

## PHARMACY BOARD [657]

### Adopted and Filed

The Board of Pharmacy hereby amends Chapter 8, “Universal Practice Standards,” 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 155A.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. In advance of the effective date of USP General Chapter 800, this amendment requires all pharmacies to ensure adequate protection of pharmacy personnel and patients from hazardous drugs and provides an official enforcement date for Iowa pharmacies to implement the standards identified in USP General Chapter 800.

#### *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**. The Board received two comments requesting clarification on the expected enforcement date in Iowa for standards identified in USP General Chapter 800. The amendment has been changed to instead provide a date upon which the Board intends to enforce the standards of USP Chapter 800, which is set for December 1, 2019 or later if so delayed by USP.

#### *Adoption of Rule Making*

This rule making was adopted by the Board on \_\_\_\_\_, 2018.

#### *Fiscal Impact*

It cannot be determined what, if any, fiscal impact this rule making will have to the state of Iowa. Of the few pharmacies funded by the state of Iowa, it is unknown to what degree hazardous drugs are in use and what safety methods have already been implemented.

#### *Jobs Impact*

After analysis and review of this rule making, no impact on jobs can be determined.

#### *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:

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, or the enforcement date identified by the United States Pharmacopeia (USP), whichever is later, the pharmacy shall be in compliance with USP General Chapter 800 for handling hazardous drugs.