ARC 6522C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to records of 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

This rule making requires documentation of all ingredient sources, lot numbers, and expiration dates and the steps involved in the compounding process for all nonsterile and sterile compounded preparations. This rule making also separates rule 657—20.23(124,126,155A) into subrules for clarity.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on June 1, 2022, as **ARC 6333C**. A public hearing was held on June 23, 2022, at 10 a.m. in the Health Professions Board Room, 400 S.W. 8th Street, Suite H, Des Moines, Iowa. No one attended the public hearing.

The Board received five comments about the proposed rule making. Three commenters expressed concern about documenting steps of a preparation when simply following a manufacturer's package insert. One commenter suggested a modification to the term "source" to alleviate confusion. One commenter suggested that the proposed requirement to include the steps involved in compounding implied that a pharmacy would be required to maintain a Master Formulation Record, currently only required by United States Pharmacopoeia (USP) General Chapter 797 (standards for sterile compounded preparations) for compounding preparations for more than one patient or from nonsterile ingredients.

The Board declined action on the comments relating to preparations made following a manufacturer's package insert because that practice is excluded from the definition of "compounding" and, thus, would not be subject to these documentation requirements. The Board also declined action on the comment relating to a Master Formulation Record because the amendment does not require a Master Formulation Record but instead requires only the addition of the compounding steps on a pharmacy's compounding record. The Board agreed with the commenter's concern about the confusion that could arise from the term "source," deleted the word "source" from paragraph 20.23(2)"a," and instead now requires documentation of each ingredient's "manufacturer or National Drug Code (NDC)."

Adoption of Rule Making

This rule making was adopted by the Board on August 24, 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 October 26, 2022.

The following rule-making action is adopted:

Amend rule 657—20.23(124,126,155A) as follows:

657—20.23(124,126,155A) Records.

20.23(1) *Retention.* All records required by this chapter shall be retained as original records of the pharmacy or outsourcing facility and shall be readily available for inspection and photocopying by agents of the board or other authorized authorities for at least two years following the date of the record.

20.23(2) *Required elements.* Records shall allow for the identification of ~~all~~ the following:

a. All ingredients used in compounding, ~~all~~ including manufacturer or National Drug Code (NDC), lot number, and expiration date.

b. The compounding steps involved in the preparation.

c. All personnel involved in compounding~~, and all~~.

d. All personnel involved in reviewing compounded preparations.

20.23(3) *Batch disbursements.* The pharmacy or outsourcing facility shall maintain records documenting the disbursements from each batch of a compounded preparation.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 9/21/22.