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CHAPTER 3

FEES FOR REGISTRATION AND RE-REGISTRATION

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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.

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

Section 12. Application Forms; Contents; Signature.

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

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

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

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

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

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

Section 13. Filing of Application; Joint Filings.

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

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

Section 14. Acceptance for Filing, Defective Applications.

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

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

Section 15. Additional Information.

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

Section 16. Amendments to and Withdrawal of Applications.

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

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application within ten (10) days, when sent by registered or certified mail, 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 21. 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 22. 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.

MODIFICATION OR TERMINATION

Section 23. 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 24. 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 25. 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 26. 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 27. 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 28. 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 29. 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 30. 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.