ARC 9912B

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 124.301 and 147.76, the Board of Pharmacy hereby amends Chapter 8, "Universal Practice Standards," Chapter 10, "Controlled Substances," Chapter 21, "Electronic Data in Pharmacy Practice," and Chapter 23, "Long-Term Care Pharmacy Practice," Iowa Administrative Code.

The amendments clarify the required elements of a valid prescription regardless of the method used to generate or prepare the prescription or the means of transmission or delivery of the prescription to the dispensing pharmacy. The amendments identify the requirements for a written prescription, for an oral prescription, for a prescription transmitted to a pharmacy via facsimile, and for a prescription that is electronically prepared, signed, and transmitted to the pharmacy. Additional requirements are identified for prescriptions that are electronically prepared but subsequently printed or transmitted to the pharmacy via facsimile, and a clear distinction is made between "electronic transmission" and "facsimile transmission" by defining those terms. Other new and amended definitions in Chapter 21 establish the difference between an "electronically prepared prescription" and an "electronic prescription" and clarify the definition of "electronic signature." The requirements for electronic prescribing of controlled substances, as established by the federal Drug Enforcement Administration (DEA), are addressed, and appropriate amendments are adopted to authorize the electronic prescribing of controlled substances pursuant to DEA requirements. Record-keeping requirements for electronically prepared prescriptions, electronic prescriptions, and prescriptions transmitted via facsimile are identified. The requirements for identification of the prescriber's agent who completes the transmission of a prescription to a pharmacy are clarified to include the first and last names and the title of the prescriber's agent.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the August 10, 2011, Iowa Administrative Bulletin as **ARC 9671B**. The Board received written comments regarding the proposed amendments. Comments from the Iowa Osteopathic Medical Association indicated that osteopathic physicians who reviewed the proposed amendments found those amendments acceptable. One pharmacist suggested that some of the language regarding prescriptions and printed prescriptions in the proposed amendments appeared contradictory. The pharmacist also expressed concerns regarding a prescriber's electronic signature on a prescription that is transmitted to the pharmacy via facsimile, the responsibilities imposed on a pharmacist for ensuring the validity of an electronically prepared or facsimile-transmitted prescription and for ensuring that all required elements of a prescription are included on the prescription, who is authorized to contact the prescriber or the prescriber's agent to verify the prescription or obtain missing elements, and which pharmacy personnel are authorized to receive a prescription transmitted by a prescriber or prescriber's agent. Another commenter suggested that the rules regarding electronic records should specifically prohibit the disclosure or sharing of credentials issued for the purpose of accessing or utilizing any functionality of the electronic application or system. The Board reviewed and considered all comments and changed the amendments in response to many of those comments.

The adopted amendments differ from those published under Notice. Subrule 10.21(5), previously indicated as "no change," has been amended to include the option of communicating with the prescriber or the prescriber's agent for the purpose of changing or adding limited information, including the prescriber's address or DEA registration number, to a prescription for a Schedule II controlled substance. The option of either a prescriber or prescriber's agent to transmit a prescription or medication order to a pharmacy, or to verify the content of a prescription, has been added in the following: rule 657—8.19(124,126,155A), introductory paragraph; subparagraph 8.19(1)"d"(3); subrule 10.21(2); rule 657—21.1(124,155A), definition of "facsimile transmission"; and rules 657—21.9(124,155A), 657—21.12(124,155A), and 657—21.13(124,155A). Language requiring that the unique authentication credentials issued to an individual for the purposes of accessing or utilizing an electronic application or

system shall be securely maintained by the individual to whom the credentials are issued and that those credentials shall not be disclosed to or shared with any other individual is added in subrule 10.21(1) and rule 657—21.2(124,155A). Paragraph 8.19(1)"b" has been changed to identify the exception to the manual signature requirement for a written prescription when the prescription is for a noncontrolled substance and the prescription is printed on security paper from an electronic prescribing system. The word "laws" has been added to the phrase "state and federal rules and regulations" in subrule 21.4(2) so that the phrase conforms to like references used throughout the Board's rules.

The amendments were approved during the November 10, 2011, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 126.10, 126.11, 155A.13, 155A.27, and 155A.29.

These amendments will become effective on January 18, 2012.

The following amendments are adopted.

