

CHAPTER 10  
CONTROLLED SUBSTANCES  
(Drugs)

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 8]

**657—10.1(124) Drug control program administrator.** For the purpose of carrying out the regulatory provisions of Iowa Code chapter 124, the secretary of the board of pharmacy shall serve as a “drug control program administrator.”

**657—10.2(124) Who must register.** Manufacturers, distributors, individual practitioners (M.D., D.O., D.D.S., D.V.M., D.P.M., O.D., P.A., pharmacy, resident physician, advanced registered nurse practitioners), institutional practitioners (hospital), health care institutions (nursing, custodial and county homes), research and analytical laboratories, and teaching institutions shall register on forms provided by the office of the drug control program administrator. To be eligible to register, individual practitioners must hold a current, active license to practice their profession.

**657—10.3(124) Registration and reregistration fee.** For each registration or reregistration to manufacture, distribute, dispense, conduct research or instructional activities and conduct chemical analysis with controlled substances listed in Schedules I through V of chapter 124, registrants shall pay a biennial fee of \$50.

**10.3(1) Time and method of payment.** Registration and reregistration fees shall be paid at the time when the application for registration or reregistration is submitted for filing. Payment should be made in the form of a personal, certified or cashier’s check or money order made payable to Treasurer, State of Iowa. Payments made in the form of stamps, foreign currency or third party endorsed checks will not be accepted.

**10.3(2) Late application.** Persons required to register or reregister under the provisions of chapter 124, division III, who file late application, shall pay an additional \$50 late payment fee.

**10.3(3) Separate registration for independent activities.** The following six groups of activities are deemed to be independent of each other:

- a. Manufacturing controlled substances;
- b. Distributing controlled substances;
- c. Dispensing, conducting research (other than research described in paragraph “d” of this sub-rule) with, and conducting instructional activities with, controlled substances listed in Schedules II through V;
- d. 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;
- e. Conducting research and instructional activities with controlled substances listed in Schedule I; and
- f. Conducting chemical analysis with controlled substances listed in any schedule.

**10.3(4) *Separate registration—coincident activities.*** 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 these paragraphs. Any person, when registered to engage in the group of activities described in each paragraph in this subrule, shall be authorized to engage in the coincident activities described in that paragraph without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, the person complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:

*a.* 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 the person is not registered to manufacture.

*b.* 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 nonnarcotic controlled substances listed in those schedules in which the person is authorized to manufacture.

*c.* 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.

*d.* A person registered to conduct chemical analysis with controlled substances shall be authorized to manufacture and import 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 persons exempted from registration pursuant to section 124.302(3), to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances.

*e.* A person registered or authorized to conduct research (other than research described in 10.3(3)“*d*”) 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 the person is authorized to conduct research to manufacture such substances if and to the extent that such 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 persons exempted from registration pursuant to Iowa Code section 124.302(3), and to conduct instructional activities with controlled substances.

*f.* A person registered to dispense, or to conduct research (other than research described in paragraph 10.3(3)“*d*”) 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.

**10.3(5) *Separate registration—one or more controlled substances.*** 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 the person has filed and had approved a research protocol.

**10.3(6) *Separate registrations for separate locations.*** The following locations shall be deemed not to be places where controlled substances are manufactured, distributed or dispensed:

*a.* 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 Iowa Code section 124.302(3).

b. 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 or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

c. 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; and

d. All activities covered by these rules not exempted above will require registration for each location.

**10.3(7) *Time for application for registration.*** 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 granted and a certificate of registration is issued by the drug control program administrator to such person.

**10.3(8) *Expiration date for application for registration.*** Any person who is registered may apply to be reregistered not less than 30 days, nor more than 60 days, before the expiration date of the registration. A registrant who fails to file for reregistration at least 30 days before the expiration date of the registration must apply for a new registration; the existing registration will expire on the date specified.

**10.3(9) *Exemption of law enforcement officials.*** 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 biennially a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this subrule. For purpose of this subrule, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this subrule.

**10.3(10) *Application forms—contents—signature.*** Application forms may be obtained at the state board of pharmacy examiners' office or by writing to the board of pharmacy examiners. Forms will be mailed, as applicable, to each registered person approximately 60 days before the expiration date of the registration; if any registered person does not receive such forms within 45 days before the expiration date of the registration, the registrant must promptly give notice of the fact and request forms by writing to the board of pharmacy examiners at the foregoing address.

a. 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.

b. 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.

