ARC 3238C

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 147.76 and 155A.13C, the Board of Pharmacy hereby amends Chapter 20, "Compounding Practices," and adopts new Chapter 41, "Outsourcing Facilities," Iowa Administrative Code.

These amendments implement the changes made to Iowa Code section 155A.13C in 2016 Iowa Acts, Senate File 453, enacted by the General Assembly, which identified as a specific license category an outsourcing facility and authorized the Board to promulgate rules for such licensure and activity. The amendments add to various rules in Chapter 20 references to Chapter 41 for outsourcing facilities. The amendments also introduce language, consistent with federal draft guidance, regarding criteria for the Board to consider when determining if a compounded drug preparation is essentially a copy of an approved drug. Compounding of a drug that is essentially a copy of an approved drug is a violation of federal regulations.

Chapter 41 establishes the requirements for licensure of outsourcing facilities and includes requirements relating to operations of an outsourcing facility, disclosure of inspection information including identification of determined deficiencies and the actions taken to cure those deficiencies, and disclosure of administrative and criminal actions taken against the facility and primary facility personnel.

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 3038C** on April 26, 2017.

The Board received one comment related to the rule regarding criteria used by the Board when determining if a compounded drug preparation is essentially a copy of an approved drug. The federal guidance upon which the language was based was, at the time of submission of the Notice, draft guidance and not yet finalized. The commenter expressed disagreement with the federal draft guidance. The Board considered the concern and recognized that future amendments could be made if the final federal guidance provides significant changes to the criteria.

These amendments are identical to those published under Notice.

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

The Pharmacy Board adopted these amendments during its regularly scheduled meeting on June 28, 2017.

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, 155A.13, and 155A.13C.

These amendments will become effective September 6, 2017.

The following amendments are adopted.

ITEM 1. Amend rule 657—20.1(124,126,155A) as follows:

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. <u>The requirements of 657—Chapter 41 apply to outsourcing facilities.</u>

ITEM 2. Amend rule **657—20.2(124,126,155A)**, definition of "Outsourcing facility," as follows:

"Outsourcing facility" or *"facility"* means ~~a~~ any compounding 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~~, as defined in 21 U.S.C. Section 353b, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state.

ITEM 3. Amend rule 657—20.5(126,155A) as follows:

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.

ITEM 4. Amend rule 657—20.6(126,155A) as follows:

657—20.6(126,155A) Compounding standards for outsourcing facilities. An FDA-registered outsourcing facility shall be properly licensed in Iowa pursuant to 657—Chapter 41 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~~ use in Iowa.

ITEM 5. Amend rule 657—20.11(126,155A) as follows:

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

ITEM 6. Adopt the following **new** subrules 20.12(1) and 20.12(2):

20.12(1) *Essentially a copy.* The board may consider the existence of the following factors as an indication that a compounded preparation is essentially a copy of an approved drug:

a. The compounded preparation has the same active pharmaceutical ingredient(s) as the commercially available drug product;

b. The active pharmaceutical ingredient(s) has the same, similar, or an easily substitutable dosage strength; and

c. The commercially available drug product can be used by the same route of administration as prescribed for the compounded preparation.

20.12(2) *Clinically significant difference.* The prescription for a compounded preparation that is essentially a copy of an approved drug shall clearly indicate the relevant change and the significant clinical difference produced for the patient. A prescription that identifies only a patient name and compounded preparation formulation is insufficient documentation for a pharmacy or outsourcing facility to rely upon to conclude that the prescriber made a determination regarding a clinically significant difference.

ITEM 7. Amend rule 657—20.15(124,126,155A) as follows:

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 pursuant to 657—Chapter 41 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 the preparations are compounded by an Iowa-licensed pharmacy or

outsourcing facility and sold directly to the practitioner by the ~~compounding~~ pharmacy or outsourcing facility.

20.15(3) and **20.15(4)** No change.

