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, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, 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.

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 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 $40.00per 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 ~~September~~ 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.

~~Sections 4 through 20 reserved for future use.~~

REQUIREMENT OF REGISTRATION

Section ~~21~~ 4. Persons Required to Register.

Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, 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 ~~22~~ 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 ~~23~~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 ~~24~~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 ~~25~~ 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 ~~26~~ 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 ~~27~~ 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.

~~Sections 28 through 30 reserved for future use~~.

Section ~~31.~~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.

Section ~~3~~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 ~~Bureau~~ Drug Enforcement Administration or by ~~writing~~ contacting~~to~~ the Wyoming State Board of Pharmacy. ~~Renewal notices will be mailed to each registered person approximately sixty (60) days before the expiration date of his registration.~~

(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 ~~3~~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 ~~3~~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 ~~Section 35~~ this chapter and has no bearing on whether the application will be granted.

Section ~~3~~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 ~~3~~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 ~~Section 46~~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.

~~Sections 37 through 40 reserved for future use.~~

Section ~~41~~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 ~~42~~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. ~~under the applicable provisions of Section 25 of the Act~~. In the event that the issuance of registration or re-registration is not in the public interest ~~under Section 25 of the Act~~, the Board shall deny the application. Before denying any application, the Board shall issue an order to show cause ~~pursuant to Section 46~~ and, if requested by the applicant, shall hold a hearing on the application. ~~pursuant to Section 51.~~

(b) The Certificate of Registration shall contain the name, address, and the ~~Bureau~~ Drug Enforcement Administration registration number of the registrant, the activity authorized by the registration, the schedules and/or Controlled Substances Code Number ~~(as set forth in Chapter 2, Section 1)~~ 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 ~~43.~~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 ~~Section 46~~ this chapter and, if requested by the registrant, shall hold a hearing pursuant to ~~Section 51~~this chapter. Notwithstanding the requirements of this section, however, the Board may suspend any registration pending a final order pursuant to ~~Section 44~~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. ~~as described in Section 26(c) of the Act.~~

(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. as ~~described in Section 26(c) of the Act.~~

Section ~~44~~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 ~~Section 46,~~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. ~~as described in Section 26(c) of the Act.~~

(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 ~~45.~~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 ~~46~~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 ~~of Section 25 of the Act~~ 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 ~~pursuant to Section 26 of the Act~~, 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. ~~pursuant to Section 54~~. If a hearing is requested, the Board shall hold a hearing at the time and place stated in the order pursuant to ~~Section 51~~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.

~~Sections 47 through 50 reserved for future use~~.

HEARINGS

Section ~~51~~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 specifically by Sections 25 and 26 of the Act, (Sections 303 and 304 of the Federal Act) by Sections 52 through 57,~~ 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 ~~52~~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 ~~53~~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 ~~54~~25. Request for Hearing; Waiver.

(a) Any person entitled to a hearing ~~pursuant to Sections 42 through 43~~ 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 ~~pursuant to Sections 42 through 43~~ 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 ~~55~~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 ~~pursuant to Section 25 of the Act (Section 303 of the Federal Act)~~ 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 ~~set forth in Section 26(a) of the Act (Section 304(a) of the Federal Act)~~ have not been met~~.~~

Section ~~56~~27. Time and Place of Hearing.

The hearing will commence at the place and time designated in the order to show cause ~~(unless expedited pursuant to Section 44),~~ 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 ~~57~~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.

~~Sections 58 through 60 reserved for future use~~.

MODIFICATION OR TERMINATION

Section ~~61~~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 ~~62~~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.

~~Sections 63 through 70 reserved for future use~~.

SECURITY REQUIREMENTS

Section ~~71~~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 ~~Sections 72 through 76~~ this chapteras 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 ~~Sections 72, 73, and 75~~this chapter may be used in lieu of the materials and construction described ~~in those sections~~.

(b) Substantial compliance with the standards set forth in ~~Sections 72 through 76~~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 ~~Sections 72 through 76~~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 ~~Sections~~

~~72 through 76~~ this chaptermay 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 ~~Sections 72, 73, and 75~~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 ~~Sections 72, 73, and 75~~this chapter, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Board.

Section ~~7~~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 ~~73~~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 ~~7~~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 ~~Bureau~~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 ~~Bureau~~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 ~~Bureau~~ Drug Enforcement Administrationand 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 ~~7~~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 ~~7~~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 ~~Bureau~~ 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 4

RECORDS AND INVENTORIES OF REGISTRANTS

Section 1. Records and Inventory Requirements Generally.

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

(a) Each registered manufacturer, distributor, importer, and narcotic treatment program shall maintain inventories and records of controlled substances as outlined in Chapter II Code of Federal Regulations (1304.01 forward).

