PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend Chapter 20, "Compounding Practices," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed 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 147.76.

Purpose and Summary

This proposed amendment would allow veterinarians who have obtained compounded preparations for office stock use to further dispense 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 accessible, no commercially available product can meet the need of the patient, lack of treatment will likely result in patient harm, and when the supply does not exceed seven days.

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.

Public Comment

Sue Mears, RPh

Board of Pharmacy

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Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1) "b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

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).

The following rule-making action is proposed:

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 accessible, no commercially available product can meet the need of the patient, lack of treatment will likely result in patient harm, and when the supply does not exceed seven 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.