

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

657—10.1(124) Who shall register. Any person or business located in Iowa that manufactures, distributes, dispenses, prescribes, imports or exports, conducts research or instructional activities, or conducts chemical analysis with controlled substances in the state of Iowa, or that proposes to engage in such activities with controlled substances in the state, shall obtain and maintain a registration issued by the board unless exempt from registration pursuant to rule 657—10.6(124). A person or business required to be registered shall not engage in any activity for which registration is required until the application for registration is granted and the board has issued a certificate of registration to such person or business.

Manufacturers, distributors, reverse distributors, importers and exporters, individual practitioners (M.D., D.O., D.D.S., D.V.M., D.P.M., O.D., P.A., resident physician, advanced registered nurse practitioner), pharmacies, hospitals and animal shelters, care facilities, researchers and dog trainers, analytical laboratories, and teaching institutions shall register on forms provided by the board office. To be eligible to register, individual practitioners must hold a current, active license in good standing, issued by the appropriate Iowa professional licensing board, to practice their profession in Iowa.

657—10.2(124) Application forms. Application forms may be obtained from the Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Forms are also available on the board's Web site, www.state.ia.us/ibpe. Registration renewal forms will be mailed to each registrant approximately 60 days before the expiration date of the registration. A registrant who has not received a renewal form 45 days before the expiration date of the registration is responsible for contacting the board to request an application.

10.2(1) Signature requirements. Each application, attachment, or other document filed as part of an application shall be signed by the applicant as follows:

a. If the applicant is an individual practitioner, the practitioner shall sign the application and supporting documents.

b. If the applicant is a business, the application and supporting documents shall be signed by the person ultimately responsible for the security and maintenance of controlled substances at the registered location.

10.2(2) Submission of multiple applications. Any person or business required to obtain more than one registration may submit all applications in one package. Each application shall be complete and shall not refer to any accompanying application or any attachment to an accompanying application for required information.

657—10.3(124) Registration and renewal. For each registration or timely renewal of a registration to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities, or conduct chemical analysis with controlled substances listed in Schedules I through V of Iowa Code chapter 124, registrants shall pay a biennial fee of \$100.

10.3(1) Time and method of payment. Registration and renewal fees shall be paid at the time the application for registration or renewal is submitted. Payment should be made in the form of a personal, certified, or cashier's check or a money order made payable to the Iowa Board of Pharmacy. Payments made in the form of foreign currency or third-party endorsed checks will not be accepted.

10.3(2) Late renewal. Any registered person or business may apply, on forms provided by the board office, for registration renewal not more than 60 days prior to the expiration of the registration. Failure to renew a registration prior to the first day of the month following expiration shall require payment of the renewal fee and a penalty fee of \$100. Payment shall be made as specified in subrule 10.3(1).

657—10.4(124) Exemptions—registration fee. The registration fee is waived for federal, state, and local law enforcement agencies and 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) *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 shall maintain a registration to conduct chemical analysis. Such laboratories shall be exempt from payment of a fee for registration.

10.4(2) *Registration and duties not exempt.* Exemption from payment of a registration or registration renewal fee as provided in this rule does not relieve the agency or institution of registration or of any other requirements or duties prescribed by law.

657—10.5(124) Separate registration for independent activities; coincident activities. The following activities are deemed to be independent of each other and shall require separate registration. Any person or business engaged in more than one of these activities shall be required to separately register for each independent activity, provided, however, that registration in an independent activity shall authorize the registrant to engage in activities identified coincident with that independent activity.

10.5(1) *Manufacturing controlled substances.* A person or business registered to manufacture controlled substances in Schedules I through V may distribute any substances for which registration to manufacture was issued. A person or business registered to manufacture controlled substances in Schedules II through V may conduct chemical analysis and preclinical research, including quality control analysis, with any substances listed in those schedules for which the person or business is registered to manufacture.

10.5(2) *Distributing controlled substances.* This independent activity includes the delivery, other than by administering or dispensing, of controlled substances listed in Schedules I through V. No coincident activities are authorized.

10.5(3) *Dispensing or instructing with controlled substances.* This independent activity includes, but is not limited to, prescribing by individual practitioners, dispensing by pharmacies and hospitals, and conducting instructional activities with controlled substances listed in Schedules II through V. A person or business registered for this independent activity may conduct research and instructional activities with those substances for which the person or business is registered to the extent authorized under state law.

10.5(4) *Conducting research with controlled substances listed in Schedule I.* A researcher may manufacture or import the substances for which registration was issued provided that such manufacture or import is permitted under the federal Drug Enforcement Administration (DEA) registration. A researcher may distribute the substances for which registration was issued to persons or businesses registered or authorized to conduct research with that class of substances or registered or authorized to conduct chemical analysis with controlled substances.

10.5(5) *Conducting research with controlled substances listed in Schedules II through V.* A researcher may conduct chemical analysis with controlled substances in those schedules for which registration was issued, may manufacture such substances if and to the extent such manufacture is permitted under the federal DEA registration, and may import such substances for research purposes. A researcher may distribute controlled substances in those schedules for which registration was issued to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to persons exempt from registration pursuant to Iowa Code subsection 124.302(3), and may conduct instructional activities with controlled substances.

10.5(6) *Conducting chemical analysis with controlled substances.* A person or business registered to conduct chemical analysis with controlled substances listed in Schedules I through V may manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempt from registration pursuant to Iowa Code subsection 124.302(3); may export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.

10.5(7) *Importing or exporting controlled substances.* A person or business registered to import controlled substances listed in Schedules I through V may distribute any substances for which such registration was issued.

657—10.6(124) Separate registrations for separate locations; exemption from registration. A separate registration is required for each principal place of business or professional practice location where controlled substances are manufactured, distributed, imported, exported, or dispensed unless the person or business is exempt from registration pursuant to Iowa Code subsection 124.302(3) or this rule.

10.6(1) *Warehouse.* A warehouse where controlled substances are stored by or on behalf of a registered person or business shall be exempt from registration except as follows:

a. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to registered locations other than the registered location from which the substances were delivered to the warehouse.

b. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to persons exempt from registration pursuant to Iowa Code subsection 124.302(3).

10.6(2) *Sales office.* An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised shall be exempt from registration. Such office shall not contain controlled substances, except substances used for display purposes or for lawful distribution as samples, and shall not serve as a distribution point for filling sales orders.

10.6(3) *Prescriber's office.* An office used by a prescriber who is registered at another location and where controlled substances are prescribed but where no supplies of controlled substances are maintained shall be exempt from registration. However, a prescriber who practices at more than one office location where controlled substances are administered or otherwise dispensed as a regular part of the prescriber's practice shall register at each location wherein the prescriber maintains supplies of controlled substances.