ITEM 1. Amend rule 657—8.19(124,126,155A) as follows:

657—8.19(124,126,155A) Manner of issuance of a prescription drug or medication order. A prescription drug order or medication order may be transmitted from a prescriber or a prescriber's agent to a pharmacy in written form, orally including telephone voice communication, by facsimile transmission as provided in rule 657—21.9(124,155A), or by electronic transmission in accordance with applicable federal and state laws, ~~and~~ rules, and regulations. Any prescription drug order or medication order provided to a patient in written or printed form shall include the original, handwritten signature of the prescriber except as provided in rule 657—21.7(124,155A).

8.19(1) *Requirements for a prescription.* A valid prescription drug order shall be based on a valid patient-prescriber relationship.

a. Written, electronic, or facsimile prescription. In addition to the electronic prescription application and pharmacy prescription application requirements of this rule, a written, electronic, or facsimile prescription shall include:

(1) The date issued.

(2) The name and address of the patient.

(3) The name, strength, and quantity of the drug or device prescribed.

(4) The name and address of the prescriber and, if the prescription is for a controlled substance, the prescriber's DEA registration number.

(5) The written or electronic signature of the prescriber.

b. Written prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* a written prescription shall be manually signed, with ink or indelible pencil, by the prescriber. The requirement for manual signature shall not apply when an electronically prepared and signed prescription for a noncontrolled substance is printed on security paper as provided in 657—paragraph 21.7(3)*"b."*

c. Facsimile prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* a prescription transmitted via facsimile shall include:

(1) The identification number of the facsimile machine used to transmit the prescription to the pharmacy.

(2) The time and date of transmission of the prescription.

(3) The name, address, telephone number, and facsimile number of the pharmacy to which the prescription is being transmitted.

(4) If the prescription is for a controlled substance and in compliance with DEA regulations, the manual signature of the prescriber.

d. Electronic prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* an electronically prepared prescription for a controlled or noncontrolled prescription drug or device that is electronically transmitted to a pharmacy shall include the prescriber's electronic signature.

(1) An electronically prepared prescription for a controlled substance that is printed out or faxed by the prescriber or the prescriber's agent shall be manually signed by the prescriber.

(2) The prescriber shall ensure that the electronic prescription application used to prepare and transmit the electronic prescription complies with applicable state and federal laws, rules, and regulations regarding electronic prescriptions.

(3) The prescriber or the prescriber's agent shall provide verbal verification of an electronic prescription upon the request of the pharmacy.

~~8.19(1)~~ 8.19(2) *Verification.* The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of any prescription drug order or medication order consistent with federal and state laws, ~~and~~ rules, and regulations. In exercising professional judgment, the prescribing practitioner and the pharmacist shall take adequate measures to guard against the diversion of prescription drugs and controlled substances through prescription forgeries.

~~8.19(2)~~ 8.19(3) *Transmitting agent.* The prescribing practitioner may authorize an agent to transmit to the pharmacy a prescription drug order or medication order orally, by facsimile transmission, or by electronic transmission provided that the ~~name~~ first and last names and title of the transmitting agent ~~is~~ are included in the order.

a. New order. A new written or electronically prepared and transmitted prescription drug or medication order shall be manually or electronically signed by the prescriber. If transmitted by the prescriber's agent, the ~~name~~ first and last names and title of the transmitting agent shall be included in the order. If the prescription is for a controlled substance and is written or printed from an electronic prescription application, the prescription shall be manually signed by the prescriber prior to delivery of the prescription to the patient or prior to facsimile transmission of the prescription to the pharmacy. An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to the electronic transmission. An electronically prepared and electronically transmitted prescription that is printed following the electronic transmission shall be clearly labeled as a copy, not valid for dispensing.

b. Refill order or renewal order. An authorization to refill a prescription drug or medication order, or to renew or continue an existing drug therapy, may be transmitted to a pharmacist through oral communication, in writing, by facsimile transmission, or by electronic transmission initiated by or directed by the prescriber.

(1) If the transmission is completed by the prescriber's agent and the ~~name~~ first and last names and title of the transmitting agent ~~is~~ are included in the order, the prescriber's signature is not required on the fax or alternate electronic transmission.

(2) If the order differs in any manner from the original order, such as a change of the drug strength, dosage form, or directions for use, the prescriber shall sign the order as provided by paragraph 8.19(3)*"a."*

~~8.19(3)~~ 8.19(4) *Receiving agent.* Regardless of the means of transmission to a pharmacy, only a pharmacist, a pharmacist-intern, or a certified pharmacy technician shall be authorized to receive a new prescription drug or medication order from a practitioner or the practitioner's agent. In addition to a pharmacist, a pharmacist-intern, and a certified pharmacy technician, a technician trainee or an uncertified pharmacy technician may receive a refill or renewal order from a practitioner or the practitioner's agent if the technician's supervising pharmacist has authorized that function.

