



## Notice of Intent to Adopt Rules

Revised July 2013

### 1. General Information

a. Agency/Board Name Wyoming State Board of Pharmacy		
b. Agency/Board Address 1712 Carey Avenue Suite 200	c. City Cheyenne	d. Zip Code 82002
e. Name of Contact Person Mary K. Walker	f. Contact Telephone Number 307-634-9636	
g. Contact Email Address mary.walker@wyo.gov		
h. Date of Public Notice September 16, 2013	i. Comment Period Ends November 4, 2013	
j. Program		

### 2. Rule Type and Information: For each chapter listed, indicate if the rule is New, Amended, or Repealed.

If "New," provide the Enrolled Act numbers and years enacted:

a. Provide the Chapter Number, Short Title, and Rule Type of Each Chapter being Created/Amended/Repealed  
Please use the Additional Rule Information form for more than 10 chapters, and attach it to this certification.

Chapter Number:	Short Title:	<input type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
1	Authority and Definitions	<input type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
2	General Information	<input type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
3	Fees for Registration and Re-Registration	<input type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
5	Rules of Practice and Procedure	<input type="checkbox"/> New <input type="checkbox"/> Amended <input checked="" type="checkbox"/> Repealed
6	Issuing, Filing and Filling of Prescriptions	<input type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
8	Prescription Drug Monitoring Program	<input type="checkbox"/> New <input checked="" type="checkbox"/> Amended <input type="checkbox"/> Repealed
		<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed
		<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed
		<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed
		<input type="checkbox"/> New <input type="checkbox"/> Amended <input type="checkbox"/> Repealed

c.  The Statement of Reasons is attached to this certification.

d.  N/A     In consultation with the Attorney General's Office, the Agency's Attorney General representative concurs that strike and underscore is not required as the proposed amendments are pervasive (Section 5 of the Rules on Rules).

e. A copy of the proposed rules\* may be obtained:

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

At the following URL: http://pharmacyboard.state.wy.us

\* If Item "d" above is not checked, the proposed rules shall be in strike and underscore format.

### 3. Public Comments and Hearing Information

a. A public hearing on the proposed rules has been scheduled.  Yes  No

If "Yes:"	Date: November 5, 2013	Time: 1:00 p.m.	City: Casper	Location: 951 N. Poplar Room 114
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b. What is the manner in which interested persons may present their views on the rulemaking action?

- By submitting written comments to the Agency at the physical and/or email address listed in Section 1 above.  
 At the following URL: \_\_\_\_\_

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

- To the Agency at the physical and/or email address listed in Section 1 above.  
 At the following URL: \_\_\_\_\_

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

### 4. Federal Law Requirements

a. These rules are created/amended/repealed to comply with federal law or regulatory requirements.  Yes  No

If "Yes:"	Applicable Federal Law or Regulation Citation: 21 CFR Part 1300 to End
	Indicate one (1): <input checked="" type="checkbox"/> The proposed rules meet, but do not exceed, minimum federal requirements. <input type="checkbox"/> 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: <input checked="" type="checkbox"/> To the Agency at the physical and/or email address listed in Section 1 above. <input type="checkbox"/> At the following URL: _____

### 5. State Statutory Requirements

a. Indicate one (1):

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

b. Indicate one (1):

- The Agency has complied with the requirements of W.S. 9-5-304. A copy of the assessment used to evaluate the proposed rules may be obtained:  
 By contacting the Agency at the physical and/or email address listed in Section 1 above.  
 At the following URL: \_\_\_\_\_  
 Not Applicable.

### 6. Authorization

a. I certify that the foregoing information is correct.

Printed Name of Authorized Individual	Mary K. Walker
Title of Authorized Individual	Executive Director
Date of Authorization	September 16, 2013

#### Distribution List:

- Attorney General and LSO: Hard copy of Notice of Intent; Statement of Reasons; clean copy of the rules; and strike-through and underline version of rules (if applicable). *Optional:* electronic copies of all items noted (in addition to hard copies) may be emailed to LSO at [Criss.Carlson@wvleg.gov](mailto:Criss.Carlson@wvleg.gov).
- Secretary of State: Electronic version of Notice of Intent sent to [Rules@wyo.gov](mailto:Rules@wyo.gov).



Randolph A. (Randy) Harrop, RPh, President  
Bessie S. McGirr, RPh, Vice President  
John R. McPherson, DDS, Secretary/Treasurer  
Charles W. Smith, Public Member  
Stephanie McAntee, RPT, Member, Ex-Officio  
Kerri J. Kilgore, RPh, Member  
Jim Massengill, RPh, Member  
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Mary K. Walker, RPh, Executive Director  
H. Richard Burton, 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

*September 2013*

All 8 chapters have been reviewed and revisions are proposed to reduce the number, the length, and the complexity of rules and regulations whenever possible. Each chapter has 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 proposed rules meet minimum substantive state statutory requirements.

The proposed rules address the following:

Chapter 1 (Authority/Definitions) has revisions to definitions and wording that are outdated.

Chapter 2 (General Information) has been updated for investigating complaints, holding hearings, and disciplinary processes. The title will be changed to "Hearings".

Chapter 3 (Fees for Registration and Re-registration) has had language regarding investigations and hearings moved to Chapter 2.

Chapter 5 (Rules of Practice and Procedure) is proposed to be REPEALED because the investigations and hearings regulations are moved to Chapter 2.

Chapter 6 (Issuing, Filling and Filing of Prescriptions) has proposed revisions to allow for multiple prescriptions for Schedule II controlled substances to meet federal regulations, to identify patients who present at the pharmacy with controlled substance prescriptions (moved from Chapter 2 of the Rules/Regulations of the WY Pharmacy Act), and to clarify what a pharmacist can change on a Schedule II prescription.

Chapter 8 (Prescription Drug Monitoring Program) has updated processes for using the online access to the database "WORx".



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## NOTICE OF INTENT TO ADOPT RULES AND REGULATIONS

*September 17, 2013*

Agency: Wyoming State Board of Pharmacy  
Address: 1712 Carey Avenue Suite 200  
Cheyenne, WY 82002  
Contact person: Mary K. Walker, Executive Director  
Telephone: 307-634-9636  
Email: [BOP@wyo.gov](mailto:BOP@wyo.gov)

Statement of Principal Reasons for Revisions, Wyoming Pharmacy Act Rules and Regulations (see "items of interest" at <http://pharmacyboard.state.wy.us> )

Statement of Principal Reasons for Revisions, Wyoming Controlled Substances Act (see "items of interest" at <http://pharmacyboard.state.wy.us>)

**PUBLIC COMMENTS WILL BE TAKEN IN WRITING BY EMAIL OR POSTAL SERVICE UNTIL 5:00 p.m. on NOVEMBER 4, 2013**

**A PUBLIC HEARING IS TO BE HELD IN CASPER, WY, AT 951 NORTH POPLAR, ROOM 114, BEGINNING AT 1:00 p.m. ON NOVEMBER 5, 2013**

A copy of the proposed revisions to existing rules in a format that clearly indicates additions to and deletions from existing language may be obtained at the Board's office at the above address, or website at <http://pharmacyboard.state.wy.us>

## CHAPTER 1

### AUTHORITY AND DEFINITIONS

Section 1. Authority. These rules and regulations are adopted as authorized by the Wyoming Administrative Procedure Act, W.S. 16-3-101 through 16-3-115; and the Wyoming Controlled Substances Act, W.S. 35-7-1001 through 35-7-1055.

Section 2. Definitions. As used herein, the following terms shall have the meanings specified:

(a) The term "Act" means the Wyoming Controlled Substances Act.