10.6(4) *Prescriber in hospital.* A prescriber who is registered at another location and who treats patients and may order the administration of controlled substances in a hospital other than the prescriber's registered practice location shall not be required to obtain a separate registration for the hospital.

10.6(5) *Affiliated interns, residents, or foreign physicians.* 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 which the individual practitioner is employed has determined that the practitioner is 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 combination thereof which shall be appended to the institution's DEA registration number, preceded by a hyphen (e.g., AP1234567-10 or AP1234567-12); and

d. The hospital or institution maintains a current list of internal code numbers identifying the corresponding individual practitioner, available for the purpose of verifying the authority of the prescribing individual practitioner.

657—10.7 to 10.9 Reserved.

657—10.10(124,147,155A) *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 or registrant in order to determine whether the applicant or registrant has met the applicable standards of Iowa Code chapter 124 and these rules.

657—10.11(124) Modification or termination of registration. A registered individual or business may apply to modify a current registration as provided by this rule.

10.11(1) *Change of substances authorized.* Any registrant may apply to modify the substances authorized by the registration by submitting a written request to the board. The request shall include the registrant's name, address, telephone number, registration number, and the substances or schedules to be added to or removed from the registration and shall be signed by the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.

10.11(2) *Change of address of registered location.*

a. Individual practitioner, researcher, analytical laboratory, or teaching institution. An entity registered under these classifications may apply to change the address of the registered location by submitting a written request to the board. The request shall include the registrant's name, current address, new address, telephone number, effective date of the address change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.

b. Pharmacy, hospital, care facility, manufacturer, distributor, importer, or exporter. An entity registered under these classifications shall apply to change the address of the registered location by submitting a completed application for registration. Applications may be obtained and shall be submitted as provided in rule 657—10.2(124). The registration fee as provided in rule 657—10.3(124) shall accompany each completed application.

10.11(3) *Change of registrant's name.*

a. Individual practitioner, researcher, analytical laboratory, or teaching institution. An entity registered under these classifications may apply to change the registrant's name by submitting a written request to the board. The request shall include the registrant's current name, the new name, address, telephone number, effective date of the name change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification. Change of name, as used in this paragraph, refers to a change of the legal name of the registrant and does not authorize the transfer of a registration issued to an individual practitioner or researcher to another individual practitioner or researcher.

b. Pharmacy, hospital, care facility, manufacturer, distributor, importer, or exporter. An entity registered under these classifications shall apply to change the registrant name by submitting a completed application for registration. Applications may be obtained and shall be submitted as provided in rule 657—10.2(124). The registration fee as provided in rule 657—10.3(124) shall accompany each completed application.

10.11(4) *Change of ownership of registered business entity.* A change of immediate ownership of a pharmacy, hospital, care facility, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall require the completion of an application for registration. Applications may be obtained and shall be submitted as provided in rule 657—10.2(124). The registration fee as provided in rule 10.3(124) shall accompany each completed application.

10.11(5) *Change of responsible individual.* Any registrant, except an individual practitioner, a researcher, a hospital, or a pharmacy, may apply to change the responsible individual authorized by the registration by submitting a written request to the board. The request shall include the registrant's name, address, telephone number, the name and title of the current responsible individual and of the new responsible individual, the effective date of the change, and the registration number, and shall be signed by the new responsible individual. No fee shall be required for the modification.

a. Individual practitioners and researchers. Responsibility under a registration issued to an individual practitioner or researcher shall remain with the named individual practitioner or researcher. The responsible individual under such registration may not be changed.

b. Pharmacies and hospitals. The responsible pharmacist may execute a power of attorney for DEA order forms to change responsibility under the registration issued to the pharmacy or hospital. The power of attorney shall include the name, address, DEA registration number, and Iowa uniform controlled substances Act (CSA) registration number of the registrant. The power of attorney shall

identify the current and new responsible individuals and shall authorize the new responsible individual to execute applications and official DEA order forms to requisition Schedule II controlled substances. The power of attorney shall be signed by both individuals, shall be witnessed by two adults, and shall be maintained by the registrant and available for inspection or copying by representatives of the board or other state or federal authorities.

10.11(6) Termination of registration. A registration issued to an individual shall terminate upon the death of the individual. A registration issued to an individual or business shall terminate when the registered individual or business ceases legal existence, discontinues business, or discontinues professional practice.

657—10.12(124) Denial, modification, suspension, or revocation of registration.

10.12(1) Grounds for suspension or revocation. The board may suspend or revoke any registration upon a finding that the registrant:

- a. Has furnished false or fraudulent material information in any application filed under this chapter;
- b. Has had the registrant's federal registration to manufacture, distribute, or dispense controlled substances suspended or revoked;
- c. Has been convicted of a public offense under any state or federal law relating to any controlled substance. For the purpose of this rule only, a conviction shall include a plea of guilty, a forfeiture of bail or collateral deposited to secure a defendant's appearance in court which forfeiture has not been vacated, or a finding of guilt in a criminal action even though entry of the judgment or sentence has been withheld and the individual has been placed on probation;
- d. Has committed such acts as would render the registrant's registration under Iowa Code section 124.303 inconsistent with the public interest as determined by that section; or
- e. Has been subject to discipline by the registrant's respective professional licensing board and the discipline revokes, suspends, or modifies the registrant's authority regarding controlled substances (including, but not limited to, limiting or prohibiting the registrant from prescribing or handling controlled substances). A certified copy of the record of licensee discipline or a copy of the licensee's surrender of the professional license shall be conclusive evidence.

10.12(2) Limited suspension or revocation. If the board finds grounds to suspend or revoke a registration, the board may limit revocation or suspension of the registration to the particular controlled substance with respect to which the grounds for revocation or suspension exist. If the 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 for the new certificate of registration. The registrant shall deliver the old certificate of registration to the board.

10.12(3) Denial of registration or registration renewal. If upon examination of an application for registration or registration renewal, including any other information the board has or receives regarding the applicant, the board determines that the issuance of the registration would be inconsistent with the public interest, the board shall serve upon the applicant an order to show cause why the registration should not be denied.

10.12(4) Considerations in denial of registration. In determining the public interest, the board shall consider all of the following factors:

- a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.
- b. Compliance with applicable state and local law.
- c. Any convictions of the applicant under any federal and state laws relating to any controlled substance.
- d. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion.
- e. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter.

f. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law.

g. Any other factors relevant to and consistent with the public health and safety.