~~8.19(4)~~ 8.19(5) *Legitimate purpose.* The pharmacist shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner acting in the usual course of the practitioner's professional practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation and without a valid preexisting patient-practitioner relationship.

~~8.19(5)~~ 8.19(6) *Refills.* ~~A prescription for a prescription drug or device that is not a controlled substance may authorize no more than 12 refills within 18 months following the date on which the prescription is issued.~~ A refill is one or more dispensings of a prescription drug or device that ~~results~~ result in the patient's receipt of the quantity authorized by the prescriber for a single fill as indicated on the prescription drug order.

a. Noncontrolled prescription drug or device. A prescription for a prescription drug or device that is not a controlled substance may authorize no more than 12 refills within 18 months following the date on which the prescription is issued.

b. Controlled substance. A prescription for a Schedule III, IV, or V controlled substance may authorize no more than 5 refills within 6 months following the date on which the prescription is issued.

ITEM 2. Amend rule 657—10.17(124) as follows:

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 or unique electronic signature or identification of a witnessing licensed health care practitioner.

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

1. to 7. No change.

ITEM 3. Amend rule 657—10.21(124,126,155A) as follows:

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. A prescription for a Schedule III, IV, or V controlled substance may include authorization to refill the prescription no more than five times within the six months following date of issue. A prescription for a Schedule II controlled substance shall not be refilled.

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 written or electronic signature. When an oral order is not permitted, or when a prescriber is unable to prepare and transmit an electronic prescription in compliance with DEA requirements for electronic prescriptions, prescriptions shall be written with ink, indelible pencil, or typed print and shall be manually signed by the prescriber. If the prescriber utilizes an electronic prescription application that meets DEA requirements for electronic prescriptions, the prescriber may electronically prepare and transmit a prescription for a controlled substance to a pharmacy that utilizes a pharmacy prescription application that meets DEA requirements for electronic prescriptions. A ~~secretary or~~ prescriber's agent may prepare a prescription for the review, authorization, and manual or electronic signature of the prescriber but the prescribing practitioner is responsible for the accuracy, completeness, and validity of the prescription. An electronic prescription for a controlled substance shall not be transmitted to a pharmacy except by the prescriber in compliance with DEA regulations. A prescriber shall securely maintain the unique authentication credentials issued to the prescriber for utilization of the electronic prescription application and authentication of the prescriber's electronic signature. Unique authentication credentials issued to any individual shall not be shared with or disclosed to any other prescriber, agent, or individual. 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 or the prescriber's agent in each case when a written or oral 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 shall verify the authenticity of the prescription with the individual prescriber or the prescriber's agent in any case when the pharmacist questions the validity of, including the legitimate

medical purpose for, the prescription. 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 legibly printed name of the intern, resident, or foreign physician as well as the prescriber's signature.

10.21(4) No change.

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~~ prescriber or the prescriber's agent 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~~.~~; and

f. The prescriber's address or DEA registration number.

ITEM 4. Amend subrule 10.22(1) as follows:

10.22(1) *Emergency situation defined.* For the purposes of authorizing an oral or ~~electronically transmitted~~ facsimile transmission of a 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. and *b.* No change.

c. It is not reasonably possible for the prescribing practitioner to provide a manually signed written prescription to be presented to the ~~person dispensing the substance prior to~~ pharmacy before the ~~dispensing~~ pharmacy dispenses the controlled substance or the prescribing practitioner is unable to provide a DEA-compliant electronic prescription to the pharmacy before the pharmacy dispenses the controlled substance.

ITEM 5. Amend subrule 10.22(2) as follows:

10.22(2) *Requirements of emergency prescription.* In the case of an emergency situation as defined ~~herein~~ in subrule 10.22(1), a pharmacist may dispense a controlled substance listed in Schedule II pursuant to ~~an electronic~~ a facsimile 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 or a DEA-compliant electronic prescription.

b. No change.