~~(b) The term "basic class" means, as to controlled substances listed in Schedules I and II:~~

~~(i) Each of the opiates, including its isomers, ethers, esters, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, salts and synthetic substances is possible within specific chemical designation listed in Section 14(b) of the Act;~~

~~(ii) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers and synthetic substances is possible within specific chemical designation listed in Section 14(b) of the Act.~~

~~(iii) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers and synthetic substances is possible within the specific chemical designation listed in Section 14(d) of the Act.~~

~~(iv) Each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:~~

~~(A) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;~~

~~(B) Apomorphine;~~

~~(C) Codeine;~~

~~(D) Ethylmorphine;~~

~~(E) Hydrocodone;~~

~~(F) Hydromorphone;~~

~~(G) Metopon;~~

~~(H) Morphine;~~

~~(I) Oxycodone;~~

~~(J) Oxymorphone;~~

~~(K) Thebaine;~~

~~(L) Mixed alkaloids of opium;~~

~~(M) Cocaine; and~~

~~(N) Ecgonine;~~

~~(v) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers and salts is possible within specific chemical designation;~~

~~(vi) Methamphetamine, including its salts, isomers and salts of isomers;~~

~~(vii) Amphetamine, its salts, optical isomers and salts of its optical isomers;~~

~~(viii) Phenmetrazine and its salts; and~~

~~(ix) Methylphenidate.~~

(c) The term "Bureau" means the Drug Enforcement Administration, United States Department of Justice.

~~(d) The term "controlled premises" means—~~

~~(i) Places where records or documents required under the Act are kept or required to be kept, and~~

~~(ii) Places, including conveyances, where persons registered or exempted from registration under the Act may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances and are permitted to handle controlled substances.~~

~~(e) The term "Director" means the Director of the Bureau. The Director has been delegated authority under the Controlled Substances Act of 1970 (84 Stat. 1242, 21 U.S.C. 801) by the Attorney General (28 C.F.R. 0.100).~~

~~(f) The term "Drug Dependent Person" means a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both arising from the use of that substance on~~

~~a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.~~

~~(g) — The term "hearing" means any hearing held pursuant to these regulations for the granting, denial, revocation or suspension of a registration pursuant to Sections 24 and 25 (302 of the Federal Act) and 27 (304 of the Federal Act).~~

~~(h) — The term "hospital" means an institution for the care and treatment of the sick and injured, approved by the Department of Health and Social Services as proper to be entrusted with the custody of controlled substances and the preferential use of controlled substances and the preferential use of controlled substances under the direction of the practitioner.~~

~~(i) — The term "laboratory" means a laboratory approved by the Board or its authorized agent as proper to be entrusted with the custody of controlled substances and the use of controlled substances for scientific and medical purposes and for purposes of instruction, administered by a person registered by the Board to possess such substances.~~

(j) The term "person" includes any individual, corporation, government or governmental subdivision or agency business trust, partnership, association or other legal entity.

(k) The term "pharmacist" means any pharmacist licensed by the Board to dispense controlled substances, and shall include any other person (e.g., a pharmacist intern) authorized by the Board to dispense controlled substances under the immediate supervision of a pharmacist licensed by the Board.

(l) The term "prescription" means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (E.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

~~(m) — The terms "register and "registration" refer only to registration required and permitted by Section 24 and 25 of the Act. (Section 303 of the Federal Act.)~~

(n) The term "registrant" means any person who is registered pursuant to either Sections 24 and 25 of the Act or Section 302 of the Federal Act.

~~(o) — Any term not defined in this section shall have the definition set forth in Section 2 of the Act. (Section 101 of the Federal Act.)~~

Section 3. Principal Reasons for Adoption of Rules. The adoption of rules requiring registration of persons engaged in the manufacture, distribution or dispensing of controlled substances is deemed to be in the public's interest in the regulation of such activities.

To implement such regulation the rules specifically provide for and establish:

- (a) Requirements pertaining to registration of persons manufacturing, distributing and dispensing controlled substances, and provide for exemption from registration designated classes.
- (b) Requirements relating to maintaining records of inventories and safeguarding inventories.
- (c) Requirements governing the issuing, filing and filling of prescriptions containing controlled substances.
- (d) Procedures for Administrative Inspection of inventories and records.
- ~~(e) Rules of Practice and Procedure Governing Hearings held pursuant to the rules adopted.~~



## CHAPTER 2

### GENERAL INFORMATION HEARINGS

#### ~~Section 1. — Controlled Substances Code Number.~~

~~(a) — Each controlled substance, or basic class thereof, listed in Schedules I through IV has been assigned a "Controlled Substances Code Number" by the Bureau for purposes of identification of the substance or class. The Controlled Substances Code Numbers assigned by the Bureau as set forth in Vol. 36, No. 80, Federal Register, Part 308, page 7802, are hereby adopted for the purposes of these Rules. On certain Certificates of Registration issued by the Bureau pursuant to the Federal Controlled Substances Act of 1970 and the rules and regulations promulgated thereunder, certain applicants for registration must include the appropriate numbers on the application as required by Federal Law.~~

~~(b) — Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Controlled Substances Code Number for any purpose.~~

#### ~~Section 2. — Application for Exception of a Stimulant or Depressant Compound.~~

~~(a) — Any person seeking to have any compound, mixture, or preparation containing any depressant or stimulant substance listed in Section 18(c) or Section 20 of the Act excepted from the application of all or any part of the Act pursuant to Section 18(f) or Section 20 (-) of the Act may apply to the Board for such exception.~~

~~(b) — An application for an exception under this section shall contain the following information:~~

~~Evidence that an exception has been granted by the Bureau under Section 202(d) of the Federal Controlled Substances Act (21 U.S.C. 812(d)).~~

~~(c) — The Board may at any time revoke, suspend, or deny any exception granted pursuant to Sections 18(f) or 20(c) of the Act upon written notice specifying the reason or reasons for revocation, suspension, or denial. The person receiving such notice shall have ten (10) days in which to request a hearing which will be conducted in accordance with the Rules of Practice and Procedure governing hearings, Chapter 5.~~

#### Section 3.1. Hearings Generally.

In any case where the Commissioner, or his designee shall hold a hearing on the issuance, amendment, or repeal of rules pursuant to ~~Section 11~~ of the Act, the procedures for such hearing and accompanying proceedings shall be governed generally by the rule making procedures set forth in the Wyoming Administrative Procedure Act ~~and specifically by Section 11 of the Act.~~

#### Section 4.2. Burden of Proof.

At any hearing held under the provisions ~~of Section 11~~ of the Act, the proponent for the issuance, amendment, or repeal of any rule or regulation shall have the burden of proof.

Section ~~5.3~~. Control Required by Statute.

(a) In the event that the Bureau has published in the Federal Register a final order designating, rescheduling, or deleting any substance as a controlled substance under the Federal Controlled Substances Act (21 U. S. C., 811), the Commissioner, pursuant to Section 11(d) of the Act may either:

(i) Within thirty (30) days after the publication of the final order in the Federal Register, object to designating, rescheduling, or deleting the substance in the same manner under the Act, or

(ii) After thirty (30) days following the publication of the final order in the Federal Register, issue a final order designating, rescheduling, or deleting the substance in the same manner without regard to findings required under Section 11(b) of the Act.

(b) In the event that the Commissioner objects to designating, rescheduling, or deleting the substance in the same manner as the Bureau, the Commissioner shall promptly notify all persons who have previously requested in writing, notification of such action. Such notice shall contain the reasons for the objection. Thereafter, the Commissioner shall hold a hearing as required by Section 11(d) of the Act. Such hearing shall conform as nearly as practicable to the provisions of the Wyoming Administrative Procedure Act regulating the adoption, amendment, or repeal of rules.

