

PHARMACY BOARD[657]

Notice of Intended Action

Proposing rule making related to records of compounded preparations and providing an opportunity for public comment

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 section 147.76.

Purpose and Summary

This proposed 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.

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

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on June 21, 2022. Comments should be directed to:

Sue Mears
Board of Pharmacy
400 S.W. 8th Street, Suite E
Des Moines, Iowa 50309
Email: sue.mears@iowa.gov

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

June 23, 2022
10 a.m.

Health Professions Board Room
400 S.W. 8th Street, Suite H
Des Moines, Iowa 50309

Persons who wish to make oral comments at the public hearing may be asked to state their names for the record and to confine their remarks to the subject of this proposed rule making.

Any persons who intend to attend the public hearing and have special requirements, such as those related to hearing or mobility impairments, should contact the Board and advise of specific needs.

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—20.23(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 source, 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.