10.12(5) *Order to show cause.* Before denying, modifying, suspending, or revoking a registration, the board shall serve upon the applicant or registrant an order to show cause why the registration should not be denied, modified, revoked, or suspended. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before an administrative law judge or the board at a time and place not less than 30 days after the date of service 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. If the order to show cause involves the possible denial of registration renewal, the order shall be served not later than 30 days before the expiration of the registration. Proceedings to refuse renewal of registration shall not abate the existing registration, which shall remain in effect pending the outcome of the administrative hearing unless the board issues an order of immediate suspension pursuant to subrule 10.12(9).

10.12(6) *Hearing requested.* If an applicant or registrant who has received an order to show cause desires a hearing on the matter, the applicant or registrant shall file a request for a hearing within 30 days after the date of service of the order to show cause. If a hearing is requested, the board shall hold a hearing pursuant to 657—Chapter 35 at the time and place stated in the order and without regard to any criminal prosecution or other proceeding. Unless otherwise ordered by the board, an administrative law judge employed by the department of inspections and appeals shall be assigned to preside over the case and to render a proposed decision for the board's consideration.

10.12(7) *Waiver of hearing.* If an applicant or registrant entitled to a hearing on an order to show cause fails to file a request for hearing, or if the applicant or registrant requests a hearing but fails to appear at the hearing, the applicant or registrant shall be deemed to have waived the opportunity for a hearing unless the applicant or registrant shows good cause for such failure.

10.12(8) *Final board order when hearing waived.* If an applicant or registrant entitled to a hearing waives or is deemed to have waived the opportunity for a hearing, the executive director of the board may cancel the hearing and issue, on behalf of the board, the board's final order on the order to show cause.

10.12(9) *Order of immediate suspension.* The board may suspend any registration simultaneously with the service upon the registrant of an order to show cause why such registration should not be revoked or suspended if it finds there is an imminent danger to the public health or safety that warrants such action. If the board suspends a registration simultaneously with the service of the order to show cause upon the registrant, it shall serve an order of immediate suspension containing a statement of its findings regarding the danger to public health or safety upon the registrant with the order to show cause. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, under the provisions of the Iowa administrative procedure Act, unless sooner withdrawn by the board or dissolved by the order of the district court or an appellate court.

10.12(10) *Disposition of controlled substances.* If the board suspends or revokes a registration, the registrant shall promptly return the certificate of registration to the board. Also, upon service of the order of the board suspending or revoking the registration, the registrant shall deliver all affected controlled substances in the registrant's possession to the board or authorized agent of the board. Upon receiving the affected controlled substances from the registrant, the board or its authorized agent shall place all such substances under seal and retain the sealed controlled substances pending final resolution of any appeals or until a court of competent jurisdiction directs otherwise. No disposition may be made of the substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of proceeds of the sale with the court. Upon a revocation order's becoming final, all such controlled substances may be forfeited to the state.

10.12(11) *Notifications.* The board shall promptly notify the DEA and the Iowa department of public safety of all orders suspending or revoking registration and all forfeitures of controlled substances.

657—10.13 and 10.14 Reserved.

657—10.15(124,155A) Security requirements. 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.

10.15(1) Physical security. Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. A registrant shall periodically review and adjust security measures based on rescheduling of substances or changes in the quantity of substances in the possession of the registrant.

a. Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

b. Controlled substances listed in Schedules II through V may be stored in a securely locked, substantially constructed cabinet. However, pharmacies and hospitals may disperse these substances throughout the stock of noncontrolled substances in a manner so as to obstruct the theft or diversion of the controlled substances.

10.15(2) 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 it deems relevant to the need for strict compliance with the requirements of this rule:

- a.* The type of activity conducted;
- b.* The type, form, and quantity of controlled substances handled;
- c.* The location of the premises and the relationship such location bears to 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 adequacy of supervision over employees having access to controlled substances, to storage areas, or to manufacturing areas;
- j.* The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
- k.* The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
- l.* The availability of local police protection or of the registrant's or applicant's security personnel; and
- m.* The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances.

10.15(3) Manufacturing and compounding storage areas. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in any schedule shall be stored pursuant to federal laws and regulations.

657—10.16(124) Report of theft or loss. A registrant shall report in writing, on forms provided by the board, any theft or significant loss of any controlled substance when the loss is attributable to other than inadvertent error. The report shall be submitted to the board office within two weeks of the discovery of the theft or loss. Thefts shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action is taken against them. A copy of the report shall be maintained in the files of the registrant, and the board will provide a copy of the report to the DEA. In addition to this required report, DEA requires the registrant to deliver notice, immediately

upon discovery of a theft or significant loss of controlled substances, to the nearest DEA field office via telephone, facsimile, or a brief written message explaining the circumstances.

657—10.17(124) Accountability of stock supply. An individual who administers a controlled substance from a non-patient-specific, stock supply in an institutional setting shall personally document on a separate readily retrievable record system each dose administered, wasted, or returned to the pharmacy. Such documentation shall not be delegated to another individual. Wastage documentation shall include the signature of a witnessing licensed health care practitioner.

Distribution records for non-patient-specific, floor-stocked controlled substances shall bear the following information:

1. Patient's name;
2. Prescriber who ordered drug;
3. Name of drug, dosage form, and strength;
4. Time and date of administration to patient and quantity administered;
5. Signature or unique electronic signature of individual administering controlled substance;
6. Returns to the pharmacy;
7. Waste, which is required to be witnessed and cosigned by another licensed health care practitioner.

657—10.18(124) Disposal. 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 pursuant to the procedures and requirements of this rule. Disposal records shall be maintained in the files of the registrant.

10.18(1) Registrant stock supply. Pharmacy personnel, registrants, and registrant staff shall remove from current inventory and dispose of controlled substances by one of the following procedures.

a. The responsible individual shall utilize the services of a DEA-registered and Iowa-licensed disposal firm.

b. 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 drugs do not become available to unauthorized persons.

10.18(2) Waste. Except as otherwise specifically provided by federal or state law or rules of the board, the unused portion of a controlled substance resulting from administration to a patient from a registrant's stock or emergency supply or resulting from drug compounding operations may be destroyed or otherwise disposed of by the registrant or a pharmacist in witness of one other licensed health care provider or a registered pharmacy technician 18 years of age or older pursuant to this subrule. A written record of the wastage shall be made and maintained by the registrant for a minimum of two years following the destruction or other disposal. The record shall include the signatures of the individual destroying or otherwise disposing of the waste controlled substance and of the witnessing licensed health care provider or registered pharmacy technician and shall identify the following:

- a.* The controlled substance wasted;
- b.* The date of destruction or other disposition;
- c.* The quantity or estimated quantity of the wasted controlled substance;
- d.* The source of the controlled substance, including identification of the patient to whom the substance was administered or the drug compounding process utilizing the controlled substance; and
- e.* The reason for the waste.