**10.3(11) *Filing of application—joint filings.*** All applications for registration shall be submitted for filing to the board of pharmacy examiners. The appropriate registration fee and any required attachments must accompany the application.

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.

**10.3(12) Acceptance for filing—defective applications.** Applications for registration and reregistration 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 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 within ten days following its receipt 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; the board shall accept for filing any application upon resubmission by the applicant, whether complete or not.

a. Accepting an application for filing does not preclude any subsequent request for additional information and has no bearing on whether the application will be granted.

b. The board of pharmacy examiners may require an applicant to submit 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 ten days 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.

c. An application for registration or reregistration 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. 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. 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, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

**10.3(13) Inspection.** The board may inspect, or cause to be inspected, the establishment of an applicant or registrant. The board shall review the application for registration and other information regarding an applicant in order to determine whether the applicable standards of Iowa Code chapter 124 and these rules have been met by the applicant.

**10.3(14) Modification in registration.** Any registrant may apply to modify a 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 or schedules to be added to the registration and shall be signed by the same person who signed the most recent application for registration or reregistration. If the registrant is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, the registrant 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 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.

**10.3(15) Termination of registration.** The registration of any person shall terminate if and when the person dies, ceases legal existence, discontinues business or professional practice or changes name or address as shown on the certificate of registration. Any registrant who ceases legal existence, discontinues business or professional practice or changes a 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.

This rule is intended to implement Iowa Code sections 124.301 to 124.303.

**657—10.4(124) Exemptions—registration fee.** The requirement of registration fee is waived for the following federal and state institutions: hospitals, health care or teaching institutions, and analytical laboratories authorized to possess, manufacture, distribute and dispense controlled substances in the course of official duties.

**10.4(1) Exemption—requirement of duties.** Exemption from payment of a registration or reregistration fee does not relieve the registrant of any other requirements of duties prescribed by law.

**10.4(2) Exemption of agents and employees—affiliated practitioners.** An individual 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 the registrant is employed provided that:

*a.* The hospital or other institution by whom the registrant is employed has determined that the individual practitioner is so permitted to dispense or prescribe drugs by the appropriate licensing board;

*b.* Such individual practitioner is acting only in the scope of employment in the hospital or institution.

*c.* 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, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., AP 1234567-10 or AP 1234567-12); and

*d.* A current list of internal codes and the corresponding individual 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 individual practitioner.

**657—10.5(124) Revision of controlled substances schedules.** Any person seeking to have any compound, mixture, or preparation containing any depressant or stimulant substance listed in Iowa Code sections 124.204, 124.206, 124.208, 124.210 and 124.212, excepted from or to have new substances added to the application of all or any part of the chapter pursuant to section 124.201 or sections 124.203, 124.205, 124.207, 124.209 and 124.211 may apply to the board of pharmacy examiners for such exception or inclusion.

**10.5(1) Application for exception of a stimulant or depressant compound.** An application for an exception under this rule shall contain the following information:

*a.* The complete quantitative composition of the dosage form.

*b.* Description of the unit dosage form together with complete labeling.

*c.* A summary of the pharmacology of the product including animal investigations and clinical evaluations and studies, with emphasis on the psychic or physiological dependence liability (this must be done for each of the active ingredients separately and for the combination product).

*d.* Details of synergisms and antagonisms among ingredients.

*e.* Deterrent effects of the noncontrolled ingredients.

*f.* Complete copies of all literature in support of claims.

*g.* Reported instances of abuse.

*h.* Reported and anticipated adverse effects.

*i.* Number of dosage units produced for the past two years.

*j.* Evidence that an exception has been granted by the bureau under Section 202(d) of the Federal Controlled Substances Act [21 U.S.C. 812(d)].

**10.5(2) Notification of application.** Within 20 days after the receipt of an application for an exception or inclusion under this rule, the board of pharmacy examiners shall notify the applicant of its acceptance or nonacceptance of the application, and if not accepted, the reason therefor. The board need not accept an application for filing if any of the requirements prescribed in 10.5(1) of these rules are lacking or are not set forth so as to be readily understood. If the applicant desires, the applicant may amend the application to meet the requirements of 10.5(1). The board shall permit any interested person to file written comments on or objections to the proposal and designate the time during which such filings may be made. After consideration of the application and any comments on or objections to the board's finding, the board shall issue its findings on the application.