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~~ facsimile transmission or a written record of the oral transmission authorizing the emergency dispensing. A written record is not required to consist of a handwritten record and may be a printed facsimile or a print of a computer-generated record of the prescription if the printed record includes all of the required elements for the prescription. If the emergency prescription is transmitted by the practitioner's agent, the record shall include the ~~name~~ first and last names and title of the individual who transmitted the prescription.

d. If the emergency prescription is transmitted via ~~electronic~~ facsimile 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~~ facsimile transmission shall not be obscured or rendered illegible due to such security features.

e. No change.

f. The pharmacist shall notify the board and the DEA if the prescribing individual fails to deliver a written prescription. Failure of the pharmacist to so notify the board and the DEA, or failure of the prescribing individual to deliver the required written prescription as herein required, shall void the authority conferred by this subrule.

ITEM 6. Amend rule 657—10.27(124,155A), introductory paragraph, as follows:

657—10.27(124,155A) Facsimile transmission of a controlled substance prescription. With the exception of an authorization for emergency dispensing as provided in rule 657—10.22(124), a prescription for a controlled substance may be transmitted via facsimile from a prescriber to a pharmacy as provided in rule 657—21.9(124,155A).

ITEM 7. Amend rule 657—21.1(124,155A) as follows:

657—21.1(124,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Application service provider" means an entity that sells electronic prescription or pharmacy prescription applications as a hosted service where the entity controls access to the application and maintains the software and records on its servers.

"DEA" means the U.S. Department of Justice, Drug Enforcement Administration.

"Electronically prepared prescription" means a prescription that is generated utilizing an electronic prescription application.

"Electronic prescription" means an electronically prepared prescription that is authorized and transmitted from the prescriber to the pharmacy by means of electronic transmission.

"Electronic prescription application" means software that is used to create electronic prescriptions and that is intended to be installed on a prescriber's computers and servers where access and records are controlled by the prescriber.

"Electronic signature" means a confidential personalized digital key, code, ~~or~~ number, or other method used for secure electronic data transmissions which identifies ~~and~~ a particular person as the source of the message, authenticates the signatory of the message, and indicates the person's approval of the information contained in the transmission.

"Electronic transmission" means the transmission ~~of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment. "Electronic transmission" includes, but is not limited to, transmission by facsimile machine, transmission to a printer as provided in subrule 21.7(3), and transmission by computer link, modem, or other communication device~~ of an electronic prescription, formatted as an electronic data file, from a prescriber's electronic prescription application to a pharmacy's computer, where the data file is imported into the pharmacy prescription application.

"Facsimile transmission" or *"fax transmission"* means the transmission of a digital image of a prescription from the prescriber or the prescriber's agent to the pharmacy. "Facsimile transmission" includes but is not limited to transmission of a written prescription between the prescriber's fax machine and the pharmacy's fax machine; transmission of an electronically prepared prescription from the prescriber's electronic prescription application to the pharmacy's fax machine, computer, or printer; or transmission of an electronically prepared prescription from the prescriber's fax machine to the pharmacy's fax machine, computer, or printer.

"Intermediary" means any technology system that receives and transmits an electronic prescription between the prescriber and the pharmacy.

"Pharmacy prescription application" means software that is used to process prescription information, is installed on a pharmacy's computers or servers, and is controlled by the pharmacy.

"Prescription drug order" or *"prescription"* means a lawful order of a practitioner for a drug or device for a specific patient that is communicated to a pharmacy, regardless of whether the communication is oral, electronic, facsimile, or in printed form.

"Readily retrievable" means that records kept by automatic data processing applications or other electronic or mechanized record-keeping systems can be separated out from all other records within a reasonable time not to exceed 48 hours of a request from the board or other authorized agent or that hard-copy records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

"Written prescription" means a prescription that is created on paper, a prescription that is electronically prepared and printed, or a prescription that is electronically prepared and transmitted from the prescriber's electronic device to a pharmacy via facsimile. A written prescription for a controlled substance shall be manually signed by the prescriber in compliance with federal and state laws, rules, and regulations.

ITEM 8. Amend rule 657—21.2(124,155A) as follows:

657—21.2(124,155A) System security and safeguards. To maintain the integrity and confidentiality of patient records and prescription drug orders, any system or computer utilized shall have adequate security including system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders. Authentication credentials shall be securely maintained by the individual to whom the credentials are issued and shall not be shared with or disclosed to any other individual. Once a drug or device has been dispensed, any alterations in either the prescription drug order data or the patient record shall be documented and shall include the identification of all pharmacy personnel who were involved in making the alteration as well as the responsible pharmacist. A pharmacy prescription application used for the receipt and processing of electronic transmissions from a prescriber's electronic prescription application shall comply with DEA requirements relating to electronic prescriptions and shall be certified compliant with DEA regulations.