10.18(3) Previously dispensed controlled substances. Controlled substances dispensed to or for a patient and subsequently requiring destruction due to discontinuance of the drug, death of the patient, or other reasons necessitating destruction may be destroyed or otherwise disposed of by a pharmacist in

witness of one other responsible adult pursuant to this subrule. All licenses and registrations issued to the pharmacy, the pharmacist, and any individual witnessing the destruction or other disposition shall not be subject to sanctions relating to controlled substances at the time of the destruction or disposition. The individuals involved in the destruction or other disposition shall not have been subject to any criminal, civil, or administrative action relating to violations of controlled substances laws, rules, or regulations within the past five years. The pharmacist in charge shall be responsible for designating pharmacists authorized to participate in the destruction or other disposition pursuant to this subrule. The authorized pharmacist shall prepare and maintain in the pharmacy a readily retrievable record of the destruction or other disposition, which shall be clearly marked to indicate the destruction or other disposition of noninventory or patient drugs. The record shall include, at a minimum, the following:

- a. Source of the controlled substance (patient identifier or administering practitioner, if applicable, and date of return);
- b. The name, strength, and dosage form of the substance;
- c. The quantity returned and destroyed or otherwise disposed;
- d. The date the substance is destroyed or otherwise disposed;
- e. The signatures or other unique identification of the pharmacist and the witness.

657—10.19 and 10.20 Reserved.

657—10.21(124,126,155A) Prescription requirements. All prescriptions for controlled substances shall be dated as of, and manually signed on, the day issued. Controlled substances prescriptions shall be valid for six months following date of issue.

10.21(1) Form of prescription. All prescriptions 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 prescriber. All prescriptions issued by individual prescribers shall include the legibly preprinted, typed, or hand-printed name of the prescriber as well as the prescriber's signature. When an oral order is not permitted, prescriptions shall be written with ink, indelible pencil, or typed print and shall be manually signed by the prescriber. A secretary or agent may prepare a prescription for the signature of the prescriber but the prescribing practitioner is responsible for the accuracy, completeness, and validity of the prescription. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this rule.

10.21(2) Verification by pharmacist. The pharmacist shall verify the authenticity of the prescription with the individual prescriber 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 or patient's agent is known to the pharmacist. The pharmacist is required to record the manner by which the prescription was verified and include the pharmacist's name or unique identifier.

10.21(3) Intern, resident, foreign physician. An intern, resident, or foreign physician exempt from registration pursuant to subrule 10.6(5) shall include on all prescriptions issued the hospital's registration number and the special internal code number assigned by the hospital in lieu of the prescriber's registration number required by this rule. Each prescription shall include the stamped or printed name of the intern, resident, or foreign physician as well as the prescriber's signature.

10.21(4) Valid prescriber/patient relationship. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or to oversee the patient's use of the controlled substance, a prescription shall lose its validity. A prescriber/patient relationship shall be deemed broken when the prescriber dies, retires, or moves out of the local service area or when the prescriber's authority to prescribe is suspended, revoked, or otherwise modified to exclude authority for the schedule in which the prescribed substance is listed. The pharmacist, upon becoming aware of the situation, shall cancel the prescription and any remaining refills. However, the pharmacist shall exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new prescription can be issued.

10.21(5) *Schedule II prescriptions.* With appropriate verification, a pharmacist may add information provided by the patient or patient's agent, such as the patient's address, to a Schedule II controlled substance prescription. A pharmacist shall never change the patient's name, the controlled substance prescribed except for generic substitution, or the name or signature of the prescriber. After consultation with the prescribing practitioner and documentation of such consultation, a pharmacist may change or add the following information on a Schedule II controlled substance prescription:

- a. The drug strength;
- b. The dosage form;
- c. The drug quantity;
- d. The directions for use; and
- e. The date the prescription was issued.

657—10.22(124) Schedule II emergency prescriptions.

10.22(1) *Emergency situation defined.* For the purposes of authorizing an oral or electronically transmitted prescription for a Schedule II controlled substance listed in Iowa Code section 124.206, the term "emergency situation" means those situations in which the prescribing practitioner determines that all of the following apply:

- a. Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.
- b. No appropriate alternative treatment is available, including administration of a drug that is not a Schedule II controlled substance.
- c. 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.

10.22(2) *Requirements of emergency prescription.* In the case of an emergency situation as defined herein, a pharmacist may dispense a controlled substance listed in Schedule II pursuant to an electronic transmission or upon receiving oral authorization of a prescribing individual practitioner provided that:

a. The quantity prescribed and dispensed is limited to the smallest available quantity to meet the needs of the patient during the emergency period. Dispensing beyond the emergency period requires a written prescription manually signed by the prescribing individual practitioner.

b. If the pharmacist does not know the prescribing individual practitioner, the pharmacist shall make a reasonable effort to determine that the authorization came from an authorized prescriber. The pharmacist shall record the manner by which the authorization was verified and include the pharmacist's name or unique identification.

c. The pharmacist shall prepare a temporary written record of the emergency prescription. The temporary written record shall consist of a hard copy of the electronic transmission or a written record of the oral transmission authorizing the emergency dispensing. If the emergency prescription is transmitted by the practitioner's agent, the record shall include the name and title of the individual who transmitted the prescription.

d. If the emergency prescription is transmitted via electronic transmission, the means of transmission shall not obscure or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the written prescription, and the hard-copy record of the electronic transmission shall not be obscured or rendered illegible due to such security features.

e. Within seven days after authorizing an emergency 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 of 657—10.21(124,126,155A), the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the emergency 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. The written prescription shall be attached to and maintained with the temporary written record prepared pursuant to paragraph "c."

f. The pharmacist shall notify the board if the prescribing individual fails to deliver a written prescription. Failure of the pharmacist to so notify the board, or failure of the prescribing individual

to deliver the required written prescription as herein required, shall void the authority conferred by this subrule.

[ARC 7636B, IAB 3/11/09, effective 4/15/09]

657—10.23(124) Schedule II prescriptions—partial filling. The partial filling of a prescription for a controlled substance listed in Schedule II is permitted as provided in this rule.

10.23(1) *Insufficient supply on hand.* If the pharmacist is unable to supply the full quantity called for in a prescription and makes a notation of the quantity supplied on the prescription record, 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. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescriber. No further quantity may be supplied beyond 72 hours without a new prescription.