**657—10.6(124) Certificate of registration—denial of registration—contents.** The board shall issue a certificate of registration to an applicant if the issuance of registration or reregistration is required under the applicable provisions. In the event that the issuance of registration or reregistration is not required, 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.

The certificate of registration shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules 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.

**657—10.7(124) Suspension or revocation of registration.** The board may suspend any registration for any period of time it determines to be justified upon the facts of the case.

**10.7(1) Revocation.** The board may revoke any registration.

**10.7(2) Order to show cause before revocation or suspension.** Before revoking or suspending any registration, the board shall issue an order to show cause and, if requested by the registrant, shall hold a hearing. Notwithstanding the requirements of this rule, however, the board may suspend any registration pending a final order.

**10.7(3) Requirements upon service of order.** Upon service of the order of the board suspending or revoking registration, the registrant shall immediately deliver the certificate of registration to the board. Also, upon service of the order of the board revoking registration, the registrant shall, as instructed by the board:

*a.* Deliver all controlled substances in the registrant's possession to the board or to authorized agents of the board; or

*b.* Place all controlled substances in the registrant's possession under seal.

**10.7(4) Limited substances.** In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new certificate of registration for all substances not affected by revocation or suspension; no fee shall be required to be paid for the new certificate of registration. The registrant shall deliver the old certificate of registration to the board. Also, the registrant shall, as instructed by the board:

*a.* Deliver to the board or to authorized agents of the board all of the particular controlled substance or substances affected by the revocation or suspension which are in the registrant's possession; or

*b.* Place all of such substances under seal.

**10.7(5) *Suspension of registration pending final order.*** 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 with the order to show cause an order of immediate suspension which shall contain a statement of its findings regarding the danger to public health or safety.

**10.7(6) *Requirements upon suspension.*** Upon service of the order of immediate suspension, the registrant shall promptly return the certificate of registration to the board. Also, upon service of the order of the board immediately suspending registration, the registrant shall, as instructed by the board:

*a.* Deliver all affected controlled substances in the registrant's possession to the board or to authorized agents of the board; or

*b.* Place all of such substances under seal.

**10.7(7) *Effectiveness pending final order.*** Any suspension 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 rule may request a hearing on the revocation or suspension of the registration at a time earlier than specified in the order to show cause, which request shall be granted by the board who shall fix a date for such hearing as early as reasonably possible.

**10.7(8) *Extension of registration pending final order.*** In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 30 days before the date on which the existing registration is due to expire, and the board has issued no order on the application, the existing registration of the applicant shall automatically be extended and continue 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 rule even though the registrant failed to apply for reregistration at least 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.

**657—10.8(124) Order to show cause.** 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 to register the applicant, the board shall serve upon the applicant an order to show cause why the registration should not be denied.

**10.8(1)** If, upon information regarding any registrant, the board determines that the registration of the 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.

**10.8(2)** 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 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.

**10.8(3)** Upon receipt of an order to show cause, the applicant or registrant must, if a hearing is desired, 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.

**10.8(4)** When authorized by the board any agent of the board may serve the order to show cause.

**657—10.9(124) Waiver or modification of rules.** The board or the presiding officer may, with the approval of the respondent, modify or waive any rule in this part by notice in advance of the hearing, if determined 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.

**10.9(1) Request for hearing.** Any person entitled to a hearing and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause, file with the board a written request for a hearing.

**10.9(2) Waiver for hearing.** 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 a position on the matters of fact and law involved in the 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.

**10.9(3) Failure to file or appear.** If any person entitled to a hearing fails to file a request for a hearing or a notice of appearance, or if the person files and fails to appear at the hearing, that person shall be deemed to have waived the opportunity for the hearing or to participate in the hearing, unless good cause is shown for the failure.

**10.9(4) Condition for cancellation of hearing.** If any person entitled to a hearing or to participate in a hearing waives or is deemed to have waived the opportunity for the hearing, or to participate in the hearing, the board may cancel the hearing, if scheduled, and issue its final order without a hearing.

**10.9(5) Burden of proof—denial of a registration.** At any hearing for the denial of a registration, the board shall have the burden of proving that the requirements for such registration are not satisfied.

