

PHARMACY BOARD[657]

Adopted and Filed Emergency

Rule making related to temporary scheduling of cannabidiol prescription drug products

The Pharmacy Board hereby amends Chapter 10, “Controlled Substances,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 124.201 and 124.201A.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 124.201A.

Purpose and Summary

This rule making temporarily places into Schedule V of the Iowa Uniform Controlled Substances Act any drugs approved by the U.S. Food and Drug Administration (FDA) which contain cannabidiol (CBD) derived from cannabis and no more than 0.1 percent tetrahydrocannabinols (THC).

*Reason for Adoption of Rule Making Without
Prior Notice and Opportunity for Public Participation*

Pursuant to Iowa Code section 17A.4(3), the Board finds that notice and public participation are unnecessary or impractical because statute so provides. Iowa Code section 124.201A authorizes the Board to adopt rules on an emergency basis to temporarily revise the Controlled Substances Act to designate as controlled substances in the appropriate schedule FDA-approved cannabidiol prescription drug products that are designated by the federal Drug Enforcement Administration as controlled substances with such rules to be effective immediately upon filing.

Reason for Waiver of Normal Effective Date

Pursuant to Iowa Code section 17A.5(2)“b”(1)(a), the Board also finds that the normal effective date of this rule making, 35 days after publication, should be waived and the rule making made effective on October 3, 2018, because, as described above, Iowa Code section 124.201A authorizes the Board to adopt rules on an emergency basis to temporarily revise the Controlled Substances Act. On September 28, 2018, a final order was published in the federal register placing “FDA-approved drugs that contain CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V” of the Controlled Substances Act.

Adoption of Rule Making

This rule making was adopted by the Board on July 24, 2018.

Concurrent Publication of Notice of Intended Action

In addition to its adoption on an emergency basis, this rule making has been initiated through the normal rule-making process and is published herein under Notice of Intended Action as **ARC 4086C** to allow for public comment.

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 has been found.

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

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).

Effective Date

This rule making became effective on October 3, 2018.

The following rule-making action is adopted:

Adopt the following **new** subrule 10.39(4):

10.39(4) Amend Iowa Code section 124.212 by adding the following new subsection “6”:

6. *Approved cannabidiol drugs.* A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

[Filed Emergency 10/3/18, effective 10/3/18]

[Published 10/24/18]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 10/24/18.