10.23(2) *Long-term care or terminally ill patient.* 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 as provided by this subrule.

a. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient.

b. The pharmacist shall record on the prescription whether the patient is “terminally ill” or an “LTCF patient.” For each partial filling, the dispensing pharmacist shall record on the back of the prescription, or on another appropriate uniformly maintained and readily retrievable record, the date of the partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

c. The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed. Schedule II prescriptions for patients in a 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 the drug.

d. Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system pursuant to rule 657—21.4(124,155A).

657—10.24(124) Schedule II medication order. Schedule II controlled substances may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.18(124,155A), as applicable.

657—10.25(124) Schedule II—issuing multiple prescriptions. An individual prescriber may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance pursuant to the provisions and limitations of this rule.

10.25(1) *Refills prohibited.* The issuance of refills for a Schedule II controlled substance is prohibited. The use of multiple prescriptions for the dispensing of Schedule II controlled substances, pursuant to this rule, ensures that the prescriptions are treated as separate dispensing authorizations and not as refills of an original prescription.

10.25(2) *Legitimate medical purpose.* Each separate prescription issued pursuant to this rule shall be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber’s professional practice.

10.25(3) *Dates and instructions.* Each prescription issued pursuant to this rule shall be dated as of and manually signed by the prescriber on the day the prescription is issued. Each separate prescription, other than the first prescription if that prescription is intended to be filled immediately, shall contain written instructions indicating the earliest date on which a pharmacist may fill each prescription.

10.25(4) *Authorized fill date unalterable.* Regardless of the provisions of subrule 10.21(5), when a prescription contains instructions from the prescriber indicating that the prescription shall not be filled before a certain date, a pharmacist shall not fill the prescription before that date. The pharmacist shall not contact the prescriber for verbal authorization to fill the prescription before the fill date originally indicated by the prescriber pursuant to this rule.

10.25(5) *Number of prescriptions and authorized quantity.* An individual prescriber may issue for a patient as many separate prescriptions, to be filled sequentially pursuant to this rule, as the prescriber deems necessary to provide the patient with adequate medical care. The cumulative effect of the filling of each of these separate prescriptions shall result in the receipt by the patient of a quantity of the Schedule II controlled substance not exceeding a 90-day supply.

10.25(6) *Prescriber's discretion.* Nothing in this rule shall be construed as requiring or encouraging an individual prescriber to issue multiple prescriptions pursuant to this rule or to see the prescriber's patients only once every 90 days when prescribing Schedule II controlled substances. An individual prescriber shall determine, based on sound medical judgment and in accordance with established medical standards, how often to see patients and whether it is appropriate to issue multiple prescriptions pursuant to this rule.

[ARC 8172B, IAB 9/23/09, effective 10/28/09]

657—10.26 Reserved.

657—10.27(124,155A) Facsimile transmission of a controlled substance prescription.

10.27(1) *Schedule II prescription.* A prescription for a Schedule II controlled substance may be transmitted via facsimile to the pharmacy only as provided in rules 657—21.12(124,155A) to 657—21.16(124,155A).

10.27(2) *Schedule III, IV, or V prescription.* A prescription for a Schedule III, IV, or V controlled substance may be transmitted via facsimile to the pharmacy only as provided in rule 657—21.9(124,155A).

657—10.28(124,155A) Schedule III, IV, or V refills. 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.

10.28(1) *Record.* Each filling and refilling of a prescription shall be entered on the prescription or on another uniformly maintained and readily retrievable record.

a. The following information shall be retrievable by the prescription number: the name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, the unique identification of the dispensing pharmacist for each refill, and the total number of refills authorized for that prescription.

b. If the pharmacist merely initials or affixes the pharmacist's unique identifier and dates the back of the prescription, it shall be deemed that the full face amount of the prescription has been dispensed.

10.28(2) *Oral refill authorization.* 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 issuance of the original prescription.

b. The pharmacist who obtains the oral authorization records from the prescriber who issued the original prescription records on or with the original prescription the date, the quantity of each refill, the number of additional refills authorized, and the pharmacist's unique identification.

c. The quantity of each additional refill 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.

10.28(3) Automated data processing record system. An automated data processing record system may be used for the storage and retrieval of Schedule III, IV, and V controlled substance prescription fill and refill information subject to the conditions and requirements of rules 657—21.4(124,155A) and 657—21.5(124,155A).

657—10.29(124,155A) Schedule III, IV, or V partial fills. The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that each partial fill is recorded in the same manner as a refill. The total quantity dispensed in all partial fills shall not exceed the total quantity prescribed. No dispensing shall occur later than six months after the date on which the prescription was issued.

657—10.30(124,155A) Schedule III, IV, and V medication order. A Schedule III, IV, or V controlled substance may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.9(124,155A), as applicable.

657—10.31(124,155A) Dispensing Schedule V controlled substances without a prescription. A controlled substance listed in Schedule V, which substance is not a prescription drug as determined under the federal Food, Drug and Cosmetic Act, and excepting products containing ephedrine, pseudoephedrine, or phenylpropanolamine, may be dispensed or administered without a prescription by a pharmacist to a purchaser at retail pursuant to the conditions of this rule.

10.31(1) Who may dispense. Dispensing shall be by a licensed Iowa pharmacist or by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor. This subrule does not prohibit, after the pharmacist has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by a nonpharmacist.

10.31(2) Frequency and quantity. Dispensing at retail to the same purchaser in any 48-hour period shall be limited to no more than one of the following quantities of a Schedule V controlled substance:

- a. 240 cc (8 ounces) of any controlled substance containing opium.
- b. 120 cc (4 ounces) of any other controlled substance.
- c. 48 dosage units of any controlled substance containing opium.
- d. 24 dosage units of any other controlled substance.

10.31(3) Age of purchaser. The purchaser shall be at least 18 years of age.

10.31(4) Identification. The pharmacist shall require every purchaser under this rule not known by the pharmacist to present a government-issued photo identification, including proof of age when appropriate.

10.31(5) Record. A bound record book (i.e., with pages sewn or glued to the spine) for dispensing of Schedule V controlled substances pursuant to this rule shall be maintained by the pharmacist. The book shall contain the name and address of each purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or unique identification of the pharmacist or pharmacist-intern who approved the dispensing of the substance to the purchaser.

10.31(6) Prescription not required under other laws. No other federal or state law or regulation requires a prescription prior to distributing or dispensing a Schedule V controlled substance.

