ARC 2194C

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 3, "Pharmacy Technicians," Chapter 6, "General Pharmacy Practice," and Chapter 7, "Hospital Pharmacy Practice"; rescinds Chapter 13, "Sterile Compounding Practices"; and rescinds Chapter 20, "Pharmacy Compounding Practices," and adopts new Chapter 20, "Compounding Practices," Iowa Administrative Code.

The amendments combine the requirements currently in Chapters 13 and 20 for the compounding of drug products into a single chapter, Chapter 20, that fully adopts national minimum practice standards for compounding found in General Chapters 795 and 797 of the United States Pharmacopeia (USP). The amendments also incorporate new federal regulations as established in the Drug Quality and Security Act of 2013, also known as the Compounding Quality Act, with respect to compounding and outsourcing facilities. Current Chapter 13 is rescinded and reserved.

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 April 29, 2015, Iowa Administrative Bulletin as **ARC 1979C**. The Board received numerous written comments regarding the proposed amendments. Comments from one national pharmacy chain questioned the need to include all identified information on the label of a compounded drug product prepared for general pharmacy or outpatient dispensing. In response to those comments, the Board determined that there is no need to include the FDA contact information on the prescription label, as such information can be provided in or on auxiliary information provided with the prescription to the patient. The Board did not agree that other required information, such as the identification of the product as a compounded product, was unnecessary.

Other comments suggested realigning and adding verbiage in the definition of "compounding" to ensure understanding of the exceptions identified in the definition. The Board determined that the definition, as proposed, accurately defines the term and identifies the exceptions to the definition.

The Board also received comments from practitioners objecting to the stated restrictions regarding the compounding of non-patient-specific products for practitioner administration to patients (office use). The Board is unable to authorize Iowa pharmacies to compound and distribute non-patient-specific products for office use unless the Iowa pharmacy is registered with the FDA as a 503B outsourcing facility. The federal Compounding Quality Act specifically addresses this issue, and the Board may not adopt less stringent requirements.

The adopted amendments differ from those published under Notice. In response to comments identified above, proposed paragraph "e" in subrule 20.19(1) was not adopted and subsequent paragraphs have been relettered appropriately. The removed paragraph would have required pharmacies to include on the prescription label of a compounded drug product packaged for general pharmacy or outpatient dispensing FDA contact information, including the FDA Web site address or toll-free telephone number.

The amendments were approved during the August 31, 2015, 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 124.302, 124.303, 124.306, 124.308, 124.501, 126.9, 126.10, 126.18, 155A.2, 155A.13, 155A.28, 155A.33, and 155A.35.

These amendments will become effective on November 18, 2015.

The following amendments are adopted.

ITEM 1. Amend rule 657—3.22(155A) as follows:

657—3.22(155A) Technical functions. At the discretion of the supervising pharmacist, the following technical functions, in addition to any of the functions authorized for a pharmacy support person pursuant to 657—Chapter 5, may be delegated to a pharmacy technician as specified in the following subrules.

3.22(1) *Certified pharmacy technician.* Under the supervision of a pharmacist, a certified pharmacy technician may perform technical functions delegated by the supervising pharmacist including, but not limited to, the following:

a. to *h.* No change.

i. Perform drug compounding processes ~~for nonsterile compounding~~ as provided in 657—Chapter 20.

~~*j.* Perform drug compounding processes for sterile compounding as provided in 657—Chapter 13.~~

~~*k.*~~ *j.* As provided in rule 657—3.24(155A), accept new prescription drug orders or medication orders communicated to the pharmacy by a prescriber or by the prescriber's agent.

3.22(2) *Pharmacy technician trainee.* Under the supervision of a pharmacist, a pharmacy technician trainee may perform only the following technical functions delegated by the supervising pharmacist:

a. to *g.* No change.

h. Under the supervision of a pharmacist who provides training and evaluates and monitors trainee competence in the compounding processes, perform drug compounding processes ~~for nonsterile compounding~~ as provided in 657—Chapter 20.