**Section 4. Complaints.**

(a) A disciplinary action is initiated against a license holder by submitting a written complaint to the Board office. A complaint concerning an alleged violation of the Act or Board Rules may be submitted by any person or entity, a Board member, or a Board staff member. The written complaint should provide as much of the following information as may be available and applicable:

(i) The name and address of the complainant;

(ii) The name, address, place of employment, and telephone number of the license holder against whom the charges are made;

(iii) The specific conduct alleged to constitute the violation;

(iv) The name and address of any other witnesses; and

(v) The signature of the complainant.

## Section 5. Review of Written Complaint.

(a) Written complaints shall be referred to the Board staff Compliance Officer/Investigator or to an Investigative Board Member (IBM) selected by Board staff from a rotating schedule. License holders against whom charges are made will be advised of the investigation and the nature of the complaint.

(i) The IBM shall not take part in the consideration of any contested case.

(ii) The IBM shall not, by this rule, be barred from attending any disciplinary hearing.

Section 6. Investigations and Board Action. Board staff shall investigate those written complaints received which merit further investigation.

(a) Upon completion of the investigation the Executive Director shall:

(i) Dismiss the complaint if no evidence of violation of the Act or Board rules is found; or

(ii) Prepare an investigative report which shall include:

(A) The findings;

(B) A list of statutes and/or Board rules believed to have been violated;  
and

(C) Any relevant additional information.

(b) The Executive Director shall forward the report and his/her recommendations to the Assistant Attorney General assigned to the Board for prosecution, and consult with the Assistant Attorney General.

(c) Following consultation with the Assistant Attorney General, the Executive Director may:

(i) Send the notice required by Section 5;

(ii) Prepare and file a formal petition and notice of hearing setting the matter for a contested case hearing before the Board;

(iii) Recommend the Board accept an offer of conditional terms for settlement, which may include educational courses;

(iv) Recommend the Board dismiss the complaint.

(d) The Board may resolve a complaint at any time by:

(i) Accepting a voluntary surrender of a license;

(ii) Accepting conditional terms for settlement;

(iii) Dismissal.

### **Section 7. Service of Notice and Opportunity to Show Compliance.**

Prior to commencement of a formal hearing, the IBM Executive Director shall give notice by mail to the license holder of the facts or conduct which warrant his/her intended action. The notice shall give the license holder an opportunity to show compliance with all lawful requirements for retention of the license within twenty (20) days of the mailing of the notice. Such notice shall be sent to the license holder's last known address both by certified mail with return receipt requested and by first class mail.

### **Section 8. Formal Hearing Procedures Prerequisites.**

(a) Formal proceedings for a hearing before the Board regarding action against a license holder shall be commenced by petition and notice of hearing, served in person, or by both certified mail and first class mail sent to the address last known by the Board at least thirty (30) days prior to the date set for the hearing. The petition and notice shall contain at least:

(i) The name and address of the license holder;

(ii) A statement, in ordinary and concise language, of the nature of the complaint filed with the Board, the facts upon which the complaint is based, as well as the specific statute(s) or Board rules and regulations alleged to have been violated;

(iii) The time, place, and nature of the hearing;

(iv) That the hearing is being held pursuant to the authority provided by W.S. § 33-24-101 through 33-24-301.

(v) The license holder shall file an Answer or Notice of Appearance, which must be received by the Board at least ten (10) working days prior to the date set for hearing, or the license holder will be in default.

**Section 9. Default.** The Board may enter an order based on the allegations in a petition in any case where the applicant or license holder has not answered or appeared in writing ten (10) working days before the hearing, or in any case in which the applicant or license holder or his/her representative has not appeared at a scheduled hearing for which they had notice.

**Section 10. Contested Case Hearings.** The Office of Administrative Hearings shall act as the hearing officer and shall preside over the formal contested case hearing which shall be conducted pursuant to the Wyoming Administrative Procedure Act and the Office of Administrative Hearings' rules concerning contested case proceedings.

(b) At the Board's discretion, contested case hearings shall either be conducted in the presence of a quorum of Board Members or a committee of one (1) or more Board Members.

(c) During the formal contested case hearing, Board Members may ask questions of the witnesses and/or the parties including their attorneys.

(d) A court reporter shall be present during the hearing and report the entire proceeding.

### **Section 11. Decisions.**

#### (a) Proposed Decisions:

(i) At the discretion and direction of the ~~Board~~ hearing officer, the parties may file proposed findings of fact, conclusions of law, and order after the hearing and before the deadline announced in the hearing's closing announcements.

(ii) At the discretion and direction of the Board, the hearing officer or the Assistant Attorney General assigned to advise the Board shall prepare proposed findings of fact, conclusions of law, and order following deliberations by the Board or its committee.

(b) Final Decisions. Proposed decisions will be given consideration but are not binding upon the Board. All final decisions will be issued by the Board and shall be based exclusively upon the evidence in the record and matters officially noticed. All final decisions issued by the Board shall be served to all parties by first class mail sent to their last known address.

**Section 12. Appeals.** A Petition for Judicial Review of the Board decision may be filed in the district court in accordance with the Wyoming Rules of Appellate Procedure.

**Section 13. Transcripts.** If a Petition for Judicial Review is filed in the district court, the petitioner shall either arrange the preparation and pay for the transcript of the testimony, or reimburse the Board for the cost of the transcript if previously prepared at Board expense.

## CHAPTER 3

### FEES FOR REGISTRATION AND RE-REGISTRATION

#### Section 1. Fee Amounts.

(a) For each registration or re-registration to manufacture controlled substances, the registrant shall pay a fee of \$250.00.

(b) For each registration or re-registration to distribute controlled substances, the registrant shall pay a fee of \$250.00

(c) For each registration or re-registration to dispense, or to conduct research or instructional activities with controlled substances listed in Schedules II through V, the registrant shall pay a fee of \$40.00 per year.

(d) For each registration or re-registration to conduct research or instructional activities with a controlled substance listed in Schedule I, the registrant shall pay a fee of \$40.00 per year.

(e) For each registration or re-registration to conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee of \$40.00 per year.

(f) Any Federal, State, or local governmental agency may be exempted in the discretion of the Board from the payment of a registration fee under this section.

#### Section 2. Time and Method of Payment; Delinquency Fee; Refund.

Registration and re-registration fees shall be paid at the time when the application for registration or re-registration is submitted for filing. Payment shall be made in the form of a personal, certified, or cashier's check or money order, or credit card using the online renewal process, made payable to the Wyoming State Board of Pharmacy. A delinquency fee of \$40.00 shall be assessed against any registrant that does not re-register by June 30th of that renewal period. In the event that the application is not accepted for filing or is denied, the payment shall be refunded to the applicant. If the check is returned for any reason, the registration issued to the applicant shall be deemed invalid.

#### Section 3. Persons Exempt from Fee.

(a) The Board may exempt from payment of a fee for registration or re-registration the following persons:

(i) Any official or agency of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans' Administration or Public Health Service who or which is authorized to procure or purchase controlled substances for official use; and

(ii) Any official, employee, or other civil officer or agency of the United States, of any State, or any political subdivision or agency thereof, who or which is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct research, instructional activities, or chemical analysis with such substances, or any combination thereof, in the course of his or its official duties or employment.

(b) Exemption from payment of a registration or re-registration fee does not relieve the registrant of any other requirements of duties prescribed by law.

