# ARC 2559C

# PHARMACY BOARD[657]

**Adopted and Filed**

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 20, "Compounding Practices," Iowa Administrative Code.

The amendments define the term "office use" as it relates to compounded drug products that are distributed to a qualified practitioner for administration to the practitioner's patient in the course of the practitioner's professional practice. The amendments also clarify that a practitioner receiving a compounded product for office use is not restricted to administration of the product to the practitioner's patient within the brick-and-mortar confines of the practitioner's office. If the practitioner's practice is not confined by office walls, the practitioner may administer to a patient a product distributed to the practitioner for office use if the administration occurs in the course of the practitioner's professional practice.

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 February 17, 2016, Iowa Administrative Bulletin as **ARC 2418C**. The Board received no written comments regarding the proposed amendments. The adopted amendments are identical to those published under Notice.

The amendments were approved during the May 4, 2016, 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 124.303, 124.306, 124.308, 126.9, 126.10, 155A.2, 155A.13, 155A.28, and 155A.35.

These amendments will become effective on July 13, 2016.

The following amendments are adopted.

ITEM 1. Adopt the following **new** definition of "Office use" in rule **657—20.2(124,126,155A)**:

*"Office use"* means that a compounded product has been prepared and distributed to a practitioner for administration to a patient by the practitioner in the course of the practitioner's professional practice. A compounded product distributed to a practitioner for "office use" shall not require a patient-specific prescription and may not be further distributed to another practitioner or dispensed to a patient for self-administration.

ITEM 2. 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 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~~ use.* 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~~ a patient in the course of the practitioner's ~~office~~ professional practice. Compounded preparations distributed for office use pursuant to this rule shall not be further distributed to other practitioners or dispensed to ~~patients for administration outside of the office~~ a patient for self-administration.

**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."

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/8/16.