~~*i.* Under the supervision of a pharmacist who provides training and evaluates and monitors trainees, and contingent on successful completion of appropriate media fill testing processes, perform drug compounding processes for sterile compounding as provided in 657—Chapter 13.~~

ITEM 2. Amend subrule 6.10(2) as follows:

6.10(2) *Exceptions.* The requirements of subrule 6.10(1) do not apply to unit dose dispensing systems, 657—22.1(155A)~~; sterile products, 657—Chapter 13;~~, and patient med paks, 657—22.5(126,155A).

ITEM 3. Amend paragraph **7.8(1)"b"** as follows:

b. Pharmacy personnel shall, except as specified in policies and procedures, prepare all sterile products in conformance with 657—Chapter ~~13~~ 20.

ITEM 4. Rescind and reserve **657—Chapter 13**.

ITEM 5. Rescind 657—Chapter 20 and adopt the following **new** chapter in lieu thereof:

CHAPTER 20
COMPOUNDING PRACTICES

657—20.1(124,126,155A) Purpose and scope. The requirements of this chapter apply to compounded preparations that are dispensed, distributed, or administered to an ultimate user in the state of Iowa, regardless of the location of the pharmacy or outsourcing facility where the preparation was compounded. This chapter applies to compounded preparations intended for humans and animals. In addition to the requirements in this chapter, all pharmacies and outsourcing facilities engaged in compounding shall comply with all applicable federal laws and regulations governing compounding and all applicable state laws, rules and regulations governing the practice of pharmacy. In the event the requirements in this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter. The requirements of 657—Chapter 16 apply to the compounding of radiopharmaceuticals.

657—20.2(124,126,155A) Definitions. For purposes of this chapter, the following definitions apply:

"Anticipatory compounding" means the compounding of preparations in advance of the pharmacy's receipt of patient-specific prescriptions.

"Batch preparation compounding" means anticipatory compounding, compounding preparations intended for multiple disbursements, or compounding preparations in a multiple-dose container for administration to more than one patient.

"Beyond-use date" means the date after which a compounded preparation should not be used, determined from the date that the preparation is compounded.

"Bulk drug substance" means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances.

"Compounding" means the combining, mixing, diluting, pooling, flavoring, or otherwise altering of a drug or bulk drug substance to create a drug. Compounding includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription products. Compounding does not include the use of a flavoring agent to flavor a drug pursuant to rule 657—20.13(124,126,155A), nor does it include mixing or reconstituting a drug according to the product's manufacturer label.

"FDA" means the Food and Drug Administration of the U.S. Department of Health and Human Services.

"Flavoring agent" means a therapeutically inert, nonallergenic substance consisting of inactive ingredients that is added to a drug to improve the drug's taste and palatability.

"Outsourcing facility" means a facility that is located at a single geographic location and has registered with the FDA as an outsourcing facility in accordance with Section 503B of the Federal Food, Drug, and Cosmetic Act.

"USP" means United States Pharmacopeia.

657—20.3(124,126,155A) Nonsterile compounding. Iowa-licensed pharmacies that compound nonsterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 795 standards. Additional USP chapters incorporated by reference into USP Chapter 795 shall also be followed.

657—20.4(124,126,155A) Sterile compounding. Iowa-licensed pharmacies that compound sterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 797 standards. Additional USP chapters incorporated by reference into USP Chapter 797 shall also be followed.

657—20.5(126,155A) Delayed compliance. A pharmacy that is unable to meet the requirements for full compliance with these rules and with USP Chapter 795 or USP Chapter 797 by May 18, 2016, shall, prior to that date, request and obtain from the board a waiver of the specific requirement or requirements that the pharmacy is unable to meet. A pharmacy that cannot meet the requirements for full compliance with these rules, including applicable USP chapters, and that has not obtained from the board a waiver of the specific requirement or requirements shall not engage in compounding until the pharmacy is in full compliance with all requirements or the board has approved a waiver of the specific requirement or requirements.

657—20.6(126,155A) Compounding standards for outsourcing facilities. An FDA-registered outsourcing facility shall be properly licensed in Iowa and shall follow the FDA's current good manufacturing practices (cGMPs) for outsourcing facilities when compounding preparations for hospitals, practitioners, or patients in the state of Iowa.

