

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 13, “Sterile Compounding Practices,” Iowa Administrative Code.

The amendment was approved at the September 28, 2010, meeting of the Board of Pharmacy.

The proposed amendment provides for an exception for the placement of a compounding aseptic isolator (CAI) within an ISO Class 8 anteroom or ante area when the CAI meets ISO Class 5 atmospheric environment conditions.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on November 23, 2010. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

This amendment is intended to implement Iowa Code sections 126.10, 155A.2, 155A.13, and 155A.28.

The following amendment is proposed.

Amend subrule 13.27(4) as follows:

13.27(4) Anteroom requirements. ~~An~~ Except for a CAI that meets the conditions specified in subrule 13.27(3) exempting the CAI from placement in an ISO Class 7 cleanroom, an anteroom or ante area shall be located adjacent to the buffer area and maintained at ISO Class 8 air quality. This area is to be used for unpacking and disinfecting supplies for storage and for hand sanitizing and gowning. If the sterile preparation area is to be used only for the compounding of low- and medium-risk preparations, the ante area shall be clearly demarcated for the compounding of low- and medium-risk preparations. If the sterile preparation area is to be used for the compounding of high-risk preparations, the ante area shall be physically separated from the buffer area.