## REQUIREMENT OF REGISTRATION

### Section 4. Persons Required to Register.

Every person who manufactures, distributes, prescribes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, prescribing or dispensing of any controlled substance shall obtain annually a registration unless exempted by law or by the regulations. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder of a parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

### Section 5. Separate Registration for Independent Activities.

- (a) The following six groups of activities are deemed to be independent of each other:
- (i) Manufacturing controlled substances;
  - (ii) Distributing controlled substances;
  - (iii) Dispensing, conducting research with (other than research described in subparagraph (4) of this paragraph), and conducting instructional activities with controlled substances listed in Schedules II through V;
  - (iv) Conducting research with narcotic drugs listed in Schedules II through V for the purpose of continuing the dependence on such drugs of a narcotic drug dependent person in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program pursuant to a Notice of Claimed Investigational Exemption for a New Drug approved by the Food and Drug Administration;
  - (v) Conducting research and instructional activities with controlled substances listed in Schedule I; and
  - (vi) Conducting chemical analysis with controlled substances listed in any



schedule.

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph.

(i) A person registered to manufacture any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture;

(ii) A person registered to manufacture any controlled substance listed in Schedules II through V shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(iii) A person registered to conduct research with a basic class of controlled substance listed in Schedule I shall be authorized to manufacture such class if and to the extent that such manufacture is set forth in the research protocol filed with the application for registration and to distribute such class to other persons registered to conduct research with such class or to conduct chemical analysis;

(iv) A person registered to conduct chemical analysis with controlled substance shall be authorized to manufacture such substances for analytical or instructional purposes, to distribute such substances to other persons registered to conduct chemical analysis or instructional activities, to persons registered or authorized to conduct research with such substances, and to conduct instructional activities with controlled substances;

(v) A person registered or authorized to conduct research (other than research described in paragraph (a) (4) of this section) with controlled substances listed in Schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research to manufacture is set forth in a statement filed with the application for registration, and to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to conduct instructional activities with controlled substances;

(vi) A person registered to dispense, or to conduct research (other than research described in paragraph (a) (4) of this section) with controlled substances listed in Schedules II through V shall be authorized to dispense and to conduct such research and to conduct instructional research with those substances.

(c) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substance listed in Schedule I for which he has filed and had approved a research protocol.

Section 6. Separate Registrations for Separate Locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(i) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of subsection 24(c)(ii) of the Act;

(ii) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes of lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

(iii) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

Section 7. Exemption of Agents and Employees; Affiliated Practitioners.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his business or employment.

(b) A practitioner (other than an intern, resident, or foreign physician) who is an agent or employee of another practitioner registered to dispense controlled substances may, when acting in the usual course of his employment, administer, and dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he practices, under the registration of the employer or principal practitioner in lieu of being registered himself. (For example, a pharmacist employed by a pharmacy need not be registered individually to fill a prescription for controlled substances if a pharmacy is so registered.)

(c) A practitioner who is an intern, resident, or foreign physician may dispense and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom he is employed provided that:

(i) Such dispensing or prescribing is done in the usual course of his professional practice;

(ii) Such individual practitioner is authorized or permitted to do so by the laws of the State of Wyoming;

(iii) The hospital or other institutions by whom he is employed has determined that the practitioner is so permitted to dispense or prescribe drugs by the State of Wyoming;

(iv) Such practitioner is acting only within the scope of his employment in the hospital or institution;

(v) The hospital or other institution authorizes the intern, resident, or foreign physician to dispense or prescribe under the hospital registration and designates a specific internal code number for each intern, resident, or foreign physician so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., AP 0123456-10 or AP 0123456-A12;

(vi) A current list of internal codes and the corresponding practitioner is kept by the hospital or other institution and is made available to the public upon request for the purpose of verifying the authority of the prescribing practitioner.

#### Section 8. Exemption of Certain Military and Other Personnel.

(a) The requirement of registration is waived for any official of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his official duties. Such officials when issuing a prescription shall state the branch of service or agency (e.g., "U. S. Army" or "Public Health Service") and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his Social Security identification number.

(b) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities.

#### Section 9. Exemption of Law Enforcement Officials.

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(i) Any officer or employee of the Drug Enforcement Administration, any officer of the United States Bureau of Customs, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his official duties; and

(ii) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State of local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his official duties.

(b) Any official exempted by this section may, when acting in the course of his official duties, possess any controlled substance and distribute any such substance to any other official who is also exempted by this section and acting in the course of his official duties.

(c) Any official exempted by this section may procure any controlled substance in the course of an inspection, in accordance with Section 46 of the Act, or in the course of any criminal investigation involving the person from whom the substance was procured.

(d) In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories must obtain annually a registration to conduct chemical analysis. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this section and within the activity described in Section 50(c) of the Act. (Section 515(d) of the Federal Act.) For purposes of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section.

#### Section 10. Exemption of Civil Defense Officials.

(a) The requirement of registration is waived for any official of a civil defense or disaster relief organization who, in the course of his official duties, is authorized to:

(i) Maintain, and distribute for such maintenance, controlled substances held for emergency use; or

(ii) Procure controlled substances for the purpose of maintaining supplies for emergency use, provided that all of such procurement is from the United States General Services Administration and in accordance with the rules of the United States office of Emergency Preparedness.

(b) The requirement of registration is waived for any official of a civil defense or disaster relief organization during a state of emergency or disaster within his jurisdiction proclaimed by the President or by a concurrent resolution of the Congress, which official, in the course of his official duties during such emergency or disaster, is authorized to:

(i) Dispense controlled substances; or

(ii) Procure or distribute controlled substances, provided that all such procurement is on a special "Civil Defense Emergency Order Form," as described in this section.

(c) Civil Defense Emergency Order Forms shall be furnished by the United States Office

of Emergency Preparedness and will contain the name of the civil defense or disaster relief organization. Such forms may be used and are valid only during a state of emergency or disaster proclaimed by the President or by a concurrent resolution of the Congress for the area in which the organization using such forms has civil defense or disaster relief jurisdiction, who shall state his position and the nature and legal designation of the emergency or disaster. Such forms may be filled by any person registered under the Act. The organization shall, upon the execution of a Civil Defense Emergency Order Form, be deemed to be registered under the Act for purposes of recordkeeping pursuant to Chapter 4.

Section 11. Time for Application for Registration; Expiration Date.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is approved. The Board will issue a "Preliminary" approval so that the registrant may become registered with the Drug Enforcement Administration. After receiving the DEA number, the Board will register them.

(b) Any person who is registered may apply to be reregistered not less than thirty (30) days, nor more than sixty (60) days, before the expiration date of his registration.

(c) The expiration date of the registration of any person will be the last day of June of each year.

(d) Any registrant who fails to renew their registration by September 30th of each calendar year shall be penalized in the amount of \$40.00. If failure to renew continues past December 31st of the calendar year, the registration shall be cancelled and the Bureau notified for cancellation of the registrants' federal registration.

(e) Any registrant who wishes to reinstate their registration when said registration has lapsed only for failure to pay renewal fees, the registrant shall pay all back renewal fees, including annual fines, up to a maximum of five (5) years.

Section 12. Application Forms; Contents; Signature.

(a) If any person is required to be registered, and is not so registered and is applying for registration, he should obtain the necessary forms from the officer of the Board.

(b) If any person is registered and is applying for re-registration, registration and renewal forms will be mailed approximately sixty (60) days before expiration date, or by May 1st of each renewal year.

(c) Registration information may be obtained at any regional office of the Drug Enforcement Administration or by contacting the Wyoming State Board of Pharmacy.

(d) Each application for registration to handle any basic class of controlled substance

listed in Schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substances listed in Schedule II, or to conduct research with any narcotic controlled substance listed in Schedule II, shall include the Controlled Substances Code Number for each basic class or substance to be covered by such registration.

(e) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(f) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division association trust or other entity.

#### Section 13. Filing of Application; Joint Filings.

(a) All applications for registration shall be submitted for filing to the Board. The appropriate registration fee and any required attachments must accompany the application.