657—10.32(124,155A) Dispensing products containing ephedrine, pseudoephedrine, or phenylpropanolamine without a prescription. A product containing ephedrine, pseudoephedrine, or phenylpropanolamine, which substance is a Schedule V controlled substance and is not listed in another controlled substance schedule, may be dispensed or administered without a prescription by a pharmacist to a purchaser at retail pursuant to the conditions of this rule.

10.32(1) Who may dispense. Dispensing shall be by a licensed Iowa pharmacist or by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor. This subrule does not prohibit, after the pharmacist has fulfilled the professional and legal responsibilities set forth in this rule and has

authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by a nonpharmacist.

10.32(2) *Packaging of nonliquid forms.* A nonliquid form of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine includes gel caps. Nonliquid forms of these products to be sold pursuant to this rule shall be packaged either in blister packaging with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

10.32(3) *Frequency and quantity.* Dispensing at retail to the same purchaser within any 30-day period shall be limited to products collectively containing no more than 7,500 mg of ephedrine, pseudoephedrine, or phenylpropanolamine; dispensing at retail to the same purchaser within a single calendar day shall not exceed 3,600 mg.

10.32(4) *Age of purchaser.* The purchaser shall be at least 18 years of age.

10.32(5) *Identification.* The pharmacist shall require every purchaser under this rule to present a current government-issued photo identification, including proof of age when appropriate. The pharmacist shall be responsible for verifying that the name on the identification matches the name provided by the purchaser and that the photo image depicts the purchaser.

10.32(6) *Record.* Purchase records shall be recorded in the real-time electronic pseudoephedrine tracking system (PTS) established and administered by the governor's office of drug control policy pursuant to 657—Chapter 100. If the real-time electronic repository is unavailable for use, the purchase record shall be recorded in an alternate format and submitted to the PTS as provided in 657—subrule 100.3(4).

a. Alternate record contents. The alternate record shall contain the following:

- (1) The name, address, and signature of the purchaser.
- (2) The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.
- (3) The date and time of the purchase.
- (4) The name or unique identification of the pharmacist or pharmacist-intern who approved the dispensing of the product.

b. Alternate record format. The record shall be maintained using one of the following options:

- (1) A hard-copy record.
- (2) A record in the pharmacy's electronic prescription dispensing record-keeping system that is capable of producing a hard-copy printout of a record.
- (3) A record in an electronic data collection system that captures each of the data elements required by this subrule and that is capable of producing a hard-copy printout of a record.

c. PTS records retrieval. Pursuant to 657—subrule 100.4(6), the pharmacy shall be able to produce a hard-copy printout of transactions recorded in the PTS by the pharmacy for one or more specific products for a specified period of time upon request by the board or its representative or to such other persons or governmental agencies authorized by law to receive such information.

10.32(7) *Notice required.* The pharmacy shall ensure that the following notice is provided to purchasers of ephedrine, pseudoephedrine, or phenylpropanolamine products and that the notice is displayed with or on the electronic signature device or is displayed in the dispensing area and visible to the public:

“WARNING: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than \$250,000 if an individual or \$500,000 if an organization, imprisoned not more than five years, or both.”

[ARC 8892B, IAB 6/30/10, effective 9/1/10]

657—10.33(124,155A) Schedule II perpetual inventory in pharmacy. Each pharmacy located in Iowa that dispenses Schedule II controlled substances shall maintain a perpetual inventory system for all Schedule II controlled substances pursuant to the requirements of this rule. All records relating to

the perpetual inventory shall be maintained by the pharmacy and shall be available for inspection and copying by the board or its representative for a period of two years from the date of the record.

10.33(1) *Record format.* The perpetual inventory record may be maintained in a manual or an electronic record format. Any electronic record shall provide for hard-copy printout of all transactions recorded in the perpetual inventory record for any specified period of time and shall state the current inventory quantities of each drug at the time the record is printed.

10.33(2) *Information included.* The perpetual inventory record shall identify all receipts for and disbursements of Schedule II controlled substances by drug or by national drug code (NDC) number. The record shall be updated to identify each prescription filled and each shipment received. The record shall also include incident reports and reconciliation records pursuant to subrules 10.33(3) and 10.33(4).

10.33(3) *Changes to a record.* If a perpetual inventory record is able to be changed, the individual making a change to the record shall complete an incident report documenting the change. The incident report shall identify the specific information that was changed including the information before and after the change, shall identify the individual making the change, and shall include the date and the reason the record was changed. If the electronic record system documents within the perpetual inventory record all of the information that must be included in an incident report, a separate report is not required.

10.33(4) *Reconciliation.* The pharmacist in charge shall be responsible for reconciling the physical inventory of all Schedule II controlled substances with the perpetual inventory balance on a periodic basis but no less frequently than annually. In case of any discrepancies between the physical inventory and the perpetual inventory, the pharmacist in charge shall determine the need for further investigation, and significant discrepancies shall be reported to the board pursuant to rule 10.16(124) and to the DEA pursuant to federal DEA regulations. Periodic reconciliation records shall be maintained and available for review and copying by the board or agents of the board for a period of two years from the date of the record. The reconciliation process may be completed using either of the following procedures or a combination thereof:

a. The dispensing pharmacist verifies that the physical inventory matches the perpetual inventory following each dispensing and documents that reconciliation in the perpetual inventory record. If controlled substances are maintained on the patient care unit, the nurse or other responsible licensed health care provider verifies that the physical inventory matches the perpetual inventory following each dispensing and documents that reconciliation in the perpetual inventory record. All discrepancies shall be reported to the pharmacist in charge. If any Schedule II controlled substances in the pharmacy's current inventory have been dispensed and verified in this manner within the year, and there are no discrepancies noted, no additional reconciliation action is required. A drug that has had no activity within the year shall be reconciled pursuant to paragraph "*b*" of this subrule.

b. A physical count of each Schedule II controlled substance stocked by the pharmacy shall be completed at least once each year, and that count shall be reconciled with the perpetual inventory record balance. The physical count and reconciliation may be completed over a period of time not to exceed one year in a manner that ensures that the perpetual inventory and the physical inventory of Schedule II controlled substances are annually reconciled. The individual performing the reconciliation shall record the date, the time, the individual's initials or unique identification, and any discrepancies between the physical inventory and the perpetual inventory. Any discrepancies between the physical inventory and the perpetual inventory shall be reported to the pharmacist in charge.

657—10.34(124,155A) Records. Every inventory or other record required to be kept under this chapter or under Iowa Code chapter 124 shall be kept by the registrant and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record except as otherwise required in these rules. Controlled substances records shall be maintained in a readily retrievable manner that establishes the receipt and distribution of all controlled substances. Original hard-copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department.