**10.9(6) Burden of proof—revocation or suspension.** 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 are satisfied.

**10.9(7) 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.

**10.9(8) Hearings—opportunity to be present—powers.** Every hearing held by the board where an order may be made or determination had against any person the same shall be by the board except as herein otherwise provided. No evidence shall be received except upon reasonable opportunity for all persons to be present. The board and the officer, agent or representative presiding at the hearing shall have the power to administer oaths and affirmations, issue subpoenas, rule upon offers of proof and receive relevant oral or documentary evidence, take or cause depositions to be taken, regulate the course of the hearing and conduct of the parties, hold informal conferences for the settlement or simplification of the issues by consent of the party or parties and dispose of procedural motions and similar matters.

**10.9(9) Informal hearings—evidence—place.** The board may conduct such hearing in an informal manner and without recourse to the technical common-law rules of evidence required in proceedings in judicial courts, and such manner of proof and introduction of evidence shall be deemed sufficient and shall govern the proof, decision, and administrative or judicial review of all questions of fact if substantial, reliable and probative evidence supports the board's determination. The board shall as a matter of policy provide for the exclusion of irrelevant, immaterial or unduly repetitious evidence. Every person who is a party to such proceedings shall have the right to submit evidence in open hearing and shall have the right of cross-examination. Hearings may be held at any place in the state determined by the board.

**10.9(10)** *Record of hearing—official reporter—employment and compensation—transcript of pleadings and evidence.* The transcript of testimony adduced and exhibits admitted together with the notice, all pleadings, exceptions, motions, requests and papers filed, other than briefs or arguments of law, shall constitute the complete and exclusive record of such hearing and determination of the board and it shall be available to all parties for examination. Any party may obtain a copy thereof at its expense.

*a.* The board may employ and engage the services of a stenographer or reporter, and pay for such services of such stenographer or reporter from any funds available to the board or from any funds which may hereafter be appropriated therefor.

*b.* Said stenographer or reporter so employed for such purposes shall be designated by the board for the purpose of any such hearing as its official reporter to take down in shorthand or stenotype all evidence and matters occurring at such hearing exclusive of oral arguments thereon. Whenever objections are filed to recommended determinations or when a petition for judicial review is filed, such evidence together with the original or a copy of all exhibits admitted and with the notice of hearing, all pleadings, exceptions, motions, requests and papers filed, other than briefs or arguments of law, shall be incorporated in a transcript and certified to by the officer, agent or representative of the board presiding at the hearing. Such transcript when so prepared and certified shall be admissible without further proof in any subsequent review or proceeding affecting such determination of such agency, and shall be prima facie evidence of all facts therein contained as the complete record of such hearing or determination.

**10.9(11)** *Finding of facts.* An issue of fact shall be considered and determined upon the record required to be made, except as herein otherwise provided as to newly discovered evidence. The board shall make an informal finding of facts which shall encompass the relevant facts shown by the evidence. Said finding of facts may be made by direct statement or by reference to the particular charges made in the complaint before the board. A reference to the particular charges in the complaint shall be sufficient as a finding of facts.

**10.9(12)** *Final orders—by whom made—proceeding for revocation or suspension of registration.* The final order or determination made by the board shall be made by a majority of the board. Proceedings for revocation or suspension of certificates of registration shall be determined by not less than a majority of the members comprising the board.

**10.9(13)** *Preliminary hearings—recommendation and record—notices—objections—final determinations.* Any board member or representative thereof may conduct the hearing on behalf of the board. In the event of such hearing before a member, agent or representative it shall be conducted in the same manner provided for a hearing before the board except that instead of making an order or determination the member, agent or representative shall make a recommendation as to the order or determination. After the recommendation is made the member, agent or representative shall present to and file with the board the complete record of the proceedings together with the recommended order or determination and notice of such filing and a copy of the recommended order or determination shall be given by ordinary mail to all persons who were parties to the hearing. Any interested and affected person may, within 20 days thereafter, or within the additional time as may be granted by the board, file with the board any objections to the entry of the order. If any objections are filed the board shall set the same for hearing. The hearing shall be on the record so filed with it. The board may hear additional evidence or refer it back to the hearing member or agent to hear additional evidence. Upon the hearing the board may adopt the recommendations of its member, agent or representative conducting the hearing, amend or modify the same or may make an order or determination as is proper on the record. If no objections are so filed the board may adopt the order or determination recommended by its member, agent or representative without further hearing. If the board does not so adopt such recommendation, order or determination where no objections are filed it shall set said matter for hearing and notify the parties present at said original hearing and proceed as though objections had been filed to the recommended order or determination. Notice of all final orders and determinations shall be given promptly by ordinary mail to all parties to the hearing by the board.