ITEM 8. Amend subrule 20.16(1) as follows:

20.16(1) *By an FDA-registered outsourcing facility.* Only an FDA-registered outsourcing facility properly licensed in Iowa pursuant to 657—Chapter 41 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).

ITEM 9. Amend paragraph **20.19(3)"k"** as follows:

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

ITEM 10. Amend **657—Chapter 20**, implementation sentence, as follows:

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.13C, 155A.28, 155A.33, and 155A.35.

ITEM 11. Adopt the following **new** 657—Chapter 41:

CHAPTER 41
OUTSOURCING FACILITIES

657—41.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standard of practice for outsourcing facilities that intend to provide compounding services in or into Iowa. The requirements of these rules, in addition to any other board rules applicable to the facility's operation, apply to all Iowa-licensed outsourcing facilities that provide compounded medications in or into Iowa whether pursuant to a patient-specific prescription or not.

657—41.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"FDA" means the United States Food and Drug Administration.

"Home state" means the state in which an outsourcing facility is located.

"Outsourcing facility" or *"facility"* means any compounding facility that is registered as an outsourcing facility, as defined in 21 U.S.C. Section 353b, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state.

657—41.3(155A) Outsourcing facility license. Beginning January 1, 2018, an outsourcing facility shall apply for and obtain an outsourcing facility license from the board prior to providing non-patient-specific compounded human drug products in this state. The applicant shall submit a completed application along with an application fee of $400. An outsourcing facility that intends to distribute controlled substances in or into Iowa shall also, prior to distributing such substances in or into Iowa, apply for and obtain an Iowa controlled substances Act registration pursuant to 657—Chapter 10.

41.3(1) *Application requirements.* The application shall require demographic information about the facility; ownership information; the name, signature and home state license number for the supervising pharmacist; an attestation that the supervising pharmacist has read and understands the laws and rules relating to sterile compounding in Iowa; information about the entity's registered agent; criminal and disciplinary history information; and a description of the scope of services to be provided in Iowa. As part of the application process, the applicant shall also:

a. Submit evidence of possession of a valid registration with the FDA as an outsourcing facility.

b. If one or more inspections have been conducted by the FDA in the five-year period immediately preceding the application, submit a copy of any correspondence from the FDA as a result of the inspection, including but not limited to any form 483s, warning letters, or formal responses, and all correspondence from the applicant to the FDA related to such inspections, including but not limited to formal responses and corrective action plans. In addition, the applicant shall submit evidence of

correction of all deficiencies discovered in such inspections and evidence of compliance with all directives from the FDA.

c. Submit evidence that the supervising pharmacist, as described in 21 U.S.C. Section 353b(a), holds a valid pharmacist license in the state in which the facility is located and that such license is in good standing.

d. Submit information to facilitate a national criminal history record check.

41.3(2) *Provision of patient-specific prescriptions.* If an outsourcing facility intends to dispense prescription drugs pursuant to patient-specific prescriptions to individual patients in Iowa, the outsourcing facility shall also obtain and maintain a valid Iowa pharmacy license. If the pharmacy is located in Iowa, the pharmacy shall obtain and maintain a valid Iowa pharmacy license pursuant to 657—Chapter 8; if the pharmacy is located outside Iowa, the pharmacy shall, prior to dispensing prescriptions to patients located in Iowa, obtain and maintain a valid Iowa nonresident pharmacy license pursuant to 657—Chapter 19.