ITEM 9. Amend rule 657—21.3(124,155A) as follows:

657—21.3(124,155A) Verifying authenticity of an electronically prepared or electronically or fax transmitted prescription. The pharmacist shall ensure the validity of the prescription as to its source of origin.

21.3(1) *Authentication measures.* Measures to be considered in authenticating prescription drug orders received via electronic transmission or fax transmission, or signed utilizing an electronic signature include but may not be limited to:

~~1.~~ *a.* Maintenance of a practitioner number reference or electronic signature file.

~~2.~~ *b.* Verification of the telephone number of the originating facsimile equipment or oral communication device.

~~3.~~ *c.* Telephone verification with the practitioner's office that the prescription was both issued by the practitioner and transmitted by the practitioner or the practitioner's authorized agent.

~~4.~~ *d.* Use of authentication processes approved by the DEA for controlled substances prescriptions.

e. Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure that the transmission was initiated by the prescriber.

21.3(2) *Prescription originally electronically transmitted.* When a pharmacist receives a written or oral prescription that indicates the prescription was originally electronically transmitted to a pharmacy, the pharmacist shall check with the pharmacy to which the prescription was originally electronically transmitted to determine whether the prescription was received and dispensed.

a. If the pharmacy that received the original electronic prescription dispensed the original prescription, the pharmacist receiving the written prescription shall mark the written prescription as void and shall not dispense the written prescription.

b. If the pharmacy that received the original electronic prescription has not dispensed the prescription, the pharmacy receiving the original electronic prescription shall mark the electronic prescription as void and shall not dispense the electronic prescription. The pharmacy that received the written or oral prescription shall dispense the prescription.

ITEM 10. Amend paragraph **21.4(1)"d"** as follows:

d. Date and quantity of each refill or partial fill, if applicable, and the total number of refills dispensed to date;

ITEM 11. Amend subrule 21.4(2) as follows:

21.4(2) *Printout of prescription fill data.* Any computerized system shall have the capability of producing a printout of any prescription fill data the user pharmacy is responsible for maintaining or producing under state and federal laws, rules and regulations. This would include a refill-by-refill audit trail for any specified strength and dosage form of any prescription drug by brand or generic name or both. Records maintained or provided in electronic format shall be sortable by prescriber name, patient name, drug dispensed, and date filled. ~~In any~~ Any computerized system employed by a user pharmacy~~, the central record-keeping location must~~ shall be capable of providing ~~the printout to~~ at the pharmacy ~~within 48 hours~~ a printout or electronic file of the records in a format that is readily understandable to the board or other authorized agents. A pharmacy may contract with an application service provider, or the pharmacy may maintain computer servers at a remote location, but all required records shall be readily retrievable at the pharmacy if requested by the board or other authorized agent. The printout or electronic record shall include the following:

a. to *f.* No change.

ITEM 12. Amend subrule 21.4(3) as follows:

21.4(3) *Auxiliary procedure for system downtime.* In the event that a pharmacy utilizing a computerized system experiences system downtime, the pharmacy shall have an auxiliary procedure that will be used for documentation of fills and refills of prescription orders. This auxiliary procedure shall ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for ~~on-line~~ online data entry when the computer system is again available for use. As soon as reasonably possible upon resuming use of the computerized system, entry of all appropriate data accumulated during the system downtime shall be completed.

ITEM 13. Adopt the following **new** subrule 21.4(4):

21.4(4) *Prescription notations.* When a pharmacist fills an electronic prescription that would require the pharmacist to make a notation on the prescription if the prescription were a written prescription, the pharmacist shall make the same notation electronically and shall retain the annotation electronically in the prescription record or in linked files.

ITEM 14. Adopt the following **new** subrule 21.4(5):

21.4(5) *Records for electronic prescriptions for controlled substances.* A pharmacy that processes electronic prescriptions for controlled substances shall use a pharmacy prescription application that complies with DEA requirements relating to electronic prescriptions and that has been certified compliant with DEA regulations. When a prescription is received electronically from a prescriber's electronic prescription application into the pharmacy prescription application, the prescription and all required annotations shall be retained electronically.

