge or magistrate.

### **Section 8.** Administrative Probable Cause.

If the District Judge or District Court Commissioner is satisfied that "administrative probable cause," as defined in Section 46 (a)(i) of the Act (Section 502(a)(1) of the Federal Act) exists, he shall issue an administrative warrant. Administrative probable cause shall not mean criminal probable cause as defined by State or Federal statute or case law.

#### **Section 9.** Execution of Warrants.

An Administrative Inspection Warrant shall be executed and returned as required by, and any inventory or seizure made shall comply with the requirements of Section 46(a)(iii) of the Act (Section 502(a)(i) of the Federal Act). The inspection shall begin as soon as is practicable after the issuance of the Administrative Inspection Warrant and shall be completed with reasonable promptness. The inspection shall be conducted during regular business hours and shall be completed in a reasonable manner.

### **Section 10.** Refusal to Allow Inspection with an Administrative Warrant.

If a registrant or any person subject to the Act refuses to permit execution of an Administrative Warrant or impedes the authorized agent in the execution of that warrant, he shall be advised that such refusal or action constitutes a violation of Section 32(a)(iv) of the Act (Section 404 (a)(4) of the Federal Act). If he persists and the circumstances warrant, he shall be arrested and the inspection shall commence or continue.

### 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.** 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 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) Days supply dispensed;
  - (x) NDC code number for drug dispensed;
  - (xi) Prescriber identification number;

- (xii) Patient last name;
- (xiii) Patient first name;
- (xiv) Patient street address;
- (xv) Patient zip code; and
- (xvi) 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 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.

#### **Section 5.** 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 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) The Board staff verifies current licensure, current WY Controlled Substance Registration and DEA number of the pharmacy or practitioner;
  - (iii) The Board staff activates the online access;
- (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 6.** 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 7.** 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.

## **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 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.

#### 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 -11011060.

## Section 2. Purpose.

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

## **Section 3.** Scope.

Applies to all registrants.

**Section 4.** Transmission of information regarding dispensing of controlled substances to certain persons.

- (a) Each resident/nonresident retail pharmacy that dispenses a controlled substance that is listed in Schedule II, III or IV 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 <u>following</u> required information: If the retail pharmacy does not dispense more than 25 controlled substance prescriptions per month to patients residing in this state, the retail pharmacy may request a waiver from the Board. The information relating to the following field names shall be transmitted:
  - (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) Days supply dispensed;
  - (x) NDC code number for drug dispensed;

- (xi) Prescriber identification number;
- (xii) Patient last name;
- (xiii) Patient first name;
- (xiv) Patient street address;
- (xv) Patient zip code; and
- (xvi) 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 shall ensure that, not later than seven (7) days after the prescription was dispensed 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.

### **Section 5.** Solicited Patient Profiles.

- (a) Occupational licensing boards may request licensee profiles from the Board provided the following are met:
- (i) All requests must 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 of the authorized agent 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; and

- (v) No licensee profile will be generated by the Board until the request is received, and no licensee profile will be sent to an occupational licensing board unless those requirements identified in W.S. § 35-7-1060 (c)(ii) have been met. All profiles generated by the Board will be mailed 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 <u>a regulatory</u> <u>an occupational licensing</u> 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 <u>paper</u> requests must be submitted on a form provided by the Board and must be mailed or faxed;
- (ii) All <u>paper</u> 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 <u>paper</u> requests must include the DEA registration number for the pharmacy or practitioner;
- (iv) All <u>paper</u> requests shall include the patient's name, date of birth, <u>purpose</u> of the request, and the date range for the profile <u>and address</u>;
- (v) All <u>paper</u> 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 or mailed to the pharmacist or practitioner at their business address, and if mailed marked "confidential, to be opened by addressee only;".
- (c) Pharmacists, and 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 online electronic requests:
- (i) The pharmacist or practitioner or their appointed delegate must first registers for access to the online system (WORx) using the online registration;
- (ii) The Board staff will verify verifies current licensure, current WY Controlled Substance Registration and DEA number of the pharmacy or practitioner;
  - (iii) The Board staff will activate activates the online access;

- (iv) The Board staff shall discontinue access to any pharmacist or practitioner whose license, DEA registration or WY Controlled Substance Registration has lapsed or been revoked or suspended;
- (iv) The Board staff shall discontinue access to any pharmacist or practitioner who fails to follow the regulations listed in this chapter of W.S. § 35-7-1060 The practitioner or pharmacist-in-charge (PIC) determines the competency of their appointed delegates before allowing registration in WORx;
- (v) <u>Practitioner appointed delegates shall be authorized agents of the practitioner:</u>
- (A) <u>A delegate registered under one practitioner may perform</u> searches on behalf of other practitioners;
  - (B) <u>Each registered practitioner may appoint up to two (2) delegates;</u>
- (C) The practitioner shall be responsible for the actions of their appointed delegates; and
- (D) <u>The practitioner shall terminate the delegate's access in the WORx system when the appointment has ended.</u>
- (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) <u>A delegate registered under one PIC may perform searches on</u> 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's office provided the following are met:
- (i) All requests shall be made in person at the Board's office. The patient requesting the profile or an the authorized agent of the patient or parents or guardians of minors requesting a profile must have proof of identification acceptable to the Board staff; and
- (ii) Any person making a request for a profile shall complete a form provided by the Board. Any profile generated by the Board staff will be available at the Board's office the same day of the request.
- (g) Other entities as authorized in W.S. § 35-7-106059 may request a copy of the patient's profile from the Board's 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's office;
- (ii) All requests must be signed by the requestor and include the business name and address-of the requestor;
- (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 6.** Unsolicited Patient Profiles.

The Board staff may generate patient profiles based on information showing use of controlled substances, which is in excess of 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 7.** Reports.

- (a) The 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 the following:
  - (i) Date <u>request</u> 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 individual requesting the profile 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 the following:
  - (i) Date generated;
  - (ii) Criteria used for profile generation; and
  - (iii) Number of profiles/cover letters mailed.

### **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 shall ensure that, not later than 7 daysthe 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. for prescription drugs no listed as controlled substances, if formally requested by the Board. As of July 1, 2017 the Board requires the reporting of:

- (a) <u>Gabapentin;</u>
- (b) <u>Cyclobenzaprine</u>; and
- (c) <u>Naloxone.</u>