(b) Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and should not refer to any accompanying application for required information.

#### Section 14. Acceptance for Filing, Defective Applications.

(a) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Board may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time prior to the expiration date.

(b) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to this chapter and has no bearing on whether the application will be granted.

#### Section 15. Additional Information.

(a) The Board may require an applicant to submit such documents or written statements of fact relevant to the application as it deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Board in granting or denying the application.

#### Section 16. Amendments to and Withdrawal of Applications.

(a) An application may be amended or withdrawn without permission of the Board at any time before the date on which the applicant receives an order to show cause pursuant to this chapter. An application may be amended or withdrawn with permission of the Board at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application within ten (10) days, when sent by registered or certified mail, ~~return receipt requested~~, shall be deemed to be a withdrawal of the application.

#### Section 17. Administrative Review Generally.

The Board may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to Section 46 of the Act. The Board shall review the application for registration and other information regarding an applicant in order to determine whether the applicable standards of Sections 24 and 25 of the Act have been met by the applicant.

#### Section 18. Certificate of Registration; Denial of Registration.

(a) The Board shall issue a Certificate of Registration to an applicant if the issuance of registration or re-registration is required. In the event that the issuance of registration or re-registration is not in the public interest, the Board shall deny the application. Before denying any application, the Board shall issue an order to show cause and, if requested by the applicant, shall hold a hearing on the application.

(b) The Certificate of Registration shall contain the name, address, and the Drug Enforcement Administration registration number of the registrant, the activity authorized by the registration, the schedules and/or Controlled Substances Code Number of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration. The registrant shall prominently display the Certificate of Registration at the registered location.

#### Section 19. Suspension or Revocation of Registration.

(a) The Board may suspend any registration pursuant to Section 26(a) of the Act for any period of time it determines.

(b) The Board may revoke any registration pursuant to Section 26(a) of the Act.

(c) Before revoking or suspending any registration, the Board shall issue an order to show cause pursuant to this chapter and, if requested by the registrant, shall hold a hearing pursuant to this chapter. Notwithstanding the requirements of this section, however, the Board may suspend any registration pending a final order pursuant to this chapter.

(d) Upon service of the order of the Board suspending or revoking registration, the registrant shall immediately surrender his Certificate of Registration and shall:

(i) Deliver all controlled substances in his possession to the Board or its authorized agents; or

(ii) Place all controlled substances in his possession under seal.

(e) In the event that revocation or suspension is limited to particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall surrender the old Certificate of Registration to the Board. Also, the registrant shall:

(i) Deliver to the Board or its authorized agents all of the particular controlled substance or substances affected by the revocation or suspension which are in his possession; or

(ii) Place all of such substances under seal.

#### Section 20. Suspension of Registration Pending Final Order.

(a) The Board may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where it finds that there is an imminent danger to the public health or safety. If the Board so suspends, it shall serve, together with the order to show cause pursuant to this chapter an order of immediate suspension which shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly surrender his Certificate of Registration, and shall:

(i) Deliver all affected controlled substances in his possession to the Board or its authorized agents; or

(ii) Place all of such substances under seal.

(c) Any suspensions shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Board or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to Section 46, which request shall be granted by the Board which shall fix a date for such hearing as early as reasonably possible.

#### Section 20. Extension of Registration Pending Final Order.



In the event that an applicant for re-registration (who is doing business under a registration previously granted and not revoked or suspended) has applied for re-registration before the date on which the existing registration is due to expire, and the Board has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Board so issues its order. The Board may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for re-registration at least thirty (30) days before expiration of the existing registration, with or without request by the registrant, if the Board finds that such extension is not inconsistent with the public health and safety.

#### Section 21. Order to Show Cause.

(a) If, upon examination of the application for registration from any applicant and other information regarding the applicant, the Board is unable to make the determinations required by the applicable provisions to register the applicant, the Board shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information regarding any registrant, the Board determines that the registration of such registrant is subject to suspension or revocation, the Board shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Board at a time and place stated in the order, which shall not be less than thirty (30) days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he desires a hearing, file a request for a hearing. If a hearing is requested, the Board shall hold a hearing at the time and place stated in the order pursuant to this chapter.

(e) When authorized by the Board, any agent of the Board may serve the order to show cause, or the Board may serve such order by mailing the same by registered or certified mail to the last known address of the applicant or registrant.

### HEARINGS

#### ~~Section 22. Hearings Generally.~~

~~(a) In any case where the Board shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Rules of Practice, and by the procedures for administrative hearings under the Act set forth in Chapter 5 of these Rules.~~

~~(b) — Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the State.~~

~~Section 23. — Purpose of Hearing.~~

~~If requested by a person entitled to a hearing, the Board shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration. Extensive argument should not be offered into evidence, but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.~~

~~Section 24. Waiver or Modification of Rules.~~

~~The Board or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.~~

~~Section 25. — Request for Hearing; Waiver.~~

~~(a) — Any person entitled to a hearing and desiring a hearing shall, within thirty (30) days after the date of receipt of the order to show cause, file with the Board a written request for a hearing in the form prescribed.~~

~~(b) — Any person entitled to a hearing may, within the period permitted for filing a request for a hearing, file with the Board a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.~~

~~(c) — If any person entitled to a hearing pursuant to Sections 42 through 43 fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.~~

~~(d) — If any person entitled to a hearing or to participate in a hearing waives or is deemed to waive his opportunity for the hearing, or to participate in the hearing, the Board may cancel the hearing, if a hearing was scheduled, and issue its final order pursuant to Section 57 without a hearing.~~

~~Section 26. — Burden of Proof.~~

~~(a) — At any hearing for the denial of a registration, the Board shall have the burden of proving that the requirements for such registration have not been met.~~

~~(b) — At any hearing for the revocation or suspension of a registration, the Board shall have the burden of proving that the requirements for such revocation or suspension have not been met.~~

~~Section 27. — Time and Place of Hearing.~~

~~The hearing will commence at the place and time designated in the order to show cause but thereafter, it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.~~

~~Section 28. — Final Order.~~

~~As soon as practicable after the hearing is closed, the Board shall issue its order on the granting, denial, revocation or suspension of registration. In the event that any application for registration is denied, or any registration is revoked or suspended, the order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Board shall serve one copy of its order upon each party in the hearing.~~

## MODIFICATION OR TERMINATION

Section 29. Modification of Registration.

Any registrant may apply to modify his registration to authorize the handling of additional controlled substances by submitting a letter of request to the Board. The letter shall contain the registrant's name, address, registration number, and the substances and/or schedules to be added to or deleted from his registration and shall be signed by the same person who signed the most recent application for registration or re-registration. If the registrant is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, he shall attach one copy of a Federally approved research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate. No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration.

Section 30. Termination of Registration.

The registration of any person shall terminate if and when such person dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the Certificate of Registration. Any registrant who ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the Certificate of Registration shall notify the Board promptly of such fact. In the event of a change in name or address, the person may apply for a new Certificate of Registration in advance of the effective date of such change by filing an application and paying the appropriate fee in the same manner as an application for new registration. The application shall be handled in the same manner as an application for registration.

## SECURITY REQUIREMENTS

### Section 31. Security Requirements Generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Board shall use the security requirements set forth in standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in this chapter may be used in lieu of the materials and construction described.

