

**PHARMACY BOARD[657]**

**Adopted and Filed**

Pursuant to the authority of Iowa Code section 124.301, the Board of Pharmacy hereby amends Chapter 10, “Controlled Substances,” Iowa Administrative Code.

The 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 (DEA).

The 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 these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the October 1, 2014, Iowa Administrative Bulletin as **ARC 1647C**. The Board received written comments objecting to the proposed temporary scheduling of tramadol and hydrocodone-containing products and requesting that the Board terminate the rule making. Regardless of whether the Board proceeded with the rule making, the drugs identified in the comments have been scheduled under federal law, and where federal and state laws differ regarding controlled substances schedules, the more stringent scheduling action prevails. The Board also received a request for clarification of the 14-day time period specified in subrule 10.16(3), questioning whether that period refers to calendar days or business days. In response to that question, the adopted amendment has been changed to require reporting within 14 calendar days of discovery of the theft or loss.

Although the Notice of Intended Action proposed to rescind current rule 657—10.38(124), the temporary scheduling provisions of the rule are still necessary. Therefore, the proposed rescission of rule 657—10.38(124) was not adopted, and the new temporary scheduling provisions have been included in the rule as new subrules 10.38(4) through 10.38(6).

The amendments were approved during the November 19, 2014, meeting of the Board of Pharmacy. 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.

These amendments will become effective on January 14, 2015.

The following amendments are adopted.

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 calendar 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. Adopt the following **new** subrules 10.38(4) to 10.38(6):

**10.38(4)** 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(5)** 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(6)** Amend Iowa Code subsection 124.210(3) by adding the following new paragraphs:

*bb.* Alfaxalone.

*bc.* Suvorexant.

[Filed 11/19/14, effective 1/14/15]

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/10/14.