

**PHARMACY BOARD[657]**

**Adopted and Filed Emergency**

Pursuant to the authority of Iowa Code sections 124.201 and 124.301, the Board of Pharmacy hereby amends Chapter 10, “Controlled Substances,” Iowa Administrative Code.

The amendment temporarily designates tapentadol, a new molecular entity with centrally acting analgesic properties, as a Schedule II controlled substance subject to the control and record-keeping requirements of Iowa Code chapter 124 for a substance designated in that schedule. The amendment also temporarily designates lacosamide as a depressant subject to the control and record-keeping requirements of a Schedule V controlled substance in Iowa Code chapter 124.

The Board may not consider requests for waiver or variance of this amendment. The scheduling of the substances that are the subject of this amendment is also regulated under federal law by the Drug Enforcement Administration.

The amendment was approved during the June 2, 2009, meeting of the Board of Pharmacy.

The Board finds, pursuant to Iowa Code section 17A.4(3), that notice and public participation are unnecessary and impracticable due to the immediate need for this amendment in order to ensure conformity between Iowa and federal laws controlling the distribution of these substances. The Board concurs with the action taken by the federal Drug Enforcement Administration to control these substances. Controlled substances laws are intended to protect the public from the potentially harmful effects resulting from the overuse, abuse, and addiction potential attributed to controlled substances while ensuring that prescribers treating patients in need of these drug therapies are authorized to prescribe, administer, and dispense these substances to and for their patients.

The Board finds, pursuant to Iowa Code subsection 17A.5(2)“b”(2), that the normal effective date of this amendment, 35 days after publication, should be waived and the amendment should be made effective to coincide with the effective date of the federal scheduling actions on June 22, 2009. This amendment confers a benefit by ensuring conformity between Iowa and federal laws controlling the distribution of these substances in Iowa while ensuring that a patient in need of these substances has a legitimate means of access through the patient’s health care providers.

This amendment became effective June 22, 2009.

This amendment is intended to implement Iowa Code sections 124.201, 124.205, 124.211, 124.301, 124.306, 124.307, and 124.308.

The following amendment is adopted.

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 section 124.206, subsection 3, by adding the following new paragraph:

*ab.* Tapentadol.

**10.38(2)** Amend Iowa Code section 124.212, subsection 5, as follows:

5. Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substance having a depressant effect on the central nervous system, including its salts: ~~pregabalin~~

a. Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide].

b. Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].

[Filed Emergency 6/11/09, effective 6/22/09]

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 7/1/09.