**10.9(14) Orders and determinations—force and effect.** Every order or determination so made shall be in full force and effect after it is duly entered in the permanent records of the board. Revocation or suspension of certificates of registration shall be effective as of the date of revocation by the board, and shall remain revoked or suspended until and unless set aside by a court on review.

**657—10.10(124) Security requirements generally.** 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 person has provided effective controls against diversion, the board shall use the security requirements set forth in these rules as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the board after evaluation of the overall security system and needs of the applicant or registrant.

**10.10(1) Security requirements of substances in possession of the registrant.** Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. 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 noncontrolled 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 normal 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 these rules when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or as 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 operation.

**10.10(2) Security requirements of locations.** Physical security controls of locations registered under the Federal Harrison Narcotic Act or the Federal Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in this rule. 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, shall not necessarily be deemed to comply substantially with the standards set forth in this rule, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved.

**10.10(3) Factors in evaluating physical security systems.** In evaluating the overall security system of a registrant or applicant necessary to maintain effective controls against theft or diversion of controlled substances, the board may consider any of the following factors as it may deem relevant to the need for strict compliance with the requirements of this rule:

- a. The type of activity conducted;
- b. The quantity of controlled substances handled;
- c. The location of the premises and the relationship such location bears on security needs;
- d. The type of building construction comprising the facility and the general characteristics of the building or buildings;
- e. The type of vault, safe and secure enclosures available;
- f. The type of closures on vaults, safes and secure enclosures;
- g. The adequacy of key control systems or combination lock control systems;
- h. The adequacy of electric detection and alarm systems, if any;

- i.* The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
- j.* The procedures for handling business guests, visitors, maintenance personnel and nonemployee service personnel;
- k.* The availability of local police protection or of the registrant's or applicant's security personnel; and
- l.* The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution and disposition of controlled substances in its operations.

**10.10(4) *Storage areas.*** Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in any schedule shall be stored in one of the following secure storage areas:

- a.* Where small quantities permit, a safe:
  - (1) Which safe has an Underwriters' Laboratories Burglary Rating of T-20, E or better, or the equivalent of such a safe;
  - (2) 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
  - (3) 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 of 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.
- b.* A vault constructed which is of substantial construction with a steel door, combination or key lock, and an alarm system.

**10.10(5) *Report of theft or loss of controlled substances.*** A registrant shall report in writing, on forms provided by the board, any theft or significant loss of any controlled substance upon discovery of the theft or loss. The report shall be submitted to the board office within two weeks of discovery of the occurrence.

**10.10(6) *Controlled substance accountability.*** An individual who administers a controlled substance from a non-patient-specific, stock supply in an institutional setting must personally document usage of each dose administered; wastage, if applicable; or return to the pharmacy, on a separate readily retrievable record system. Such documentation cannot be delegated to another individual.

**10.10(7) *Disposal of controlled substances.*** Any persons legally authorized to possess controlled substances in the course of their professional practice or the conduct of their business shall dispose of such drugs by the following procedures:

- a.* The responsible individual shall utilize the services of a DEA-registered and Iowa-licensed disposal firm, or
- b.* The responsible individual shall send to the board a list which includes the names and quantities of the controlled substances to be disposed. The board may authorize and instruct the registrant to dispose of the controlled substances in one of the following manners:
  - (1) By delivery to an agent of the board or to the board office;
  - (2) By destruction of the drugs in the presence of a board officer, agent, inspector, or other authorized individual; or
  - (3) By such other means as the board may determine to ensure that the drugs do not become available to unauthorized persons.

**657—10.11(124) Manner of issuance of prescriptions.** All prescriptions for controlled substances shall be dated as of, and manually signed on, the day when issued and shall bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; and the name, address, and DEA registration number of the practitioner. A practitioner must manually sign a prescription in the same manner the practitioner would sign a check or legal document. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by those regulations.