657—20.7 and **20.8** Reserved.

657—20.9(124,155A) Prescriber/patient/pharmacist relationship. All compounded preparations shall be dispensed pursuant to a patient-specific prescription unless the compounded preparation is distributed pursuant to rule 657—20.15(124,126,155A) or 657—20.16(124,126,155A). A prescription for a compounded preparation shall be authorized by the prescriber for a specific patient. Prescriptions for all compounded preparations shall be maintained on file at the dispensing pharmacy.

657—20.10(126,155A) Anticipatory compounding.

20.10(1) *Outsourcing facilities.* Outsourcing facilities are authorized to engage in anticipatory compounding. Outsourcing facilities are not required to obtain patient-specific prescriptions in order to distribute compounded preparations.

20.10(2) *Pharmacies.* Pharmacies may engage in anticipatory compounding only if the anticipatory compounding is based on a history of receiving valid prescriptions generated solely within an established prescriber/patient/pharmacist relationship, so long as each compounded preparation is dispensed pursuant to a patient-specific prescription.

657—20.11(126,155A) Prohibition on resale of compounded preparations. The sale of compounded preparations to other pharmacies, prescribers, or facilities, except as explicitly authorized by this chapter, is considered manufacturing.

657—20.12(126,155A) Compounding copies of an approved drug. A pharmacy or outsourcing facility may only compound preparations that are essentially copies of approved drugs if the compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. A pharmacy or outsourcing facility may compound a preparation that is essentially a copy of an approved drug if the approved drug is identified as currently in shortage on the FDA drug shortages database published on the FDA Web site, http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

657—20.13(124,126,155A) Use of flavoring agents. A flavoring agent may be added to a drug at the discretion of the pharmacist or upon the request of the prescriber, the patient, or the patient's agent. The pharmacist may add flavoring agents not to exceed 5 percent of the total volume of the drug to which the flavoring agents are added. The pharmacist shall label the flavored drug with a beyond-use date no greater than 14 days past the date the flavoring agent is added if the drug is required to be stored in a refrigerator. A different beyond-use date or alternate storage conditions may be indicated if such variation is supported by peer-reviewed medical literature. The pharmacist shall electronically or manually document that a flavoring agent was added to a drug, and such documentation shall be made available for inspection and copying upon the request of the board or an agent of the board.

657—20.14 Reserved.

657—20.15(124,126,155A) Compounding for office use.

20.15(1) *Human compounded preparations.* Only an FDA-registered outsourcing facility properly licensed in Iowa may distribute to a practitioner for office use human compounded preparations without a patient-specific prescription.

20.15(2) *Veterinary compounded preparations.* Veterinary compounded preparations may be sold to a practitioner for office use if compounded by an Iowa-licensed pharmacy and sold directly to the practitioner by the compounding pharmacy.

20.15(3) *Office administration.* Compounded preparations distributed for office use pursuant to subrule 20.15(1) or 20.15(2) and in accordance with the labeling requirements of subrule 20.15(4) do not require a patient-specific prescription but do require that the compounded preparation be administered to an individual patient in the practitioner's office. Compounded preparations distributed for office use pursuant to this rule shall not be further distributed to other practitioners or to patients for administration outside of the office.

20.15(4) *Labeling.* Compounded preparations for office use, in addition to the labeling requirements specified in rule 657—20.19(124,126,155A), shall include on the prescription label the practitioner's name in place of the patient's name. The label shall state "For Office Use Only—Not for Resale." If the sterility or integrity of the compounded preparation cannot be maintained after the initial opening of the container, the label shall state "Single-Dose Only."

657—20.16(124,126,155A) Compounding for hospital use. Compounded preparations distributed or dispensed to a hospital or hospital pharmacy pursuant to this rule shall be administered to an individual patient in the hospital.

20.16(1) *By an FDA-registered outsourcing facility.* Only an FDA-registered outsourcing facility properly licensed in Iowa may distribute human compounded preparations to a hospital or hospital pharmacy in the absence of a patient-specific prescription. The compounded preparation shall be labeled in compliance with subrule 20.19(3).