ITEM 15. Amend rule 657—21.5(124,155A) as follows:

657—21.5(124,155A) Pharmacist verification of controlled substance refills—daily printout or logbook. The individual pharmacist who makes use of the ~~system~~ pharmacy prescription application shall provide documentation of the fact that the refill information entered into ~~a computer~~ the pharmacy prescription application each time the pharmacist refills an original written, fax, or oral prescription order for a controlled substance is correct. If the ~~system~~ pharmacy prescription application provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout

shall be verified, dated, and signed by each individual pharmacist who refilled a controlled substance prescription order. Each individual pharmacist must verify that the data indicated is correct and sign this document in the same manner as the pharmacist would sign a check or legal document (e.g., J. H. Smith or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data shall be generated by and available at each pharmacy using a computerized ~~system~~ pharmacy prescription application within 48 hours of the date on which the refill was dispensed. The printout shall be verified and signed by each pharmacist involved with such dispensing.

In lieu of preparing and maintaining printouts as provided above, the pharmacy may maintain a bound logbook or separate file. The logbook or file shall include a statement signed each day by each individual pharmacist involved in each day's dispensing that attests to the fact that the refill information entered into the ~~computer~~ pharmacy prescription application that day has been reviewed by the pharmacist and is correct as shown. Pharmacist statements shall be signed in the manner previously described. The ~~log book~~ logbook or file shall be maintained at the pharmacy for a period of two years after the date of dispensing the appropriately authorized refill.

ITEM 16. Amend subrule 21.7(1) as follows:

21.7(1) *Controlled substances.* A prescription for a controlled substance prepared pursuant to this rule may be transmitted to a pharmacy via facsimile transmission as provided by rule 657—21.9(124,155A) or rules 657—21.12(124,155A) through 657—21.16(124,155A). The transmitted prescription shall include the prescriber's original signature or electronic signature. A prescription for a controlled substance may be transmitted by a prescriber to a pharmacy via electronic transmission pursuant to DEA requirements for electronic prescribing of controlled substances. Both the prescriber's electronic prescription application and the pharmacy prescription application shall be certified compliant with DEA regulations for electronic prescriptions. An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to the electronic transmission. An electronically prepared and electronically transmitted prescription that is printed following the electronic transmission shall be clearly labeled as a copy only, not valid for dispensing.

ITEM 17. Amend subrule 21.7(2) as follows:

21.7(2) *Noncontrolled prescription drugs.* A prescription for a noncontrolled prescription drug prepared pursuant to this rule may be transmitted to a pharmacy via ~~computer-to-computer~~ electronic transmission as provided in rule 657—21.8(124,155A) or via facsimile transmission as provided in rule 657—21.9(124,155A). The transmitted prescription shall include the prescriber's original signature or electronic signature.

ITEM 18. Amend subrule 21.7(3) as follows:

21.7(3) *Printed (hard-copy) prescriptions.* A prescription prepared pursuant to this rule may be printed by the prescriber or prescriber's agent for delivery to a pharmacy. An electronically prepared and electronically transmitted prescription that is printed following the electronic transmission shall be clearly labeled as a copy, not valid for dispensing.

a. No change.

b. If the prescriber authenticates a prescription for a noncontrolled prescription drug utilizing an electronic signature, the printed prescription shall be printed on security paper that is designed to prevent photocopying or other duplication of the printed prescription by prominently disclosing the word "void" or "copy" on the duplication or by including a watermark or background that will not appear on duplication. If a watermark or background is used, the prescription shall include a statement that unless the watermark or background appears, the prescription is not valid. Security paper that complies with the security requirements of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, shall be deemed to comply with the security requirements of this paragraph.

c. No change.

ITEM 19. Amend rule 657—21.8(124,155A) as follows:

657—21.8(124,155A) ~~Computer-to-computer~~ Electronic transmission of a prescription. Prescription drug orders~~, excluding orders for controlled substances,~~ may be communicated directly from a prescriber's computer or other electronic device utilizing an electronic prescription application to a ~~pharmacy's computer prescription processing system~~ pharmacy prescription application by electronic transmission. The receiving pharmacist shall be responsible for verifying the authenticity of an electronically transmitted prescription or of an electronic signature as provided by rule 657—8.19(124,126,155A) or 657—21.3(124,155A). The authenticity of a prescription transmitted via electronic transmission between a DEA-certified electronic prescription application and a DEA-certified electronic pharmacy prescription application shall be deemed verified by virtue of the security processes included in those applications.

