ARC 2418C

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 20, "Compounding Practices," Iowa Administrative Code.

The amendments were approved at the January 13, 2016, regular meeting of the Board of Pharmacy.

The proposed 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 Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on March 8, 2016. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

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.

The following amendments are proposed.

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."