In each case when a prescription for a Schedule II controlled substance is presented for filling and neither the prescribing individual practitioner issuing the prescription, nor the patient, nor an agent of the patient is known to the pharmacist, the pharmacist shall verify the authenticity of the prescription with the individual practitioner. The pharmacist is required to record the appropriate identifying information, or the manner by which the prescription was verified, on the reverse side of the prescription and sign the pharmacist's name or initials. Pharmacists' verification or identifying information shall be one of the following:

- (1) That the individual practitioner's signature was verified; or
- (2) That the pharmacist called the prescribing individual practitioner's office and that the prescription was verified by the prescribing individual practitioner or an agent (listing agent's name and position).

**10.11(1) Intern—resident—foreign physician.** An intern, or foreign physician exempted from registration under Iowa Code section 124.302 shall include on all hospital orders issued the registration number of the hospital or other institution and the special internal code number assigned by the hospital or other institution as herein provided, in lieu of the registration number of the practitioner required by this rule. Each hospital order shall have the name of the intern, or foreign physician stamped or printed on it.

**10.11(2) Requirements on prescriptions of exempted officials.** An official exempted from registration under section 124.302 shall include on all prescriptions issued, the official's branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and service identification number, in lieu of the registration number of the practitioner required by this rule. The service identification number for a Public Health Service employee is a 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.

**10.11(3) Identifying prescribers in institutions.** All prescriptions issued by individual practitioners (M.D., D.O., et al.) practicing in institutions (hospitals or hospital emergency rooms) or other health care systems that do not use prescriber identified prescription forms shall have the name of the individual practitioner typed or hand-printed on it, as well as the usual signature and federal registration number of the physician.

**657—10.12(124) 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 purposes of continuing a 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 professional practice or research" in Iowa Code section 124.101(1).

**657—10.13(124) Controlled substances—requirement of prescription, emergency prescriptions, and partial fills.** In the case of an emergency situation, as defined by 10.13(5), a pharmacist may dispense a controlled substance listed in Schedule II pursuant to an electronic transmission in accordance with the requirements of rule 657—21.7(124,155A). In the case of an emergency situation, as defined by subrule 10.13(5), a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

**10.13(1) *Quantity limited.*** 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 prescription manually signed by the prescribing individual practitioner);

**10.13(2) *Written prescription.*** The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required except for the signature of the prescribing individual practitioner;

**10.13(3) *Practitioner unknown to pharmacist.*** If the prescribing individual practitioner is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which must include a callback to the prescribing individual practitioner using a telephone number as listed in the telephone directory or other good faith efforts to ensure practitioner identity; and

**10.13(4) *Emergency prescription.*** Within seven days after authorizing an emergency oral prescription, the prescribing individual 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, 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 seven-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. Failure of the pharmacist to do so shall void the authority conferred by this subrule to dispense without a written prescription of a prescribing individual practitioner.

**10.13(5) *Emergency situations.*** For the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the Uniform Controlled Substances Act [Iowa Code chapter 124] the term “emergency situation” means those situations in which the prescribing practitioner determines:

*a.* That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user;

*b.* That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of chapter 124;

*c.* That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

**10.13(6) *Partial filling of prescriptions.*** The partial filling of a prescription for a controlled substance listed in Schedule II is permissible only as follows:

*a.* If the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription), a partial fill of the prescription is permitted. The remaining portion of the prescription must 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 individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

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

c. Information pertaining to current Schedule II prescriptions for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display and printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription, and the information required in this subrule.

(2) Immediate (real-time) updating of the prescription record each time a partial filling of the prescription is conducted.

(3) Retrieval of partially filled Schedule II prescription information as required in 657—subrule 21.11(6).

**10.13(7) Requirement of prescription.** An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III or IV pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

**10.13(8) Refilling of prescriptions.** No prescription for a controlled substance listed in Schedule III, IV or V shall be filled or refilled more than six months after the date on which it was issued nor be refilled more than five times. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as a medication record, the document must be uniformly maintained and readily retrievable. If maintained in an automated data processing system, all requirements of rule 657—21.11(124,155A) shall be met. The following information must be retrievable by the prescription number: the name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription, it shall be deemed that the full face amount of the prescription has been dispensed. The prescribing practitioner may authorize additional refills of Schedule III, IV or V controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist, provided the following conditions are met:

a. The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

b. The pharmacist who obtains the oral authorization records on the reverse of the original prescription the date, quantity of refill, number of additional refills authorized, and initials the prescription showing who received the authorization from the prescribing practitioner who issued the original prescription.

c. The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

d. The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five refill, six-month limitation.