10.34(1) *Schedule I and II records.* Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the registrant.

10.34(2) *Schedule III, IV, and V records.* Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the required information is readily retrievable from the ordinary business records of the registrant.

10.34(3) *Date of record.* The date on which a controlled substance is actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution.

10.34(4) *Receipt and disbursement records.* Each record of receipt or disbursement of controlled substances, unless otherwise provided in these rules or pursuant to federal law, shall include the following:

- a. The name of the substance;
- b. The strength and dosage form of the substance;
- c. The number of units or commercial containers acquired from other registrants, including the date of receipt and the name, address, and DEA registration number of the registrant from whom the substances were acquired;
- d. The number of units or commercial containers distributed to other registrants, including the date of distribution and the name, address, and DEA registration number of the registrant to whom the substances were distributed; and
- e. The number of units or commercial containers disposed of in any other manner, including the date and manner of disposal and the name, address, and DEA registration number of the registrant to whom the substances were distributed for disposal, if appropriate.

10.34(5) *Dispensing records.* Each record of dispensing of controlled substances to a patient or research subject shall include the following information:

- a. The name and address of the person to whom dispensed;
- b. The date of dispensing;
- c. The name of the substance;
- d. The quantity of the substance dispensed; and
- e. The name or unique identification of the individual who dispensed or administered the substance.

10.34(6) *Ordering or distributing Schedule I or II controlled substances - DEA Form 222.* Except as otherwise provided by subrule 10.34(7) and under federal law, a DEA Form 222 is required for each distribution of a Schedule I or II controlled substance. An order form may be executed only on behalf of the registrant named on the order form and only if the registrant's DEA and Iowa registrations for the substances being purchased have not expired or been revoked or suspended by the issuing agency.

a. Order forms shall be obtained, executed, and filled pursuant to DEA requirements. Each form shall be complete, legible, and properly prepared, executed, and endorsed and shall contain no alteration, erasure, or change of any kind.

b. The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier.

c. The purchaser shall maintain Copy 3 of the order form in the files of the registrant. Upon receipt of the substances from the supplier, the purchaser shall record on Copy 3 of the order form the quantity of each substance received, and the date of receipt, and shall initial each line identifying a substance received.

d. The supplier shall record on Copy 1 and Copy 2 of the order form the quantity of each substance distributed to the purchaser and the date on which the shipment is made. The supplier shall maintain Copy 1 of the order form in the files of the supplier and shall forward Copy 2 of the order form to the DEA district office.

e. Order forms shall be maintained separately from all other records of the registrant.

f. Each unaccepted, defective, or otherwise "void" order form and any attached statement or other documents relating to any order form shall be maintained in the files of the registrant.

g. If the registration of any purchaser of Schedule I or II controlled substances is terminated for any reason, or if the name or address of the registrant as shown on the registration is changed, the registrant shall return all unused order forms to the DEA district office.

10.34(7) *Ordering or distributing Schedule I or II controlled substances - electronic ordering system.* A registrant authorized to order or distribute Schedule I or II controlled substances via the DEA Controlled Substances Ordering System (CSOS) shall comply with the requirements of the DEA relating to that system, including the maintenance and security of digital certificates, signatures, and passwords and all record-keeping and reporting requirements.

a. For an electronic order to be valid, the purchaser shall sign the electronic order with a digital signature issued to the purchaser or the purchaser's agent by the DEA.

b. An electronic order may include controlled substances that are not in Schedules I and II and may also include noncontrolled substances.

c. A purchaser shall submit an order to a specific wholesale distributor appropriately licensed to distribute in Iowa.

d. Prior to filling an order, a supplier shall verify the integrity of the signature and the order, verify that the digital certificate has not expired, check the validity of the certificate, and verify the registrant's authority to order the controlled substances.

e. The supplier shall retain an electronic record of every order, including a record of the number of commercial or bulk containers furnished for each item and the date on which the supplier shipped the containers to the purchaser. The shipping record shall be linked to the electronic record of the order. Unless otherwise provided under federal law, a supplier shall ship the controlled substances to the registered location associated with the digital certificate used to sign the order.

f. If an order cannot be filled for any reason, the supplier shall notify the purchaser and provide a statement as to the reason the order cannot be filled. When a purchaser receives such a statement from a supplier, the purchaser shall electronically link the statement of nonacceptance to the original electronic order. Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

g. When a purchaser receives a shipment, the purchaser shall create a record of the quantity of each item received and the date received. The record shall be electronically linked to the original order and shall identify the individual reconciling the order. A purchaser shall, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser shall also retain all copies of each unfilled or defective order and each linked statement.

h. A supplier shall retain each original order filled and all linked records for two years. A supplier shall, for each electronic order filled, forward to the DEA within two business days either a copy of the electronic order or an electronic report of the order in a format specified by the DEA.

i. Records of CSOS electronic orders and all linked records shall be maintained by a supplier and a purchaser for two years following the date of shipment or receipt, respectively. Records may be maintained electronically or in hard-copy format. Records that are maintained electronically shall be readily retrievable from all other records, shall be easily readable or easily rendered into a readable format, shall be readily retrievable at the registered location, and shall be made available to the board, to the board's agents, or to the DEA upon request. Records maintained in hard-copy format shall be maintained in the same manner as DEA Form 222.

[ARC 8539B, IAB 2/24/10, effective 4/1/10]

657—10.35(124,155A) Physical count and record of inventory. Responsibility for ensuring that a required inventory is timely completed shall rest with the registrant or, in the case of a registered business, shall rest with the owner of the business. A registrant or owner of a registered business may delegate the actual taking of any inventory. The person or persons responsible for taking the inventory shall sign the completed inventory record.

10.35(1) *Record and procedure.* Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.33(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.

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

b. Each inventory shall be maintained in a handwritten, typewritten, or electronically printed form at the registered location. An inventory of Schedule II controlled substances shall be maintained separately from an inventory of all other controlled substances.

c. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant. These shall include prescriptions prepared for dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical services programs or care facility emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant.

d. A separate inventory shall be made for each registered location and for each independent activity registered except as otherwise provided under federal law.

e. The inventory shall be taken either prior to opening or following the close of business on the inventory date, and the inventory record shall identify either opening or close of business.

f. The inventory record, unless otherwise provided under federal law, shall include the following information:

- (1) The name of the substance;
- (2) The strength and dosage form of the substance; and
- (3) The quantity of the substance.

g. For all substances listed in Schedule I or II, and for all solid oral and injectable hydrocodone-containing products, the quantity shall be an exact count or measure of the substance.

h. For all substances listed in Schedule III, IV, or V, except for hydrocodone-containing products identified in paragraph "g" herein, the quantity may be an estimated count or measure of the substance unless the container has been opened and originally held more than 100 dosage units. If the opened commercial container originally held more than 100 dosage units, an exact count of the contents shall be made. Liquid oral hydrocodone-containing products packaged in incremented containers shall be measured to the nearest increment; products packaged in nonincremented containers may be estimated to the nearest one-fourth container.