(b) Each registered individual practitioner shall keep records with respect to narcotic and non-narcotic controlled substances II - V which he prescribes or administers. Said practitioner shall keep additional records of such substances which he dispenses, whether he charges his patients either separately or together with charges for other professional services.

(c) Each registered pharmacy shall maintain inventories and records of controlled substances as follows:

(i) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file in consecutive numbers.

(ii) Inventories and records of controlled substances listed in Schedules III - V shall be maintained separately from all other records of the pharmacy and prescriptions for such substances shall be maintained in separate prescription files for controlled substances in consecutive numbers.

(iii) All invoices for controlled substances shall be dated and signed when received by the pharmacist in charge or his/her designated agent. Invoices shall be maintained on file for two years and readily available for inspection by the board.

(iv) All retail and institutional pharmacies shall maintain a perpetual inventory for all schedule II controlled substances. This inventory shall be reconciled no less than once a quarter. Discrepancies discovered during reconciliation shall be reported to the board within 10 calendar days of discovery. Only those discrepancies, which are considered a significant loss or gain shall be reported. For the purpose of this section a significant loss or gain shall exist whenever the actual inventory differs from the recorded inventory by more than five percent (5%) for any drug product.

(d) Every inventory and other records required to be kept shall be kept by the

registrant and be made available for at least two years from the date of such inventory or record.

Section 2. Inventory Requirements.

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

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

(b) A separate inventory shall be made by a registrant for each registered address. Each inventory shall be kept at the registered location for which it is taken.

(c) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate the time the inventory was taken on the inventory record.

(d) An inventory must be maintained in a legible written, typewritten, or printed form.

(e) Each registered pharmacy shall forward one copy of the annual inventory to the office of the Board of Pharmacy, including the name of the pharmacy, date and time (beginning of business or close of business) the inventory was taken, and the signature of the responsible person(s).

Section 3. Order Forms.

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

(a) An order form may be executed only by or on behalf of the registrant named thereon and only if his registration is current.

(b) Order forms issued by DEA will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and the schedules of the registrant. This information cannot be altered or changed in any manner.

(c) Order forms shall be prepared by use of a typewriter, pen or indelible pencil.

(d) A registrant may authorize another individual to obtain and execute order forms on his behalf by executing a power of attorney. The power of attorney shall be filed with and retained for the same period as any order form bearing the signature of the attorney. The power

of attorney shall be available for inspection.

(e) The purchaser registrant shall submit Copy 1 and Copy 2 of the DEA order form 222 to the supplier and retain Copy 3 with his own records. The supplier shall enter the suppliers DEA registration number, number of packages shipped, and the date shipped on Copies 1 and 2. If supplier is another local registrant (not a registrant manufacturer or distributor) Copy 2 may be forwarded directly to the DEA Regional Office or the office of the Board of Pharmacy.

(f) The purchaser registrant shall record on Copy 3 of the order form the number of containers received on each item of the order form and the date received.

(g) Order forms must be maintained separately from all other records of the registrant for a period of two years. Order forms must be available for inspection during that time.

(h) The use of electronic 222 forms issued by the Drug Enforcement Administration is authorized.

Section 4. Methamphetamine Precursor Records

(a) The retail sale of nonliquid methamphetamine precursor drugs or liquid products with ephedrine or pseudoephedrine as the sole active ingredient shall be limited to those amounts as described in W.S.§ 35-7-1059

(b) The seller shall maintain a written or electronic list of such sales (logbook) as described in W.S.§ 35-7-1059.

(c) The sale shall be documented as follows:

(i) The prospective purchaser shall present an identification card that provides a photograph and is issued by a state or the federal government, an alien registration receipt card, a foreign passport, or an employment authorization document which contains a photograph

(ii) The prospective purchaser must sign the logbook and enter in the logbook his or her name, address and the date and time of the sale

(iii) The seller must determine that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct.

(iv) The seller must enter into the logbook the name of the product and the quantity sold.

(d) The logbook must contain a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under 18 U.S.C.§ 1001 and such notice must specify the maximum fine ($250,000.00) and term of imprisonment (5 years).

CHAPTER 4

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(b) Each registered individual practitioner shall keep records with respect to narcotic and non-narcotic controlled substances II - V which he prescribes or administers. Said practitioner shall keep additional records of such substances which he dispenses, whether he charges his patients either separately or together with charges for other professional services.

(c) Each registered pharmacy shall maintain inventories and records of controlled substances as follows:

(i) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file in consecutive numbers.

(ii) Inventories and records of controlled substances listed in Schedules III - V shall be maintained separately from all other records of the pharmacy and prescriptions for such substances shall be maintained in separate prescription files for controlled substances in consecutive numbers.

(iii) All invoices for controlled substances shall be dated and signed when received by the pharmacist in charge or his/her designated agent. Invoices shall be maintained on file for two years and readily available for inspection by the board.