(b) Substantial compliance with the standards set forth in this chapter may be deemed sufficient by the Board after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Board may consider any of the following factors as it may deem relevant to the need for strict compliance with security requirements:

(i) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(ii) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or non-usable powders);

(iii) The quantity of controlled substances handled;

(iv) The location of the premises and the relationship such location bears on security needs;

(v) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(vi) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(vii) The type of closures on vaults, safes, and secure enclosures;

(viii) The adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and stand-by power sources;

(ix) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(x) The adequacy of supervision over employees having access to manufacturing and storage areas;

(xi) The procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;

(xii) The availability of local police protection or of the registrant's or applicant's security personnel, and;

(xiii) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a non-controlled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in this chapter when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in this chapter, may submit any plans, blueprints, sketches or other materials regarding the proposed security system to the Board.

(e) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 20, 1971, shall be deemed to comply substantially with the standards set forth in this chapter. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Drug Enforcement Administration, shall not necessarily be deemed to comply substantially with the standards set forth in this chapter, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Board.

### Section 32. Physical Security Controls for Nonpractitioners; Storage Areas.

(a) Schedules I and II. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II shall be stored in one of the following secure storage areas:

(i) Where small quantities permit, a safe:

(A) When the safe has an Underwriters' Laboratories Burglary Rating of T-20, E or better, or the equivalent of such a safe;

(B) Which safe, if it weighs less than 750 pounds, is bolted, or cemented to

the floor or wall in such a way that it cannot be readily removed; and

(C) Which safe, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Board may approve.

(ii) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(iii) A vault constructed after September 1, 1971:

(A) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2 inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(B) The door of which vault contains a multiple-position combination lock or the equivalent, a relocking device or the equivalent, and steel plate with a thickness of at least 1/2 inch or with a two-hour fire rating or the equivalent;

(C) Which vault, if operations require it to remain open for frequent access, is equipped with a "day gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(D) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station, protection company, or a local or State Police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Board may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(E) The door of which vault is equipped with contact switches; and

(F) Which vault has one of the following: complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Board.

(b) Schedules III, IV, and V.

Raw materials, bulk materials waiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V shall be stored in one of the following secure storage areas:

(i) Where small quantities permit, a safe which complies with the requirements set forth in paragraph (a) (1) of this section;

(ii) A vault which complies with the requirements set forth in either paragraph (a)(2) or (3) of this section; or

(iii) A building or area located within a building, which building or area:

(A) Has walls or perimeter fences of sufficient height and construction to provide security from burglary;

(B) Has substantial doors which may be securely locked during non-working hours by a multiple-position combination or key lock;

(C) Is equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local, or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Board may approve; and

(D) In which all controlled substances are segregated from all other merchandise and kept under constant surveillance during normal business hours.

(c) Multiple Storage Areas.

Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) Accessibility to Storage Areas.

The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

Section-33. Physical Security Controls for Nonpractitioners; Manufacturing Areas.

All manufacturing activities (including processing, packaging, and labeling) involving controlled substances listed in any schedule shall be conducted in accordance with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where

a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins, or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. "Limited access" may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted: provided that he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

#### Section 34. Other Security Controls for Nonpractitioners.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Drug Enforcement Administration or with the Wyoming State Board of Pharmacy, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Board and the Drug Enforcement Administration of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Drug Enforcement Administration and the Board of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The registrant shall also complete an inventory regarding such theft or loss and submit a copy of such inventory to the Board. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

#### (d) Distribution of Controlled Substance Samples.

(i) The registrant shall not distribute any controlled substance listed in Schedule II or III as a complimentary sample to any potential or current customer or patient except in the



following manner:

(A) Manufacturers/distributors of samples of controlled substance pharmaceutical products must be registered with the Board of Pharmacy and Drug Enforcement Administration before shipping controlled substances into the State of Wyoming.

(B) Manufacturers/distributors shall send to the Wyoming Board of Pharmacy a record of all such transactions involving the shipment of samples to a Wyoming registrant. The Board shall be notified of any unreasonable order requests or records shall be sent upon request. Records kept and provided by the manufacturer/distributor shall include:

(I) Manufacturer/Distributor name and DEA registration number.

(II) Address of Manufacturer/Distributor.

(III) Name, address and registration (DEA#) number of registrant receiving samples.

(IV) Drug name, strength, quantity/package, quantity/number of packages - total quantity sent to registrant.

(V) Date of shipment or delivery to the registrant.

(ii) Registrants (practitioners) requesting controlled substance samples shall do so in the following manner:

(A) Registrant (or agent) must sign for samples upon receipt.

(B) Retain the invoice of controlled substances samples received.

(C) Records must be kept of all samples dispensed or administered.

The registrant's office record shall include: date of dispensing or administering; patient name; drug sample name; strength; quantity given (total number of tablets or volume of liquid); initial of practitioner or agent.

(D) Registrant shall personally sign or initial records of samples dispensed or administered at the bottom of each page on a regular basis.

(E) Make such records available to the Wyoming State Board of Pharmacy inspector or Drug Enforcement Administration agent upon request.

(iii) Samples of controlled substances listed in Schedule IV and V are exempted from requirements further than those imposed by the Drug Enforcement Administration for distribution in the State of Wyoming.

Section 35. Physical Security Controls for Practitioners.

(a) Controlled substances listed in Schedule I and II shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(b) Controlled substances listed in Schedules III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) This section shall also apply to non-practitioners authorized to conduct research or chemical analysis under another registration.

Section 36. Other Security Controls for Practitioners.

(a) The registrant shall not employ as an agent or employee any person, who has access to controlled substances, who has had an application for registration denied, or has had his registration revoked, suspended, or limited at any time.

(b) The registrant shall notify the Board and the Drug Enforcement Administration of the theft or significant loss of any controlled substances upon discovery of such loss or theft. The registrant shall also complete an inventory regarding such loss or theft and submit it in writing to the Board.

## CHAPTER 5

### ~~RULES OF PRACTICE AND PROCEDURE GOVERNING HEARINGS~~

#### ~~Section 1. — Scope of Chapter 5.~~

~~Rules governing all hearings before the Board when a hearing is required by the Act, or these rules to be held.~~

#### ~~Section 2. — Notice of Hearing.~~

~~The Board shall cause Written Notice of any hearing held under these rules to be served upon each contestant at least ten (10) days prior to the date set for the hearing. Such notice shall include a statement of:~~

- ~~(a) — The time, place and nature of the hearing;~~
- ~~(b) — The legal authority and jurisdiction under which the hearing is to be held;~~
- ~~(c) — Such other matters as may be required by the Wyoming Administrative Procedure Act and Chapter 3 of these Rules.~~

#### ~~Section 3. — Service of Notice.~~

~~Service may be made either personally or by publication as follows:~~

##### ~~(a) — Personally.~~

~~Said service, if made by Sheriff, or other official, shall be made in the manner prescribed by the Wyoming Rules of Civil Procedure. Said service may be made by any person, not an officer, who is of lawful age, and not a party in interest. The return of said service shall be made by the certification of the officer who made such service, or if made by a person other than an officer, by his affidavit. Such return of service must be filed with the Board prior to the commencement of the hearing.~~

##### ~~(b) — Publication —~~

~~If it is determined by the Board that personal service may not be made, service may be made by one publication in a newspaper published in the county where the hearing shall be held. Following such publication, the Board shall mail a true and correct printed copy of any such notice, by certified or registered mail to the last known post office address of the contestant. Proof of such service shall be kept and retained in the records of the Board. Where indispensable and necessary parties are composed of a large class, notice of hearings may be served upon a reasonable number thereof or by giving notice by publication in the manner specified by an order of the, Board. All other pleadings, motions or notices shall be served in the same manner as provided in this section.~~

~~Section 4. — Motions. —~~

~~The Board may at any time after three (3) days notice to all parties hear orally, or otherwise, any motion filed in connection with hearings under these rules.~~