10.35(2) *Initial inventory.* A new registrant shall take an inventory of all stocks of controlled substances on hand on the date the new registrant first engages in the manufacture, distribution, or dispensing of controlled substances. If the registrant commences business or the registered activity with no controlled substances on hand, the initial inventory shall record that fact.

10.35(3) *Annual inventory.* After the initial inventory is taken, a registrant shall take a new inventory of all stocks of controlled substances on hand at least annually. The annual inventory may be taken on any date that is within one year of the previous inventory date.

10.35(4) *Change of ownership.* Both the current owner and the prospective owner shall be responsible for ensuring that an inventory of all controlled substances is timely completed whenever there is a change of ownership of any pharmacy or drug wholesaler licensed pursuant to Iowa Code section 155A.13 or 155A.17, respectively.

10.35(5) *Change of pharmacist in charge (PIC).* An inventory of all controlled substances shall be completed whenever there is a change of PIC. The inventory shall be taken following the close of business the last day of the terminating PIC's employment and prior to opening for business the first day of the new PIC's employment. A single inventory shall be sufficient if there is no lapse between employment of the terminating PIC and the new PIC.

10.35(6) *Change of registered location.* A registrant shall take an inventory of all controlled substances whenever there is a change of registered location. The inventory shall be taken following the close of business the last day at the location being vacated. This inventory shall serve as the ending inventory for the location being vacated as well as a record of beginning inventory for the new location.

10.35(7) *Discontinuing registered activity.* A registrant shall take an inventory of controlled substances at the close of business the last day the registrant is engaged in registered activities. If the registrant is selling or transferring the remaining controlled substances to another registrant, this

inventory shall serve as the ending inventory for the registrant discontinuing business as well as a record of additional or starting inventory for the registrant to whom the substances are transferred.

10.35(8) *Newly controlled substances.* On the effective date of the addition of a previously noncontrolled substance to any schedule of controlled substances, any registrant who possesses the newly controlled substance shall take an inventory of all stocks of the substance on hand. That initial inventory record shall be maintained with the most recent controlled substances inventory record. Thereafter, the newly controlled substance shall be included in each inventory made by the registrant.

657—10.36(124) Samples and other complimentary packages—records. Complimentary packages and samples of controlled substances may be distributed to practitioners pursuant to federal and state law only if the person distributing the items leaves with the practitioner a specific written list of the items delivered.

10.36(1) *Distribution record.* The record form for the distribution of complimentary packages of controlled substances shall contain the following information:

- a. The name, address, and DEA registration number of the supplier;
- b. The name, address, and DEA registration number of the practitioner;
- c. The name, strength, and quantity of the specific controlled substances delivered; and
- d. The date of delivery.

10.36(2) *Reports to the board.* Any person who distributes controlled substances pursuant to this rule shall report all such distributions to the board. Reports shall:

- a. Include the information identified in subrule 10.36(1). Reports may consist of copies of those distribution records or may be computer-generated listings identifying those distributions.
- b. Be submitted as soon as practicable after distribution to the practitioner but no less often than once each calendar quarter.

10.36(3) *Practitioner records.* A practitioner who regularly administers or dispenses controlled substances shall keep records of the receipt and disbursement of such drugs, including complimentary packages and samples. Records shall be filed in a readily retrievable manner in accordance with federal requirements and shall be made available for inspection and copying by agents of the board or other authorized individuals for at least two years from the date of the record.

657—10.37(124,126) Revision of controlled substances schedules.

10.37(1) *Application for exception.* Any person seeking to have any compound, mixture, or preparation containing any depressant or stimulant substance listed in any of the schedules in Iowa Code chapter 124 excepted from the application of all or any part of that chapter may apply to the board for such exception.

- a. An application for an exception under this rule shall provide evidence that an exception has been granted under the federal Controlled Substances Act.
- b. The board shall permit any interested person to file written comments on or objections to the proposal for exception and shall designate the time during which such filings may be made. After consideration of the application and any comments on or objections to the proposal for exception, the board shall issue its findings on the application.

10.37(2) *Designation of new controlled substance.* The board may designate any new substance as a controlled substance to be included in any of the schedules in Iowa Code chapter 124 no sooner than 30 days following publication in the Federal Register of a final order so designating the substance under federal law. Designation of a new controlled substance under this subrule shall be temporary as provided in Iowa Code section 124.201, subsection 4.

10.37(3) *Objection to designation of a new controlled substance.* The board may object to the designation of any new substance as a controlled substance within 30 days following publication in the Federal Register of a final order so designating the substance under federal law. The board shall file objection to the designation of a substance as controlled, shall afford all interested parties an opportunity to be heard, and shall issue the board's decision on the new designation as provided in Iowa Code section 124.201, subsection 4.

657—10.38(124) Temporary designation of controlled substances.

10.38(1) Amend Iowa Code section 124.206, subsection 3, by adding the following new paragraph:

ab. Tapentadol.

10.38(2) Amend Iowa Code section 124.212, subsection 5, as follows:

5. Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substance having a depressant effect on the central nervous system, including its salts: ~~pregabalin~~

a. Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide].

b. Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].

10.38(3) Amend Iowa Code section 124.210, subsection 3, by adding the following new paragraph:

az. Fospropofol.

[ARC 7906B, IAB 7/1/09, effective 6/22/09; ARC 8411B, IAB 12/30/09, effective 12/1/09]

657—10.39(124,126) Excluded substances. The Iowa board of pharmacy hereby excludes from all schedules the current list of “Excluded Nonnarcotic Products” identified in Title 21, CFR Part 1308, Section 22. Copies of the list of excluded products may be obtained by written request to the board office at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

657—10.40(124,126) Anabolic steroid defined. Anabolic steroid, as defined in Iowa Code section 126.2, paragraph 2, includes any substance identified as such in Iowa Code section 124.208, paragraph 6, or in Iowa Code section 126.2, paragraph 2.

These rules are intended to implement Iowa Code sections 124.201, 124.301 to 124.308, 124.402, 124.403, 124.501, 126.2, 126.11, 147.88, 147.95, 147.99, 155A.13, 155A.17, 155A.26, 155A.37, and 205.3.

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