

PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed 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 healthcare 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 healthcare workers, patients, and the environment and will become effective (enforceable) December 1, 2019. In advance of the effective date of USP Chapter <800>, this proposed amendment requires all pharmacies to ensure adequate protection of pharmacy personnel and patients from hazardous drugs and encourages pharmacies to implement the standards identified in USP Chapter <800>.

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 can be determined. The Board has been made aware of many pharmacies (such as hospitals and compounding pharmacies) proactively enhancing pharmacy facilities to be compliant with USP Chapter <800> with no reports of a negative impact on jobs. It cannot be determined the extent to which pharmacies with minimal handling or compounding of hazardous drugs will upgrade facilities or adjust procedures to ensure compliance with USP Chapter <800>.

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 Pharmacy Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Public Comment

Any interested person may submit comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Pharmacy Board no later than 4:30 p.m. on _____, 2018. Comments should be directed to: Sue Mears, RPh, Compliance Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309; or by e-mail at sue.mears@iowa.gov.

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)“b,” an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

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:

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 and is encouraged to implement protective methods identified in United States Pharmacopeia General Chapter <800>.