**10.13(9) *Partial filling of prescriptions.*** The partial filling of a prescription for a controlled substance listed in Schedule III, 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 months after the date on which the prescription was issued.

**10.13(10) *Requirement of prescription.*** 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. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription; if no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with these rules and fill the prescription.

**10.13(11) *Individual practitioner.*** An individual practitioner may administer or dispense a controlled substance listed in Schedule V in the course of professional practice without a prescription, subject to these rules.

**10.13(12) *Institutional practitioner.*** An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule V only pursuant to a written prescription signed by the prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

**10.13(13) *Dispensing without prescription.*** A controlled substance listed in Schedule V 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. Dispensing is made only by a licensed Iowa pharmacist and not by a nonpharmacist employee even if under the direct supervision of a pharmacist. (Although after the pharmacist has fulfilled the professional and legal responsibilities set forth in this subrule, the actual cash, credit transaction or delivery may be completed by a nonpharmacist.)

b. Not more than 240cc. (8 ounces) of any controlled substance containing opium, nor more than 120cc, (4 ounces) of any other controlled substance, nor more than 48 dosage units of any controlled substance containing opium, nor more than 24 dosage units of any other controlled substance may be distributed at retail to the same purchaser in any given 48-hour period.

c. The purchaser is at least 18 years of age.

d. The pharmacist requires every purchaser of a controlled substance under this rule not known by the pharmacist 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.

*f.* A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state or local law.

This rule is intended to implement Iowa Code section 124.308.

**657—10.14(124,155A) Facsimile transmission of a prescription for Schedule II controlled substances.** A prescription for a Schedule II controlled substance may be transmitted via facsimile to the pharmacy only as provided in rules 657—21.6(124,155A) to 657—21.10(124,155A).

**657—10.15(124) Records form—complimentary packages.** The records form for the distribution of complimentary packages of controlled substances shall contain the name, address, Iowa wholesale drug license number, and DEA registration number of the supplier; the name, address, Iowa controlled substance registration number, and DEA registration number of the practitioner; the name and quantity of the specific controlled substances delivered; and the date of that delivery.

This rule is intended to implement Iowa Code section 124.306.

**657—10.16(124) Who can administer.**

**10.16(1)** Only the following are designated by the board as qualified individuals to whom a physician can delegate the administration of controlled substances:

*a.* Persons who have successfully completed a medication administration course reviewed by the board of pharmacy examiners.

*b.* Advanced emergency medical technicians and paramedics.

*c.* Licensed physician assistants.

*d.* Licensed pharmacists.

**10.16(2)** A podiatrist may delegate the administration of controlled substances to a nurse or intern.

**10.16(3)** A dentist may delegate the administration of controlled substances to a dental assistant.

**10.16(4)** A veterinarian may delegate the administration of controlled substances to a veterinary assistant.

This rule is intended to implement Iowa Code sections 124.101(1)“*b*,” 147.107, and 155A.4(2)“*c*.”

**657—10.17(124) Imitation controlled substance.** The following substance is designated as an imitation controlled substance:

Co-Caine. A product which, as of September 1982, was being marketed in Iowa by S. A. Importers, Suite 110, 2200 West 66th Street, Richfield, MN 55423.

**657—10.18(124) Controlled substance inventory.** It shall be the responsibility of both the current pharmacy owner and the prospective pharmacy owner to take an inventory of all controlled substances whenever there is a change in ownership of any establishment licensed by the board as defined in Iowa Code section 155A.13. It shall be the responsibility of the pharmacy owner to take an inventory of all controlled substances whenever there is a change in the pharmacist in charge of any establishment licensed by the board as defined in Iowa Code section 155A.13. A pharmacy owner may delegate the actual taking of such inventory.