(iv) All retail and institutional pharmacies shall maintain a perpetual inventory for all schedule II controlled substances. This inventory shall be reconciled no less than once a quarter. Discrepancies discovered during reconciliation shall be reported to the board within 10 calendar days of discovery. Only those discrepancies, which are considered a significant loss or gain shall be reported. For the purpose of this section a significant loss or gain shall exist whenever the actual inventory differs from the recorded inventory by more than five percent (5%) for any drug product.

(d) Every inventory and other records required to be kept shall be kept by the

registrant and be made available for at least two years from the date of such inventory or record.

Section 2. Inventory Requirements.

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

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

(b) A separate inventory shall be made by a registrant for each registered address. Each inventory shall be kept at the registered location for which it is taken.

(c) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate the time the inventory was taken on the inventory record.

(d) An inventory must be maintained in a legible written, typewritten, or printed form.

~~(e) Every year on the anniversary of the date on which the initial inventory was taken by the registrant, a new inventory shall be taken of all stocks of controlled substances on hand.~~

(~~f~~e) Each registered pharmacy shall forward one copy of the annual inventory to the office of the Board of Pharmacy, including the name of the pharmacy, date and time (beginning of business or close of business) the inventory was taken, and the signature of the responsible person(s).

Section 3. Order Forms.

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

(a) An order form may be executed only by or on behalf of the registrant named thereon and only if his registration is current.

(b) Order forms issued by DEA will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and the schedules of the registrant. This information cannot be altered or changed in any manner.

(c) Order forms shall be prepared by use of a typewriter, pen or indelible pencil.

(d) A registrant may authorize another individual to obtain and execute order forms on his behalf by executing a power of attorney. The power of attorney shall be filed with and retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection.

(e) The purchaser registrant shall submit Copy 1 and Copy 2 of the DEA order form 222 to the supplier and retain Copy 3 with his own records. The supplier shall enter the suppliers DEA registration number, number of packages shipped, and the date shipped on Copies 1 and 2. If supplier is another local registrant (not a registrant manufacturer or distributor) Copy 2 may be forwarded directly to the DEA Regional Office or the office of the Board of Pharmacy.

(f) The purchaser registrant shall record on Copy 3 of the order form the number of containers received on each item of the order form and the date received.

(g) Order forms must be maintained separately from all other records of the registrant for a period of two years. Order forms must be available for inspection during that time.

(h) The use of electronic 222 forms issued by the Drug Enforcement Administration is authorized.

Section 4. Methamphetamine Precursor Records

(a) The retail sale of nonliquid methamphetamine precursor drugs or liquid products with ephedrine or pseudoephedrine as the sole active ingredient shall be limited to those amounts as described in W.S.§ 35-7-1059

(b) The seller shall maintain a written or electronic list of such sales (logbook) as described in W.S.§ 35-7-1059.

(c) The sale shall be documented as follows:

(i) The prospective purchaser shall present an identification card that provides a photograph and is issued by a state or the federal government, an alien registration receipt card, a foreign passport, or an employment authorization document which contains a photograph

(ii) The prospective purchaser must sign the logbook and enter in the logbook his or her name, address and the date and time of the sale

(iii) The seller must determine that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct.

(iv) The seller must enter into the logbook the name of the product and the quantity sold.

(d) The logbook must contain a notice to purchasers that entereing false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under 18 U.S.C.§ 1001 and such notice must specify the maximum fine ($250,000.00) and term of imprisonment (5 years).

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).

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 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.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 by on 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 of 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.

Section7. 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 8. 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 proving an incentive to refer patient to a particular pharmacy.

Section 9. 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 callback 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 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 change the patient's address with proper verification without consulting the prescribing practitioner.

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

(iv) 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 10. Refilling Prescriptions-Schedule II.

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

Section 11. 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. 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. 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. 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. 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.

Section16. 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. 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. 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. 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 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).

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 ~~2.~~ 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 ~~3.~~ 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. ~~An order purporting to be a prescription within the meaning and intent of Section 30 of the Act (Section 308 of the Federal Act) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to penalties provided for violations of the provisions of law relating to controlled substances.~~

(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 ~~4.~~ 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 ~~if signed after January 1, 2007~~.

(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; ~~and~~

(D) Security warning list on the front and 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, ~~Section 4 (a) (i)~~. 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.

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

(~~e~~ g) An intern, resident, or foreign physician exempted from registration under Chapter 3, ~~Section 24~~ 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 of other institution as provided in Chapter 3, ~~Section 24,~~ 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.

(~~f~~ h) An official exempted from registration under Chapter 3 ~~Section 25~~ 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 ~~5~~ 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 ~~6~~ 7 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 8. 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 Sschedule 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 proving an incentive to refer patient to a particular pharmacy.