20.16(2) *By a pharmacy that is not an FDA-registered outsourcing facility.* Human compounded preparations that are not compounded at an FDA-registered outsourcing facility may be dispensed to a hospital or hospital pharmacy by an Iowa-licensed pharmacy pursuant to a prescriber's authorization for administration to a specific patient. The compounded preparation shall be labeled in compliance with subrule 20.19(2).

657—20.17 and **20.18** Reserved.

657—20.19(124,126,155A) Labeling. The label, or attached auxiliary labeling if necessary, affixed to the container of any compounded preparation dispensed or distributed into or within Iowa shall contain at least the information identified in one of the following subrules, as applicable.

20.19(1) *General pharmacy or outpatient dispensing.* The label shall meet the labeling requirements of 657—subrule 6.10(1) and shall include the following additional information:

a. The name and concentration of each active ingredient.

b. The date that the preparation was compounded.

c. The beyond-use date of the compounded preparation.

d. Special storage and handling instructions, if applicable.

e. The statement "COMPOUNDED PREPARATION" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

f. If the compounded preparation is sterile, the word "STERILE."

g. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

20.19(2) *Hospital pharmacy or inpatient administration.* The label shall meet the labeling requirements of 657—subrule 22.1(3) and shall include the following additional information:

a. The name and concentration of each active ingredient.

b. The date that the preparation was compounded.

c. The beyond-use date of the compounded preparation.

d. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

e. Special storage and handling instructions, if applicable.

20.19(3) *Outsourcing facility distribution or dispensing.* The label, or auxiliary labeling if necessary, shall include the following information:

a. The statement "THIS IS A COMPOUNDED DRUG" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

b. The name, address, and telephone number of the outsourcing facility that compounded the preparation.

c. The established name of the preparation.

d. The dosage form and strength.

e. The quantity of the preparation.

f. The date that the preparation was compounded.

g. The beyond-use date of the compounded preparation.

h. Storage and handling instructions.

i. The lot or batch identification or control number.

j. The national drug code number, if available.

k. The statement "Not for resale" and, if the preparation is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "OFFICE USE ONLY."

l. The following additional information, which can be included on the labeling of a container (such as a plastic bag containing individual product syringes) from which individual units of the drug are removed for dispensing or for administration if there is not space on the label for such information:

(1) Directions for use including, as appropriate, dosage and administration;

(2) A list of the active and inactive ingredients, identified by established name and quantity or proportion of each ingredient;

(3) FDA contact information (www.fda.gov/medwatch and 1-800-FDA-1088 or successor Web site or telephone number) to facilitate adverse event reporting.

m. If the preparation is compounded pursuant to a prescription for a specific patient, the label shall also include the label requirements in 657—subrule 6.10(1).

n. If the preparation is compounded for office use, the label shall also include the label requirements in subrule 20.15(4).

657—20.20(126,155A) Labeling for batch preparation compounding. Compounded preparations resulting from batch preparation compounding shall be labeled with the following information until such time as the preparations are labeled pursuant to rule 657—20.19(124,126,155A) for distribution to hospitals or practitioners or for dispensing or administration to patients:

1. The date that the preparation was compounded.
2. Compounded preparation name or formula.
3. Dosage form.
4. Strength.
5. Quantity per container.
6. Unique internal batch identification or control number.
7. Beyond-use date.
8. Special storage and handling instructions, if applicable.

657—20.21 and **20.22** Reserved.

657—20.23(124,126,155A) Records. All records required by this chapter shall be retained as original records of the pharmacy or outsourcing facility and shall be readily available for inspection and photocopying by agents of the board or other authorized authorities for at least two years following the date of the record. Records shall allow for the identification of all ingredients used in compounding, all personnel involved in compounding, and all personnel involved in reviewing compounded preparations. The pharmacy or outsourcing facility shall maintain records documenting the disbursements from each batch of a compounded preparation.

These rules are intended to implement Iowa Code sections 124.302, 124.303, 124.306, 124.308, 124.501, 126.9, 126.10, 126.18, 155A.2, 155A.13, 155A.28, 155A.33, and 155A.35.

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