**657—10.19(124) Excluded substances.** The following substances are classified as products exempted from classification as controlled substances:

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
Bioline Laboratories	Theophed	00719-1945	TB	Phenobarbital	8.00
Goldline Laboratories	Guiaphed Elixir	00182-1377	EL	Phenobarbital	4.00
Goldline Laboratories	Tedrigen Tablets	00182-0134	TB	Phenobarbital	8.00
Hawthorne Products Inc.	Choate's Leg Freeze		LQ	Chloral hydrate	246.67
Parke-Davis & Co.	Tedral	00071-0230	TB	Phenobarbital	8.00
Parke-Davis & Co.	Tedral Elixir	00071-0242	EX	Phenobarbital	40.00
Parke-Davis & Co.	Tedral S.A.	00071-0231	TB	Phenobarbital	8.00
Parke-Davis & Co.	Tedral Suspension	00071-0237	SU	Phenobarbital	80.00
Parmed Pharmacy	Asma-Ese	00349-2018	TB	Phenobarbital	8.10
Rondex Labs	Azma-Aids	00367-3153	TB	Phenobarbital	8.00
Smith Kline Consumer	Benzedrex	49692-0928	IN	Propylhexedrine	250.00
Sterling Drug, Inc.	Bronkolixir	00057-1004	EL	Phenobarbital	0.80
Sterling Drug, Inc.	Bronkotabs	00057-1005	TB	Phenobarbital	8.00
Vicks Chemical Co.	Vicks Inhaler	23900-0010	IN	I-Desoxyephedrine	113.00
White Hall Labs	Primatene (P-tablets)	00573-2940	TB	Phenobarbital	8.00

This rule is intended to implement Iowa Code sections 124.210(4) and 124.211.

**657—10.20(124) Temporary designation of controlled substances.**

**10.20(1)** Amend Iowa Code subsection 124.206(7) by rescinding paragraph “b” and relettering paragraph “c” as “b.”

**10.20(2)** Amend Iowa Code section 124.208 by adopting the following new subsection:

8. Hallucinogenic substances. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved product. Some other names for dronabinol: (6aR-trans)-6a, 7, 8, 10a-tetrahydro-6, 6, 9-trimethyl-3-pentyl-6H-dibenzo [b,d] pyran-1-ol, or (-)-delta-9-(trans)-tetrahydrocannabinol.

**657—10.21(205) Purpose of issue of prescription.** Any order purporting to be a prescription for a Schedule III dronabinol product not issued for indications approved by the Food and Drug Administration is not a prescription within the meaning and intent of the federal law (21 U.S.C. 829) or of Iowa Code section 205.3. Any person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. Nothing in this rule shall be deemed to prohibit the prescribing of dronabinol products approved by the Food and Drug Administration for other than indications for use approved by the Food and Drug Administration by a researcher or registered practitioner conducting research, provided that the research is conducted in accordance with research protocol provisions approved by the board or federal law (21 CFR 1301.18 as of April 1, 1999).

This rule is intended to implement Iowa Code section 205.3.

**657—10.22(205) Requirement of prescription.** An individual practitioner as defined in Iowa Code subsection 124.101(23) may not administer or dispense Schedule III dronabinol products unless such administering or dispensing is for indications for use approved by the Food and Drug Administration. Any person knowingly administering or dispensing Schedule III dronabinol products contrary to this rule shall be subject to the penalties provided for violation of the provisions of law relating to controlled substances. Nothing in this rule shall be deemed to prohibit the administering or dispensing of Schedule III dronabinol products for other indications for use approved by the Food and Drug Administration by a researcher or registered practitioner conducting research provided that the research is conducted in accordance with research protocol provisions approved by the board or federal law (21 CFR 1301.18 as of April 1, 1999).

This rule is intended to implement Iowa Code section 205.3.

**657—10.23(124) Exempt anabolic steroid products.** The Iowa board of pharmacy examiners hereby adopts the table of “Exempt Anabolic Steroid Products” contained in Title 21 CFR, Part 1308, Section 34, as published in the Federal Register dated November 24, 1992, Vol. 57, No. 227, page 55091, and as amended by the addition of two new entries to the table as published in the Federal Register dated June 29, 1993, Vol. 58, No. 123, page 34707. Copies of the table may be obtained by written request to the board office at 1209 East Court Avenue, Executive Hills West, Des Moines, Iowa 50319.

These rules are intended to implement Iowa Code sections 124.201, 124.202, 124.208, 124.306, 124.501, 124.506, and 205.3.

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