PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby amends Chapter 8, "Universal Practice Standards," and Chapter 20, "Compounding Practices," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 147.76, 155A.2, and 155.13.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 155A.2 and 155A.13.

Purpose and Summary

The United States Pharmacopeial Convention (USP) establishes national minimum standards for a number of health care related topics. USP General Chapter 800, enforceable by the federal Food and Drug Administration, provides the national minimum standard for the proper handling of hazardous drugs to protect health care workers, patients, and the environment and will become effective (enforceable) December 1, 2019. The amendments require all pharmacies to comply with the standards set forth in USP General Chapter 800 as of the enforcement date as determined by USP while providing an opportunity for pharmacies engaged in compounding of hazardous drugs to seek board approval for delayed compliance of no more than 18 months.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on August 29, 2018, as **ARC 3978C**.

An Amended Notice of Intended Action was published in the Iowa Administrative Bulletin on December 19, 2018, as **ARC 4172C**.

The board received numerous comments from the public, health care associations, and the Administrative Rules Review Committee seeking either delayed enforcement of USP General Chapter 800 by 18 months or an opportunity for entities to seek permission from the Board for delayed compliance. The amendments retain the enforcement date as determined by USP but allow for an opportunity to seek delayed compliance of up to 18 months.

Adoption of Rule Making

This rule making was adopted by the Board on _____, 2019.

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 _____, 2019.

The following rule-making action is adopted:

ITEM 1. Amend rule 657—8.5(155A) as follows:

657—8.5(155A) Environment and equipment requirements. There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy pursuant to rule 657—8.3(155A). Space and equipment shall be available in an amount and type to provide secure, environmentally controlled storage of drugs ~~shall be available~~.

8.5(1) to **8.5(10)** No change.

8.5(11). *Hazardous drugs.* The pharmacy shall ensure pharmacy personnel and patients are adequately protected from unnecessary exposure to hazardous drugs. As of December 1, 2019, the pharmacy shall be in compliance with United States Pharmacopeia (USP) General Chapter 800 for handling hazardous drugs. A pharmacy engaged in compounding of hazardous drugs may request delayed compliance for specific requirements in USP General Chapter 800 pertaining to compounding in accordance with rule 657—20.5(126,155A).

ITEM 2. Amend rule 657—20.5(126,155A) as follows:

657—20.5(126,155A) Delayed compliance. A pharmacy that cannot meet the requirements for full compliance with ~~these rules, including~~ applicable USP chapters~~, and that has not obtained from the board a waiver of the specific requirement or requirements~~ by the enforcement date established by USP shall not engage in compounding until the pharmacy is in full compliance with all requirements or the board has approved ~~a waiver of~~ delayed compliance for the specific requirement or requirements requested. The board may establish a committee to grant or deny requests for delayed compliance. The board or committee may grant a request for delayed compliance only if the pharmacy can demonstrate progress towards full compliance and adequate protection of the public health, safety, and welfare during the period of delayed compliance. The

board or committee may only grant a request for delayed compliance of specific requirements in USP General Chapter 800 for a maximum of 18 months.