~~Section 7~~ 8 ~~through 10 reserved for future use.~~

Section ~~11~~ 9. 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 ~~paragraph (c) and (e) of~~ 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 ~~by paragraph (g) of~~ 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 ~~Chapter 6, Section 4,~~ 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 callback 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 ~~Section 4,~~ 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 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 change the patient's address with proper verification without consulting the prescribing practitioner.

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

(iv) 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 20 (c)~~.

Section ~~12~~ 10. Refilling Prescriptions-Schedule II.

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

Section ~~13~~ 11. 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 ~~face of the written~~ 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 ~~14~~ 12. 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 ~~15~~ 13. 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~~, Section 1~~ of these regulations.

~~Section 16 through 20 reserved for future use.~~

Section ~~21~~ 14. 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 ~~Section 4~~ this chapter, except for the signature of the prescribing practitioner, or an electronically transmitted prescription provided it meets all requirements in Chapter 2~~, Section 29~~ of the Board's Rules and federal law, or a faxed prescription provided it meets all requirements in Chapter 2~~, Section 20~~ 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, ~~Section 4~~ 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~~, subject to Section 6~~.)

Section ~~22~~ 15. 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 ~~entered on the back of the prescription or on another appropriate uniformly maintained~~ documented on a readily retrievable record, such as medication records, which indicate 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. ~~If the pharmacist merely initials and dates the back of the prescription, he shall be deemed to have dispensed a refill for the full face amount of the prescription.~~ 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 ~~as provided in Section 21 which shall be a new and separate prescription~~.

Section ~~23~~ 16. Partial Filling of Prescriptions-Schedules III and IV.

The partial filling of a prescription for a controlled substance listed in Schedules III or IV, ~~or V,~~ 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 ~~24~~ 17. 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 ~~25~~ 18. 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~~, Section 1~~ of these regulations.

~~Section 26 through 30 reserved for future use.~~

Section ~~31~~ 19. 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 ~~Section 21~~ 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 ~~Section 23~~ this chapter and file the prescription in accordance with ~~Section 24~~ 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 ~~Section 24~~ this chapter.

~~Section 32. Dispensing Without Prescriptions.~~

~~A controlled substance listed in Schedule V, and a controlled substance listed in Schedules II, III or IV which is not a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:~~

~~(a) Such dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery may be completed by a non-pharmacist);~~

~~(b) Not more than 240 cc. (8 ounces) of any such controlled substance may be distributed at retail to the same purchaser in any given 48 hour period;~~

~~(c) The purchaser is at least eighteen (18) years of age;~~

~~(d) The pharmacist requires every purchaser of a controlled substance under this section no known to him to furnish suitable identification (including proof of age where appropriate);~~

~~(e) A bound record book for dispensing of controlled substances (other than by prescription) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the record keeping requirements of Chapter 4, Section 1 of these regulations); and~~

~~(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State, or local law.~~

CHAPTER 8

PRESCRIPTION DRUG MONITORING PROGRAM

Section 1. Authority.

These regulations are promulgated as authorized by the Wyoming Controlled Substance 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:

(i) All requests must be submitted on a form provided by the board and must be mailed, 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 shall include the patient's name, date of birth, purpose of the request, and the date range for the profile;

(iv) A statement indicating a pharmacist/patient or practitioner/patient relationship exists; and

(v) 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) 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.

(d) 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 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:

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

(b) Carisprodol, including any combination product where carisprodol is an active ingredient.

CHAPTER 8

PRESCRIPTION DRUG MONITORING PROGRAM

Section 1. Authority.

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

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(a) Each resident/nonresident retail pharmacy that ~~uses a computerized system to record information concerning prescriptions and 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. ~~set forth in the "ASAP Telecommunications Format for Controlled Substances", May 1997 edition, published by the American Society for Automation in Pharmacy, which is hereby adopted by reference.~~ 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) ~~Pharmacy~~ Dispenser identification number;

(ii) ~~Birth date;~~ Patient date of birth;

(iii) ~~Sex Code~~Patient gender;

(iv) Date prescription filled;

(v) ~~Rx~~ Prescription number;

(vi) ~~New/refill code~~ Prescription is new or is a refill;

(vii) ~~Metric~~ Quantity dispensed;

(viii) Date ~~Rx written~~ Prescription issued by prescriber;

(ix) Days supply dispensed;

(x) NDC code number for drug dispensed;

(xi) Prescriber ~~ID~~identification number;

(xii) Patient last name;

(xiii) Patient first name;

(xiv) Patient street address; ~~and~~

(xv) Patient zip code.

(b) The resident/nonresident retail pharmacy shall ensure that, not later than ~~the 10th day of the month immediately following the month in which~~ seven (7) days after the prescription was dispensed, the information required pursuant to ~~Section 2 (a) of~~ 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.