21.8(1) *Secure transmission and patient's choice.* Orders shall be sent only to the pharmacy of the patient's choice, and no ~~unauthorized intervening person or other entity~~ intermediary shall change the content of the prescription drug order or compromise its confidentiality during the transmission process. The electronic format of the prescription drug order may be changed by the intermediary to facilitate the transmission between electronic applications as long as the content of the prescription drug order remains unchanged. This subrule does not prohibit the receiving pharmacist from amending or adding to the content of a prescription as necessary in compliance with federal and state laws, rules, or regulations.

21.8(2) *Information required.* ~~The~~ In addition to the information requirements for a prescription, an electronically transmitted prescription drug order shall identify the transmitter's telephone number for verbal confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission as well as any other information required by federal or state laws, rules, or regulations.

21.8(3) *Who may transmit.* Orders shall be initiated and authorized only by ~~an authorized~~ a prescriber licensed and authorized under state law to prescribe the drug or device identified in the prescription and shall include the prescriber's electronic signature. An order for a controlled substance shall include the prescriber's DEA registration number. Orders may be transmitted by the prescriber or the prescriber's agent. An order transmitted by the prescriber's agent shall include the agent's first and last names and title.

21.8(4) *Original prescription.* The electronic transmission shall be deemed the original prescription drug order provided it meets the requirements of this rule. The electronic transmission of a prescription drug order for a controlled substance shall meet all requirements of the DEA for electronic prescribing. An electronically prepared and transmitted prescription shall be maintained electronically in the prescriber's electronic prescription application and the pharmacy prescription application for a minimum period of two years following the date of last activity on that prescription record. Once a prescription is created and transmitted electronically, the prescription record shall not be printed and retained as a hard-copy record.

21.8(5) *Failure of electronic transmission.* If the transmission of an electronic prescription fails, the intermediary shall notify the prescriber of that transmission failure and the prescriber may print the prescription, manually sign the printed prescription, and deliver the prescription to the pharmacy via facsimile transmission. The faxed prescription shall indicate that it was originally transmitted to the named pharmacy, the date and time of the original electronic transmission, and the fact that the original transmission failed.

ITEM 20. Amend rule 657—21.9(124,155A) as follows:

657—21.9(124,155A) Facsimile transmission (fax) of a prescription. A pharmacist may dispense noncontrolled and controlled drugs, excluding Schedule II controlled substances, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the practitioner's agent. A pharmacist may dispense a Schedule II controlled substance to fill an emergency prescription authorization pursuant to the requirements of rule 657—10.22(124). The means of transmission via facsimile shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription. The faxed prescription

drug order shall serve as the original prescription, shall be maintained for a minimum of two years from the date of last fill or refill, and shall contain all information required by Iowa Code section 155A.27, including the prescriber's signature or electronic signature. The faxed prescription drug order, if transmitted by the practitioner's agent, shall identify the transmitting agent by ~~name~~ first and last names and title and shall include the prescriber's signature or electronic signature. A prescription for a controlled substance shall include the prescriber's manual signature. If the controlled substance prescription is not manually signed by the prescriber, the pharmacist shall orally verify the authenticity and the content of the prescription by contacting the prescriber or the prescriber's agent via telephone. The receiving pharmacist shall be responsible for verifying the authenticity of an electronically transmitted prescription or of an electronic signature as provided by rule 657—8.19(124,126,155A) or 657—21.3(124,155A). This rule shall not apply to a prescription drug order transmitted pursuant to 657—~~subrule 8.15(1),~~ paragraph 8.15(1)*"d."*

ITEM 21. Amend rule 657—21.12(124,155A) as follows:

657—21.12(124,155A) Prescription drug orders for Schedule II controlled substances. A pharmacist may dispense Schedule II controlled substances pursuant to an electronic transmission to the pharmacy of an electronically prepared prescription if both the prescriber's electronic prescription application and the pharmacy prescription application have been certified to comply with DEA requirements for electronic prescribing of controlled substances. Records of electronically prepared and transmitted prescriptions shall be maintained electronically. A pharmacist may dispense Schedule II controlled substances pursuant to ~~an electronic~~ facsimile transmission to the pharmacy of a written, signed prescription from the prescribing practitioner or the practitioner's agent provided that the original written, signed prescription is received by the pharmacist prior to the actual dispensing of the controlled substance. ~~If the~~ An emergency authorization ~~is~~ transmitted to the pharmacy by the practitioner's agent~~, the transmission~~ shall include the ~~name~~ first and last names and title of the individual who transmitted the prescription. The means of transmission shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription. The original prescription shall be verified against the transmission at the time the substance is actually dispensed, shall be properly annotated, and shall be retained with the electronic transmission for filing.