41.3(3) *License renewal.* The outsourcing facility license shall be renewed by January 1 of each year. The facility shall submit the license application and fee as provided in this rule. An outsourcing facility may renew its license beginning November 1 prior to license expiration. An initial outsourcing facility license issued between November 1 and December 31 shall not require renewal until the following calendar year. The fee for license renewal shall be $400.

a. Delinquent license grace period. If an outsourcing facility license has not been renewed or canceled prior to expiration, but the facility is in the process of renewing the license, the license becomes delinquent on January 1. An outsourcing facility that submits a completed license renewal application, application fee, and late penalty fee of $400 postmarked or delivered to the board office by January 31 shall not be subject to disciplinary action for continuing to provide services to Iowa customers in the month of January.

b. Delinquent license reactivation beyond grace period. If an outsourcing facility license has not been renewed prior to the expiration of the one-month grace period identified in paragraph 41.3(3)*"a,"* the facility may not continue to provide services to Iowa customers. An outsourcing facility that continues to provide services to Iowa customers without a current license may be subject to disciplinary sanctions. An outsourcing facility without a current license may apply for reactivation by submitting an application for license reactivation and a $1,600 reactivation fee. As part of the reactivation application, the facility shall disclose the services, if any, that were provided to Iowa customers while the license was delinquent.

41.3(4) *License changes.* If an outsourcing facility has a change of name, ownership, location or supervising pharmacist, the facility shall submit to the board an outsourcing facility license application and applicable fee within ten days of the FDA's issuance of an updated registration. Following processing of the completed license application and fee, the board shall issue a new license certificate that reflects the change or changes.

41.3(5) *License cancellation.* If an outsourcing facility ceases to be registered as an outsourcing facility with the FDA, the facility shall immediately cease distribution of non-patient-specific compounded drug products in or into this state and shall return its Iowa outsourcing facility license to the board within ten days of such occurrence. Upon receipt, the board shall administratively cancel the outsourcing facility license. If an outsourcing facility intends to discontinue business in this state, the facility shall notify the board in writing of its intent at least 30 days in advance of the discontinuation of services and request that the license be administratively canceled. To the extent possible to avoid unnecessary delays in obtaining product for patients, an outsourcing facility that intends to discontinue services in Iowa should provide advance notice to its customers of the date that the outsourcing facility intends to cease distributing products in this state. The notice requirements of this rule shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster.

657—41.4(155A) Applicability of board rules. An outsourcing facility shall comply with all requirements of this chapter, 657—Chapter 20, and any other board rules relating to the services that are provided to Iowa customers.

41.4(1) *Controlled substances.* An outsourcing facility providing prescription drugs identified as controlled substances under Iowa Code chapter 124 to Iowa customers or patients shall comply with all requirements of 657—Chapter 10.

41.4(2) *Electronic data.* An outsourcing facility utilizing any electronic data processing or transmission devices or services shall comply with all requirements of 657—Chapter 21.

41.4(3) *Patient-specific prescriptions.* An outsourcing facility that also provides patient-specific compounded medications pursuant to a prescription shall comply with all requirements of 657—Chapters 8, 19, and 20.

657—41.5(155A) Reporting discipline and criminal convictions. An outsourcing facility shall provide written notice to the board of any disciplinary or enforcement action imposed by any licensing or regulatory authority on any license or registration held by the facility. Written notice shall be received no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. An outsourcing facility shall provide written notice to the board of any criminal conviction of the facility or of any owner that is related to the operation of the facility no later than 30 days after the conviction. The term "criminal conviction" includes instances when the judgment of conviction or sentence is deferred.

657—41.6(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on an outsourcing facility license for any of the following:

1. Any violation of the Federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the FDA shall be conclusive evidence of a violation.
2. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the outsourcing facility, supervising pharmacist, or individual owner, or if the outsourcing facility is an association, joint stock company, partnership, or corporation, by any managing officer.
3. Refusing access to the outsourcing facility or facility records to an agent of the board for the purpose of conducting an inspection or investigation.
4. Failure to maintain licensure pursuant to 657—Chapter 8 or 657—Chapter 19 when dispensing compounded drugs pursuant to patient-specific prescriptions into the state.
5. Any violation of Iowa Code chapter 155A, 124, 124A, 124B, 126, or 205 or any rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

These rules are intended to implement Iowa Code sections 124.301 and 155A.13C.

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