

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to compounded preparations

The Board of Pharmacy hereby amends Chapter 20, “Compounding Practices,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 147.76.

Purpose and Summary

These amendments allow veterinarians who have obtained compounded preparations for office stock use to dispense the compounded preparations to the owner of a veterinary patient to treat an immediate medical need when timely access to a patient-specific supply of compounded medication is not available, no commercially available product can meet the need of the patient, lack of treatment will likely result in patient harm, and the supply does not exceed 14 days.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on February 9, 2022, as **ARC 6178C**. The Board received three written comments. One comment expressed support for the rule making.

The other two comments requested modification of the limitation that the supply of compounded preparation does not exceed 14 days when dispensed to treat an immediate medical need of a veterinary patient if the compounded preparation is obtained from a U.S. Food and Drug Administration (FDA)-registered, Iowa-licensed outsourcing facility. One comment suggested raising the limit to 30 days on the dispensing of compounded preparations obtained from an outsourcing facility, while the other comment suggested imposing no limit at all on the dispensing of compounded medications obtained from an outsourcing facility.

While the Board recognizes that preparations compounded by an outsourcing facility and a pharmacy are subject to different product quality standards (current Good Manufacturing Practices vs. United States Pharmacopoeia, respectively), compounded preparations from an outsourcing facility are not without risk because they are not subject to the complete FDA approval process as required of commercially available drug products. The commenters rightly noted that a compounded preparation obtained from an outsourcing facility has a longer shelf life as a result of the higher quality standard required of its production. The longer shelf life of a product from an outsourcing facility provides incentive for veterinarians to seek out preparations from these facilities, if available, as opposed to a compounded preparation with a shorter shelf life from a licensed pharmacy. The 14-day limit is not intended to imply that compounded preparations obtained from an outsourcing facility and pharmacy are inherently of the same quality. Providing separate quantity limits based on the supplier of the compounded preparation, as suggested, would likely cause confusion for veterinarians who may not know the type of license held by the compounder.

This rule making seeks to provide veterinarians with an option to provide their patients with a compounded preparation from office stock in limited situations when there is an immediate medical need and is intended to provide a sufficient supply of the medication to meet the immediate need of the patient. When a treatment is needed for longer than 14 days, the Board’s expectation is that if

a compounded preparation is required, the compounded preparation will be dispensed pursuant to a patient-specific prescription from an Iowa-licensed pharmacy or outsourcing facility that also holds an Iowa pharmacy license.

No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Board on May 3, 2022.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

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

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 6, 2022.

The following rule-making actions are adopted:

ITEM 1. Amend rule **657—20.2(124,126,155A)**, definition of “Office use,” as follows:

“*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, except as provided in subrule 20.15(2).

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) No change.

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 pharmacy or outsourcing facility. Veterinary compounded preparations sold to a practitioner for office use may be dispensed to the owner of a veterinary patient to treat an immediate medical need when timely access to a patient-specific supply of compounded medication is not available, no commercially available product can meet the need of the patient, lack of treatment will likely result in patient harm, and the supply does not exceed 14 days.

20.15(3) *Office 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 a patient in the course of the practitioner's professional practice. Compounded preparations distributed for office use pursuant to this rule shall not be further distributed to other practitioners or dispensed to a patient for self-administration, except as provided in subrule 20.15(2).

20.15(4) No change.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/1/22.