~~Section 5. — Docket.~~

~~When a contestant is entitled to a hearing under these rules, a copy of the order to show cause and the notice of hearing shall be filed with the Board which shall then assign it a docket number and enter the proceeding with the date of its filing on a separate page of a docket provided for such purpose. The clerk shall establish a separate file for each docketed case in which shall be systematically placed all papers, pleadings, documents, transcripts and evidence pertaining thereto, and all such items shall have noted thereon the docket number assigned and the date of filing.~~

~~Section 6. — Form of Pleadings.~~

~~The form of pleadings or other papers filed in each docketed case shall be substantially as follows:~~

~~BEFORE THE WYOMING STATE BOARD OF PHARMACY~~

~~STATE OF WYOMING~~

~~IN THE MATTER OF~~

~~Docket No. — Contestant~~

~~(Body of Pleading or Motion)~~

~~(Signature)~~

~~\_\_\_\_\_ Name (typed or printed)~~

~~(Signature)~~

~~\_\_\_\_\_ Name (typed or printed)~~

~~Address  
Attorney~~

~~Section 7. — Settlements.~~

~~Unless precluded by law informal disposition may be made of any hearing by stipulation,~~

~~agreed settlement, consent, order or default.~~

~~Section 8. — Continuances.~~

~~For good cause shown, continuances and extensions of time may be granted or denied in the discretion of the Board, provided that except where both parties agree, no continuance shall be granted which shall extend the time for hearing beyond the time in which such hearing must be held as provided by law.~~

~~Section 9. — Pre-Hearing Conference.~~

~~At a time on or before the day of the hearing, the Board may direct the attorneys for the parties to appear before the Board to consider:~~

~~(a) — The simplification of the issues.~~

~~(b) — The necessity or desirability of amending the pleadings.~~

~~(c) — The possibility of obtaining admissions of fact and of documents which will avoid unnecessary proof.~~

~~(d) — Such other matters as may aid in the disposition of the case.~~

~~Such conferences shall be conducted informally. A memorandum will be prepared which recites the actions taken at the conference, amendments allowed, agreements of the parties and limitation of the issues to those undisposed of by admissions or agreements of counsel and the parties. The prehearing memorandum will control the course of the hearing unless modified by the Board to prevent manifest injustice.~~

~~Section 10. — Subpoenas.~~

~~The Chairman of the Board, upon written application of any party or his attorney, shall issue a subpoena requiring the appearance of witnesses for the purpose of taking evidence or requiring the production of any books, papers or other documents relevant or material to the inquiry, all subject to the provisions of Section 16-3-107 of the Wyoming Administrative Procedures Act.~~

~~Section 11. — Order of Procedure at Hearing.~~

~~As nearly as may be, hearings shall be conducted in accordance with the following order of procedure:~~

~~(a) — The Chairman shall announce that the Board is open to transact business and call by docket number and title the case to be heard.~~

~~(b) — The Board will be allowed an opening statement to briefly explain its position and outline the evidence it proposes to offer, together with the purpose thereof.~~

~~— (c) — The contestant will be allowed an opening statement.~~

~~— (d) — Any additional parties will be allowed an opening statement.~~

~~(e) — The Board's evidence will be heard. Witnesses may be cross-examined by the contestant or his attorney and by members of the Board and legal counsel for the Board. The Board's offered exhibits will be marked by letters of the alphabet, beginning with "A".~~

~~(f) — The evidence of the contestant will be heard, and exhibits of such contestant will be marked with numbers, beginning with "1". Each member of the Board, and the attorney for the Board, shall have the right to cross-examine all witnesses presented on behalf of the contestant.~~

~~(g) — The Board may offer rebuttal evidence.~~

~~(h) — The Board may, in its discretion, allow evidence to be offered out of order, as herein prescribed.~~

~~— (i) — Closing statements will be made in the following sequence:~~

~~(i) — Board~~

~~(ii) — Contestant~~

~~(iii) — Board in rebuttal~~

~~The time for oral argument may be limited by the Chairman.~~

~~— (j) — The Chairman may recess the hearing as required.~~

~~(k) — After all interested parties have been offered an opportunity to be heard, the Chairman shall excuse all witnesses and declare the evidence closed. The evidence of the case may be re-opened at a later date, for good cause shown, by order of the Board upon motion of any party to the proceeding, the Chairman, or the Board itself.~~

~~(l) — Parties may tender briefs, or the Board may call for such briefs as may be desirable.~~

~~(m) — The Chairman may declare that the matter is taken under advisement and that the decision and order of the Board will be announced at a later date.~~

~~Section 12. — Witnesses at Hearings to be Sworn.~~

~~All persons testifying at any hearing before the Board shall stand and be administered the following oath by a member of the Board:~~

~~"Do you swear (or affirm) to tell the truth, the whole truth, and nothing but the truth in the matter now before the Board, so help you, God?"~~

~~No testimony will be received from a witness except under such oath or affirmation.~~

~~Section 13.—Applicable Rules of Civil Procedure.~~

~~The rules of practice and procedure contained in the Rules of Civil Procedure of the State of Wyoming, insofar as the same may be applicable and not inconsistent with the laws of the State of Wyoming, shall apply in all hearings before the Board. For the application of such rules, the clerk is designated to be in the same relationship to the Board as a clerk of court to a court.~~

~~Section 14.—Attorneys.~~

~~The filing of a pleading or other appearance by an attorney constitutes his appearance for the party for whom made. The Board must be notified in writing of his withdrawal from any matter. Any person appearing before the Board at a hearing in a representative capacity shall be precluded from examining or cross-examining any witness, unless such person shall be an attorney licensed to practice law in the State of Wyoming, or a nonresident attorney associated with a Wyoming attorney. This rule shall not be construed to prohibit any person from representing himself in any hearing before the Board.~~

~~Section 15.—Attorney for the Board.~~

~~In all hearings before the Board, the Chairman shall request the attorney for the Board to be present to assist and advise the Board.~~

~~Section 16.—Taking of Testimony—Reporter.~~

~~In all hearings, the proceedings, including all testimony, shall be reported verbatim, stenographically or by any other appropriate means determined by the Board or the officer presiding at the hearing.~~

~~Section 17.—Decisions, Findings of Fact, Conclusions of Law, Orders.~~

~~The Board, following a full and complete hearing shall make and enter a written decision and order containing findings of fact, and conclusions of law based upon the evidence, both testimonial and documentary, introduced and admitted during the course of the hearing. In addition, all matters which have been officially noticed by the Board will be taken into consideration as a basis for making findings of fact and conclusions of law. Such decisions, findings of fact, conclusions of law and order shall be filed with the clerk and will, without further action, become the decision, findings of fact, conclusions of law and order based upon the hearing. The clerk shall upon receipt of any~~

~~decision, and order send a copy to contestant and interested parties involved by certified mail, postage prepaid.~~

~~Section 18.—Members of Board Present.~~

~~No member of the Board shall vote upon a decision of the Board unless he shall have been present at the hearing or has read the transcript of the proceedings. The vote of the Board shall be shown in its decision.~~

~~Section 19.—Appeals to District Court.~~

~~Appeals to the District Court from decisions of the Board may be taken in the manner prescribed by the Wyoming Administrative Procedure Act.~~

~~Section 20.—Transcripts.~~

~~Oral proceedings or any part thereof shall be transcribed on request of any party upon payment of the cost thereof. In case of an appeal to the District Court, the party appealing shall secure and file a transcript of the testimony and other evidence offered at the hearing with the Board, which transcript shall be verified by the oath of the reporter or transcribed as a true and correct transcript of the testimony and other evidence in the hearing. The cost of making the transcript shall be paid by the party prosecuting such appeal. The complete record on appeal, including the transcript of testimony, shall be verified by the clerk.~~



## CHAPTER 6

### ISSUING, FILING AND FILLING OF PRESCRIPTIONS

#### Section 1. Scope of Chapter 6

Rules governing the issuance, filling and filing of prescriptions pursuant to ~~Section 30 of the Act (Section 308 of the Federal Act)-The Wyoming Controlled Substances Act WYO.STAT. § 35-7-1001 through 35-7-1062.~~

#### Section 2. 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;
  - (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.
- (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 paper or computer generated to be printed or transmitted via facsimile 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 hours (48 hr.).