~~(c) Upon a showing of good cause, the board may, for a period of 90 days, waive the requirements set forth in this section for a pharmacy that cannot transmit the information required pursuant to Section 2 (a) of this chapter before October 1, 2004. The board may renew the waiver.~~

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:

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(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 shall include the patient's name, date of birth, purpose of the request, and the date range for the profile;

(iv) A statement indicating a pharmacist/patient or practitioner/patient relationship exists; and

(v) 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) 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.

(d) 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.

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(iv) Date profile 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:

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(i) ~~Pharmacy~~ Dispenser identification number;

(ii) ~~Birth date;~~ Patient date of birth;

(iii) ~~Sex Code~~Patient gender;

(iv) Date prescription filled;

(v) ~~Rx~~ Prescription number;

(vi) ~~New/refill code~~ Prescription is new or is a refill;

(vii) ~~Metric~~ Quantity dispensed;

(viii) Date ~~Rx written~~ Prescription issued by prescriber;

(ix) Days supply dispensed;

(x) NDC code number for drug dispensed;

(xi) Prescriber ~~ID~~identification number;

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(iv) The request shall be mailed or faxed to the board's office; and

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

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(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;

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(d) 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:

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(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.

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

(b) Carisprodol, including any combination product where carisprodol is an active ingredient.

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, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, 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.

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 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 $40.00per 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 ~~September~~ 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.

~~Sections 4 through 20 reserved for future use.~~

REQUIREMENT OF REGISTRATION

Section ~~21~~ 4. Persons Required to Register.

Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, 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 ~~22~~ 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 ~~23~~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 ~~24~~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 ~~25~~ 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 ~~26~~ 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 ~~27~~ 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.

~~Sections 28 through 30 reserved for future use~~.

Section ~~31.~~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.

Section ~~3~~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 ~~Bureau~~ Drug Enforcement Administration or by ~~writing~~ contacting~~to~~ the Wyoming State Board of Pharmacy. ~~Renewal notices will be mailed to each registered person approximately sixty (60) days before the expiration date of his registration.~~

(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 ~~3~~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 ~~3~~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 ~~Section 35~~ this chapter and has no bearing on whether the application will be granted.

Section ~~3~~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 ~~3~~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 ~~Section 46~~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.

~~Sections 37 through 40 reserved for future use.~~

Section ~~41~~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 ~~42~~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. ~~under the applicable provisions of Section 25 of the Act~~. In the event that the issuance of registration or re-registration is not in the public interest ~~under Section 25 of the Act~~, the Board shall deny the application. Before denying any application, the Board shall issue an order to show cause ~~pursuant to Section 46~~ and, if requested by the applicant, shall hold a hearing on the application. ~~pursuant to Section 51.~~

(b) The Certificate of Registration shall contain the name, address, and the ~~Bureau~~ Drug Enforcement Administration registration number of the registrant, the activity authorized by the registration, the schedules and/or Controlled Substances Code Number ~~(as set forth in Chapter 2, Section 1)~~ 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 ~~43.~~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 ~~Section 46~~ this chapter and, if requested by the registrant, shall hold a hearing pursuant to ~~Section 51~~this chapter. Notwithstanding the requirements of this section, however, the Board may suspend any registration pending a final order pursuant to ~~Section 44~~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. ~~as described in Section 26(c) of the Act.~~

(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. as ~~described in Section 26(c) of the Act.~~

Section ~~44~~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 ~~Section 46,~~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. ~~as described in Section 26(c) of the Act.~~

(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 ~~45.~~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 ~~46~~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 ~~of Section 25 of the Act~~ 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 ~~pursuant to Section 26 of the Act~~, 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. ~~pursuant to Section 54~~. If a hearing is requested, the Board shall hold a hearing at the time and place stated in the order pursuant to ~~Section 51~~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.

~~Sections 47 through 50 reserved for future use~~.

HEARINGS

Section ~~51~~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 specifically by Sections 25 and 26 of the Act, (Sections 303 and 304 of the Federal Act) by Sections 52 through 57,~~ 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 ~~52~~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 ~~53~~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 ~~54~~25. Request for Hearing; Waiver.

(a) Any person entitled to a hearing ~~pursuant to Sections 42 through 43~~ 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 ~~pursuant to Sections 42 through 43~~ 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 ~~55~~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 ~~pursuant to Section 25 of the Act (Section 303 of the Federal Act)~~ 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 ~~set forth in Section 26(a) of the Act (Section 304(a) of the Federal Act)~~ have not been met~~.~~

Section ~~56~~27. Time and Place of Hearing.

The hearing will commence at the place and time designated in the order to show cause ~~(unless expedited pursuant to Section 44),~~ 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 ~~57~~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.

~~Sections 58 through 60 reserved for future use~~.

