

**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 124.301, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 10, “Controlled Substances,” Iowa Administrative Code.

The amendments were approved at the September 11, 2014, meeting of the Board of Pharmacy.

The proposed amendments temporarily classify as Schedule IV controlled substances products containing tramadol, alfaxalone, and suvorexant and temporarily remove the classification of hydrocodone combination products from Schedule III, effectively classifying all hydrocodone-containing products in Schedule II of the Controlled Substances Act in conformance with recent control of these same substances by the U.S. Department of Justice, Drug Enforcement Administration.

The proposed amendments also provide clearer direction for the notification process when a registrant has experienced a theft or loss of controlled substances. The amendment regarding the reporting of a theft or loss of controlled substances requires immediate notification to the DEA and, in certain circumstances, to the Board, upon discovery of a theft or loss of a significant quantity of controlled substances, followed by submission to the Board and to the DEA of a formal report within 14 days of discovery of the theft or loss.

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 amendments not later than 4:30 p.m. on October 21, 2014. 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](mailto:terry.witkowski@iowa.gov).

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 124.201(4) and 124.301.

The following amendments are proposed.

ITEM 1. Rescind rule 657—10.16(124) and adopt the following **new** rule in lieu thereof:

**657—10.16(124) Report of theft or loss.** A registrant shall report to the board and the DEA any theft or significant loss of controlled substances when the loss is attributable to other than inadvertent error. Thefts or other losses of controlled substances shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them.

**10.16(1) Immediate notice to board.** If the theft was committed by a registrant or licensee of the board, or if there is reason to believe that the theft was committed by a registrant or licensee of the board, the registrant from whom the controlled substances were stolen shall notify the board immediately upon discovery of the theft and shall identify to the board the registrant or licensee suspected of the theft.

**10.16(2) Immediate notice to DEA.** A registrant shall deliver notice, immediately upon discovery of a reportable theft or loss of controlled substances, to the Des Moines DEA field office via telephone, facsimile, or a brief written message explaining the circumstances of the theft or loss.

**10.16(3) Timely report submission.** Within 14 days of discovery of the theft or loss, a registrant shall submit directly to the DEA a Form 106 or alternate required form via the DEA Web site at <http://www.deadiversion.usdoj.gov/>. A copy of the report that was completed and submitted to the

DEA shall be immediately submitted to the board via facsimile, e-mail attachment, or personal or commercial delivery.

**10.16(4)** *Record maintained.* A copy of the report shall be maintained in the registrant's files for a minimum of two years following the date the report was completed.

ITEM 2. Rescind rule 657—10.38(124) and adopt the following **new** rule in lieu thereof:

**657—10.38(124) Temporary designation of controlled substances.**

**10.38(1)** Amend Iowa Code subsection 124.208(5), paragraph (a), by rescinding subparagraphs (3) and (4) and by renumbering remaining subparagraphs (5) through (8) as subparagraphs (3) through (6).

**10.38(2)** Amend Iowa Code subsection 124.210(2) by adding the following new paragraph:

*c.* 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers (including tramadol).

**10.38(3)** Amend Iowa Code subsection 124.210(3) by adding the following new paragraphs:

*bb.* Alfaxalone.

*bc.* Suvorexant.