ITEM 22. Amend rule 657—21.13(124,155A) as follows:

657—21.13(124,155A) ~~Prescription drug orders~~ Facsimile transmission of a prescription for Schedule II controlled substances—emergency situations. A pharmacist may in an emergency situation as defined in 657—subrule 10.22(1) dispense Schedule II controlled substances pursuant to ~~an electronic~~ a facsimile transmission to the pharmacy of a written, signed prescription from the prescribing practitioner or the practitioner's agent pursuant to the requirements of 657—10.22(124). The facsimile or a print of the ~~electronic~~ facsimile transmission shall serve as the temporary written record required by 657—subrule 10.22(2).

ITEM 23. Amend rule 657—21.14(124,155A) as follows:

657—21.14(124,155A) Facsimile transmission of a prescription for Schedule II narcotic substances—parenteral. A prescription for a nonoral dosage unit of a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by a practitioner or the practitioner's agent to the pharmacy via facsimile. If the prescription is transmitted by the practitioner's agent, the transmission shall include the ~~name~~ first and last names and title of the individual who transmitted the prescription. The means of transmission shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription. The facsimile serves as the original written prescription.

ITEM 24. Amend rule 657—21.15(124,155A), introductory paragraph, as follows:

657—21.15(124,155A) Facsimile transmission of Schedule II controlled substances—long-term care facility patients. A prescription for any Schedule II controlled substance for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy via facsimile. If the prescription is transmitted by the practitioner's agent, the transmission shall include the ~~name~~ first and last names and title of the individual who transmitted the prescription. The means of transmission shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription.

ITEM 25. Amend rule 657—21.16(124,155A), introductory paragraph, as follows:

657—21.16(124,155A) Facsimile transmission of Schedule II controlled substances—hospice patients. A prescription for a Schedule II controlled substance for a patient enrolled in a hospice care program licensed pursuant to Iowa Code chapter 135J or a program certified or paid for by Medicare under Title XVIII may be transmitted via facsimile by the practitioner or the practitioner's agent to the dispensing pharmacy. If the prescription is transmitted by the practitioner's agent, the transmission shall include the ~~name~~ first and last names and title of the individual who transmitted the prescription. The means of transmission shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription.

ITEM 26. Amend subrule 23.9(3) as follows:

23.9(3) *Who may transmit medication orders.* An authorized prescriber or prescriber's agent or any person who is employed by a long-term care facility and who is authorized by the facility's policies and procedures may transmit to the long-term care pharmacy a medication order lawfully ordered by a practitioner authorized to prescribe drugs and devices. An order transmitted by the prescriber's agent shall include the agent's first and last names and title.

ITEM 27. Amend rule 657—23.18(124,155A) as follows:

657—23.18(124,155A) Schedule II orders. This rule shall not apply to Schedule II controlled substances orders in facilities that utilize a floor stock distribution system as provided in subrule 23.11(4). Schedule II controlled substances in all other facilities shall be dispensed only upon receipt of an electronic prescription prepared, transmitted, and received in compliance with DEA regulations for electronic prescriptions or an original written order signed by the prescribing individual practitioner or upon receipt of a facsimile transmission of an original written order signed by the prescribing individual practitioner pursuant to rule 657—21.15(124,155A). In emergency situations as defined in 657—subrule 10.22(1), Schedule II controlled substances may be dispensed in compliance with the requirements of rule 657—10.22(124) or rule 657—21.13(124,155A), as applicable. In all cases, any order for a Schedule II controlled substance shall specify the total quantity authorized by the prescriber.

ITEM 28. Amend rule 657—23.20(124,155A), introductory paragraph, as follows:

657—23.20(124,155A) Partial filling of Schedule II controlled substances. A medication order for a Schedule II controlled substance ~~written~~ for a resident in a long-term care facility (LTCF) may be filled in partial quantities to include individual dosage units. The pharmacist shall record on the written or electronic medication order that the patient is an "LTCF patient." A medication order that is partially filled and does not contain the notation "LTCF patient" shall be deemed to have been filled in violation of the controlled substances Act.

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