MODIFICATION OR TERMINATION

Section ~~61~~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 ~~62~~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.

~~Sections 63 through 70 reserved for future use~~.

SECURITY REQUIREMENTS

Section ~~71~~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 ~~Sections 72 through 76~~ this chapteras 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 ~~Sections 72, 73, and 75~~this chapter may be used in lieu of the materials and construction described ~~in those sections~~.

(b) Substantial compliance with the standards set forth in ~~Sections 72 through 76~~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 ~~Sections 72 through 76~~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 ~~Sections~~

~~72 through 76~~ this chaptermay 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 ~~Sections 72, 73, and 75~~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 ~~Sections 72, 73, and 75~~this chapter, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Board.

Section ~~7~~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 ~~73~~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 ~~7~~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 ~~Bureau~~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 ~~Bureau~~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 ~~Bureau~~ Drug Enforcement Administrationand 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 ~~7~~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 ~~7~~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 ~~Bureau~~ 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 4

RECORDS AND INVENTORIES OF REGISTRANTS

Section 1. Records and Inventory Requirements Generally.

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

(a) Each registered manufacturer, distributor, importer, and narcotic treatment program shall maintain inventories and records of controlled substances as outlined in Chapter II Code of Federal Regulations (1304.01 forward).

(b) Each registered individual practitioner shall keep records with respect to narcotic and non-narcotic controlled substances II - V which he prescribes or administers. Said practitioner shall keep additional records of such substances which he dispenses, whether he charges his patients either separately or together with charges for other professional services.

(c) Each registered pharmacy shall maintain inventories and records of controlled substances as follows:

(i) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file in consecutive numbers.

(ii) Inventories and records of controlled substances listed in Schedules III - V shall be maintained separately from all other records of the pharmacy and prescriptions for such substances shall be maintained in separate prescription files for controlled substances in consecutive numbers.

(iii) All invoices for controlled substances shall be dated and signed when received by the pharmacist in charge or his/her designated agent. Invoices shall be maintained on file for two years and readily available for inspection by the board.

(iv) All retail and institutional pharmacies shall maintain a perpetual inventory for all schedule II controlled substances. This inventory shall be reconciled no less than once a quarter. Discrepancies discovered during reconciliation shall be reported to the board within 10 calendar days of discovery. Only those discrepancies, which are considered a significant loss or gain shall be reported. For the purpose of this section a significant loss or gain shall exist whenever the actual inventory differs from the recorded inventory by more than five percent (5%) for any drug product.

(d) Every inventory and other records required to be kept shall be kept by the

registrant and be made available for at least two years from the date of such inventory or record.

Section 2. Inventory Requirements.

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

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

(b) A separate inventory shall be made by a registrant for each registered address. Each inventory shall be kept at the registered location for which it is taken.

(c) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate the time the inventory was taken on the inventory record.

(d) An inventory must be maintained in a legible written, typewritten, or printed form.

(e) Each registered pharmacy shall forward one copy of the annual inventory to the office of the Board of Pharmacy, including the name of the pharmacy, date and time (beginning of business or close of business) the inventory was taken, and the signature of the responsible person(s).

Section 3. Order Forms.

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

(a) An order form may be executed only by or on behalf of the registrant named thereon and only if his registration is current.

(b) Order forms issued by DEA will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and the schedules of the registrant. This information cannot be altered or changed in any manner.

(c) Order forms shall be prepared by use of a typewriter, pen or indelible pencil.

(d) A registrant may authorize another individual to obtain and execute order forms on his behalf by executing a power of attorney. The power of attorney shall be filed with and retained for the same period as any order form bearing the signature of the attorney. The power

of attorney shall be available for inspection.

(e) The purchaser registrant shall submit Copy 1 and Copy 2 of the DEA order form 222 to the supplier and retain Copy 3 with his own records. The supplier shall enter the suppliers DEA registration number, number of packages shipped, and the date shipped on Copies 1 and 2. If supplier is another local registrant (not a registrant manufacturer or distributor) Copy 2 may be forwarded directly to the DEA Regional Office or the office of the Board of Pharmacy.

(f) The purchaser registrant shall record on Copy 3 of the order form the number of containers received on each item of the order form and the date received.

(g) Order forms must be maintained separately from all other records of the registrant for a period of two years. Order forms must be available for inspection during that time.

(h) The use of electronic 222 forms issued by the Drug Enforcement Administration is authorized.

Section 4. Methamphetamine Precursor Records

(a) The retail sale of nonliquid methamphetamine precursor drugs or liquid products with ephedrine or pseudoephedrine as the sole active ingredient shall be limited to those amounts as described in W.S.§ 35-7-1059

(b) The seller shall maintain a written or electronic list of such sales (logbook) as described in W.S.§ 35-7-1059.