(j) “Security” or “secure system” means a system to maintain the confidentiality and integrity of patient records which are being transmitted electronically.

### Section 3. Persons Entitled to Issue Prescriptions.

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

### Section 4. 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.

~~(c) — A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drug, in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.~~

Section 5. Manner of Issuance of Written, Typed or Computer Generated Prescriptions.

(a) Effective January 1, 2007, 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) Shall 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) Erasure protection on green or blue background is utilized on the front side;

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

(D) Security warning list on the front ~~and~~ or back of the blank;

(E) Quantity check-off boxes plus numeric forms of quantity values or alpha and numeric forms of quantity value;

(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 suppliers of security paper must be approved by the Board. Approval will be based on the suppliers’ product meeting the requirements of ~~Chapter 6~~ 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.

(iv) All controlled substance 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 are not allowed, unless electronic prescriptions are used according to this chapter.

(v) 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.

(vi) Prescriptions shall be dated as of, and signed on, the day when issued and shall bear the full name, address, telephone number and DEA registration number of the issuing practitioner. No post dating of controlled substance prescriptions are allowed.

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

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

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

(d) 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.

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

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

(g) An intern, resident, or foreign physician exempted from registration under Chapter 3, 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, 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.

(h) An official exempted from registration under Chapter 3 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 for 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 6. Persons Entitled to Fill Prescriptions.

A prescription for 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 17.7.~~ Identification of a Patient. ~~Move to Chapter 6 of CSA R&R from Chapter 2~~

(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 be recorded on the reverse of the 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 ~~7.8~~ 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” ~~in Section 2(a)(xx) of the Act (Section 101(t) of the Federal Act).~~

Section § 9. Electronic Prescription Transmission.

(a) A pharmacist may dispense directly any legend drug which requires a prescription to dispense only pursuant to the following:

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

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

(iii) An oral prescription made by an individual practitioner or their agent and promptly reduced to hard copy by the pharmacist or pharmacy intern containing all information required.

(b) Electronic prescriptions for controlled substances shall include the requirements listed in 21 CFR § 1311 including:

(i) 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 the individual practitioner has obtained a two-factor authentication credential for signing.

(ii) 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.

(iii) 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.

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

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

(e) A pharmacist or pharmacy shall not enter into any agreement to provide or receive a computer or 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.

(f) 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 **9 10**. 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 dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription.

(c) In the case of an emergency situation, as defined in this section, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that:

(i) The quantity prescribed and dispensed is limited to the amount 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 oral 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 prescribing practitioner;

(iii) If the prescribing practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral 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 directory and/or other good faith efforts to ensure his identity; and

(iv) Within 7 days after authorizing an emergency oral prescription, the prescribing 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 oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be

postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Board if the prescribing individual fails to deliver a written prescription 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.

(d) A prescription for a Schedule II controlled substance shall be valid up to six 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 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
- (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 prescription drug order and computer generated data on the prescription drug order satisfies these requirements.

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



~~(iv)~~(vi) A pharmacist is not permitted to 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 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 Chapter 2, General Practice of Pharmacy Regulations.

Section ~~4011~~.Refilling Prescriptions-Schedule II; issuance of multiple prescriptions

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

(b) 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:

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

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

(iii) 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;

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

Section ~~11~~ 12. Partial Filling of a Prescription-Schedule II.

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

Section ~~12-13~~: Labeling of Substances-Schedule II.

The pharmacist filling a written, electronic, or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing 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 ~~13~~ 14. Filing of Prescription-Schedule II.

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

Section ~~14~~ 15. 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 Federal Food, Drug and Cosmetic Act, only pursuant to either a written or electronic prescription signed by a prescribing practitioner or an oral 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 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.

(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) A practitioner may administer or dispense directly (but not prescribe) controlled substances listed in Schedules III or IV pursuant to a written prescription signed by a prescribing practitioner, or pursuant to an oral prescription made by a prescribing practitioner and promptly reduced to writing by the pharmacist (containing all information required in Chapter 6, except for the signature of the prescribing practitioner, or pursuant to an order for medication made by a practitioner which is dispensed for immediate administration to the ultimate user.)

Section ~~15~~ 16. Refilling of Prescription-Schedules III and IV.

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. No such prescription authorized to be refilled may be refilled more than five (5) times. 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 initialed, and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed. 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 ~~16~~ 17. 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 ~~17~~ 18. Labeling of Substances-Schedule 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 ~~18~~ 19 Filing Prescription-Schedules III and IV.

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

Section ~~19~~ 20. 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 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.

## CHAPTER 8

### PRESCRIPTION DRUG MONITORING PROGRAM

#### Section 1. Authority.

These regulations are promulgated as authorized by the Wyoming Controlled Substances Act.

#### Section 2. 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 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.

(b) The resident/nonresident retail pharmacy shall ensure that, not later than seven (7) days after the prescription 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 1/4 of an inch wide and is used to transmit information between computerized systems;

(iv) Paper printout.

### Section 3. Solicited Patient Profiles.

(a) Occupational licensing boards may request licensee profiles from the board provided the following are met:

(i) All requests must 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 for the occupational licensing board;

(iv) The request shall be mailed 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 to the occupational licensing board, and marked "confidential, to be opened by addressee only".

(vi) A lengthy profile may be converted to a spreadsheet and provided electronically to a regulatory 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 requests must be submitted on a form provided by the board and must be mailed or faxed; ~~or by using the online process to the board's office;~~

(ii) All 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 requests must include the DEA registration number for the pharmacy or practitioner;

~~(iii)~~ (iv) All requests shall include the patient's name, date of birth, purpose of the request, and the date range for the profile;

(iv) All 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"; ~~or the profile shall be generated using the online process to be reviewed or printed by the requestor.~~

(c) Pharmacists and practitioners 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 must first register for access to the online system (WORx) using the online registration;

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

(iii) The Board staff will activate 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.

(v) The Board staff shall discontinue access to any pharmacist or practitioner who fails to follow the regulations listed in this chapter or W.S. § 35-7-1060.

(ed) 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 authorized agent of the patient or parent's or guardians of minors requesting a profile must have proof of identification acceptable to the board;

(ii) Any person making a request for a profile shall complete a form provided by the board. Any profile generated by the board will be available at the board's office, the same day of the request.

~~(de)~~ Other entities as authorized in W.S. § 35-7-1059 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.

(iv) The requirements identified in W.S. § 35-7-1060 (c)(ii) 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 4. Unsolicited Patient Profiles

The board may generate patient profiles based on information showing use of controlled substances, which is in excess of 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 5. Reports.

(a) The board shall maintain a register for solicited patient profile requests. The register shall include the following:

(i) Date 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; and



(iv) Date profile ~~was provided to the requestor. mailed or faxed.~~

(b) The board shall maintain a register 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 6. 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 7. Reporting of Non-Controlled Prescription Drugs.

Resident and nonresident retail pharmacies shall ensure that, not later than 7 days after the prescription was dispensed, the information required pursuant to this chapter is transmitted to the board or its agent ~~for the following prescription drugs: for prescription drugs not listed as controlled substances if formally requested by the board.~~

~~(a) — Tramadol, including any combination product where tramadol is an active ingredient.~~

~~(b) — Carisoprodol, including any combination product where carisoprodol is an active ingredient.~~