(c) The sale shall be documented as follows:

(i) The prospective purchaser shall present an identification card that provides a photograph and is issued by a state or the federal government, an alien registration receipt card, a foreign passport, or an employment authorization document which contains a photograph

(ii) The prospective purchaser must sign the logbook and enter in the logbook his or her name, address and the date and time of the sale

(iii) The seller must determine that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct.

(iv) The seller must enter into the logbook the name of the product and the quantity sold.

(d) The logbook must contain a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under 18 U.S.C.§ 1001 and such notice must specify the maximum fine ($250,000.00) and term of imprisonment (5 years).

CHAPTER 4

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(b) Each registered individual practitioner shall keep records with respect to narcotic and non-narcotic controlled substances II - V which he prescribes or administers. Said practitioner shall keep additional records of such substances which he dispenses, whether he charges his patients either separately or together with charges for other professional services.

(c) Each registered pharmacy shall maintain inventories and records of controlled substances as follows:

(i) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file in consecutive numbers.

(ii) Inventories and records of controlled substances listed in Schedules III - V shall be maintained separately from all other records of the pharmacy and prescriptions for such substances shall be maintained in separate prescription files for controlled substances in consecutive numbers.

(iii) All invoices for controlled substances shall be dated and signed when received by the pharmacist in charge or his/her designated agent. Invoices shall be maintained on file for two years and readily available for inspection by the board.

(iv) All retail and institutional pharmacies shall maintain a perpetual inventory for all schedule II controlled substances. This inventory shall be reconciled no less than once a quarter. Discrepancies discovered during reconciliation shall be reported to the board within 10 calendar days of discovery. Only those discrepancies, which are considered a significant loss or gain shall be reported. For the purpose of this section a significant loss or gain shall exist whenever the actual inventory differs from the recorded inventory by more than five percent (5%) for any drug product.

(d) Every inventory and other records required to be kept shall be kept by the

registrant and be made available for at least two years from the date of such inventory or record.

Section 2. Inventory Requirements.

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

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

(b) A separate inventory shall be made by a registrant for each registered address. Each inventory shall be kept at the registered location for which it is taken.

(c) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate the time the inventory was taken on the inventory record.

(d) An inventory must be maintained in a legible written, typewritten, or printed form.

~~(e) Every year on the anniversary of the date on which the initial inventory was taken by the registrant, a new inventory shall be taken of all stocks of controlled substances on hand.~~

(~~f~~e) Each registered pharmacy shall forward one copy of the annual inventory to the office of the Board of Pharmacy, including the name of the pharmacy, date and time (beginning of business or close of business) the inventory was taken, and the signature of the responsible person(s).

Section 3. Order Forms.

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

(a) An order form may be executed only by or on behalf of the registrant named thereon and only if his registration is current.

(b) Order forms issued by DEA will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and the schedules of the registrant. This information cannot be altered or changed in any manner.

(c) Order forms shall be prepared by use of a typewriter, pen or indelible pencil.

(d) A registrant may authorize another individual to obtain and execute order forms on his behalf by executing a power of attorney. The power of attorney shall be filed with and retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection.

(e) The purchaser registrant shall submit Copy 1 and Copy 2 of the DEA order form 222 to the supplier and retain Copy 3 with his own records. The supplier shall enter the suppliers DEA registration number, number of packages shipped, and the date shipped on Copies 1 and 2. If supplier is another local registrant (not a registrant manufacturer or distributor) Copy 2 may be forwarded directly to the DEA Regional Office or the office of the Board of Pharmacy.

(f) The purchaser registrant shall record on Copy 3 of the order form the number of containers received on each item of the order form and the date received.

(g) Order forms must be maintained separately from all other records of the registrant for a period of two years. Order forms must be available for inspection during that time.

(h) The use of electronic 222 forms issued by the Drug Enforcement Administration is authorized.

Section 4. Methamphetamine Precursor Records

(a) The retail sale of nonliquid methamphetamine precursor drugs or liquid products with ephedrine or pseudoephedrine as the sole active ingredient shall be limited to those amounts as described in W.S.§ 35-7-1059

(b) The seller shall maintain a written or electronic list of such sales (logbook) as described in W.S.§ 35-7-1059.

(c) The sale shall be documented as follows:

(i) The prospective purchaser shall present an identification card that provides a photograph and is issued by a state or the federal government, an alien registration receipt card, a foreign passport, or an employment authorization document which contains a photograph

(ii) The prospective purchaser must sign the logbook and enter in the logbook his or her name, address and the date and time of the sale

(iii) The seller must determine that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct.

(iv) The seller must enter into the logbook the name of the product and the quantity sold.

(d) The logbook must contain a notice to purchasers that entereing false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under 18 U.S.C.§ 1001 and such notice must specify the maximum fine ($250,000.00) and term of imprisonment (5 years).

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).

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 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.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 by on 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 of 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.

Section7. 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 8. 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 proving an incentive to refer patient to a particular pharmacy.

Section 9. 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 callback 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 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 change the patient's address with proper verification without consulting the prescribing practitioner.

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

(iv) 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 10. Refilling Prescriptions-Schedule II.

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

Section 11. 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. 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. 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. 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. 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.

Section16. 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. 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. 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. 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 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).

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 ~~2.~~ 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 ~~3.~~ 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. ~~An order purporting to be a prescription within the meaning and intent of Section 30 of the Act (Section 308 of the Federal Act) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to penalties provided for violations of the provisions of law relating to controlled substances.~~

(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 ~~4.~~ 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 ~~if signed after January 1, 2007~~.

(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; ~~and~~

(D) Security warning list on the front and 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, ~~Section 4 (a) (i)~~. 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.

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

(~~e~~ g) An intern, resident, or foreign physician exempted from registration under Chapter 3, ~~Section 24~~ 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 of other institution as provided in Chapter 3, ~~Section 24,~~ 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.

(~~f~~ h) An official exempted from registration under Chapter 3 ~~Section 25~~ 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 ~~5~~ 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 ~~6~~ 7 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 8. 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 Sschedule 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 proving an incentive to refer patient to a particular pharmacy.

~~Section 7~~ 8 ~~through 10 reserved for future use.~~

Section ~~11~~ 9. 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 ~~paragraph (c) and (e) of~~ 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 ~~by paragraph (g) of~~ 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 ~~Chapter 6, Section 4,~~ 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 callback 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 ~~Section 4,~~ 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 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 change the patient's address with proper verification without consulting the prescribing practitioner.

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

(iv) 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 20 (c)~~.

Section ~~12~~ 10. Refilling Prescriptions-Schedule II.

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

Section ~~13~~ 11. 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 ~~face of the written~~ 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 ~~14~~ 12. 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 ~~15~~ 13. 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~~, Section 1~~ of these regulations.

~~Section 16 through 20 reserved for future use.~~

Section ~~21~~ 14. 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 ~~Section 4~~ this chapter, except for the signature of the prescribing practitioner, or an electronically transmitted prescription provided it meets all requirements in Chapter 2~~, Section 29~~ of the Board's Rules and federal law, or a faxed prescription provided it meets all requirements in Chapter 2~~, Section 20~~ 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, ~~Section 4~~ 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~~, subject to Section 6~~.)

Section ~~22~~ 15. 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 ~~entered on the back of the prescription or on another appropriate uniformly maintained~~ documented on a readily retrievable record, such as medication records, which indicate 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. ~~If the pharmacist merely initials and dates the back of the prescription, he shall be deemed to have dispensed a refill for the full face amount of the prescription.~~ 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 ~~as provided in Section 21 which shall be a new and separate prescription~~.

Section ~~23~~ 16. Partial Filling of Prescriptions-Schedules III and IV.

The partial filling of a prescription for a controlled substance listed in Schedules III or IV, ~~or V,~~ 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 ~~24~~ 17. 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 ~~25~~ 18. 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~~, Section 1~~ of these regulations.

~~Section 26 through 30 reserved for future use.~~

Section ~~31~~ 19. 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 ~~Section 21~~ 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 ~~Section 23~~ this chapter and file the prescription in accordance with ~~Section 24~~ 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 ~~Section 24~~ this chapter.

~~Section 32. Dispensing Without Prescriptions.~~

~~A controlled substance listed in Schedule V, and a controlled substance listed in Schedules II, III or IV which is not a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:~~

~~(a) Such dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery may be completed by a non-pharmacist);~~

~~(b) Not more than 240 cc. (8 ounces) of any such controlled substance may be distributed at retail to the same purchaser in any given 48 hour period;~~

~~(c) The purchaser is at least eighteen (18) years of age;~~

~~(d) The pharmacist requires every purchaser of a controlled substance under this section no known to him to furnish suitable identification (including proof of age where appropriate);~~

~~(e) A bound record book for dispensing of controlled substances (other than by prescription) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the record keeping requirements of Chapter 4, Section 1 of these regulations); and~~

~~(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State, or local law.~~

CHAPTER 8

PRESCRIPTION DRUG MONITORING PROGRAM

Section 1. Authority.

These regulations are promulgated as authorized by the Wyoming Controlled Substance 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:

(i) All requests must be submitted on a form provided by the board and must be mailed, 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 shall include the patient's name, date of birth, purpose of the request, and the date range for the profile;

(iv) A statement indicating a pharmacist/patient or practitioner/patient relationship exists; and

(v) 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) 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.

(d) 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 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:

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

(b) Carisprodol, including any combination product where carisprodol is an active ingredient.