ARC 3505C

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 sections 124.301, 124.552, and 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 10, "Controlled Substances," and Chapter 37, "Iowa Prescription Monitoring Program," Iowa Administrative Code.

These proposed amendments were approved at the November 1, 2017, regular meeting of the Board of Pharmacy.

During the 2017 Legislative Session, the Iowa Legislature passed and the Governor signed 2017 Iowa Acts, chapters 152 and 162. 2017 Iowa Acts, chapter 162, requires the Board to adopt rules to administer new Iowa Code section 124.201A, which relates to cannabidiol investigational products and which requires the Board to reschedule a cannabidiol product upon being approved by FDA and rescheduled by DEA. 2017 Iowa Acts, chapter 152, allows the Board to provide information from the drug prescribing and dispensing information program (Iowa Prescription Monitoring Program) to a medical examiner investigator recognized by the State Medical Examiner's office when the information relates to an investigation being conducted by the medical examiner or investigator.

The proposed amendments also increase the frequency of a dispenser's reporting of controlled substance dispensing to the Iowa Prescription Monitoring Program (PMP) from "at least weekly" to "the next business day following dispensing." The amendments increase the frequency of such reporting to provide prescribers and pharmacists more timely information when utilizing the data in their prescribing and dispensing decision making.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on January 19, 2018. Such written materials may be sent to Terry Witkowski, Executive Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by email to terry.witkowski@iowa.gov.

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

After analysis and review of this rule making, no impact on jobs is anticipated.

These amendments are intended to implement 2017 Iowa Acts, chapters 152 and 162, and Iowa Code section 124.552.

The following amendments are proposed.

ITEM 1. Adopt the following **new** subrule 10.38(3):

10.38(3) *Cannabidiol investigational product.* If a cannabidiol investigational product approved as a prescription drug medication by the United States Food and Drug Administration is eliminated from or revised in the federal schedule of controlled substances by the DEA and notice of the elimination or revision is given to the board, the board shall similarly eliminate or revise the prescription drug medication in the schedule of controlled substances. Such action by the board shall be immediately effective upon the date of publication of the final regulation containing the elimination or revision in the Federal Register.

ITEM 2. Amend subrule 37.3(3) as follows:

37.3(3) *Reporting periods.* A record of each reportable prescription dispensed shall be submitted by each dispenser ~~at least weekly~~ no later than the next business day following dispensing. Records may be submitted with greater frequency than required by this subrule. ~~Records of reportable prescriptions dispensed between Sunday and Saturday each week shall be submitted no later than the following~~

~~Wednesday. However, a pharmacy that is currently submitting prescription dispensing records to another state's PMP on an alternative weekly reporting schedule may request authority to submit records to the Iowa PMP pursuant to that established schedule. The request shall be submitted in writing via e-mail, fax, or regular mail to the PMP administrator. The request shall identify the pharmacy by name, address, and Iowa pharmacy license number and shall define the alternative reporting period and the reason for the requested alternative reporting period. The PMP administrator is hereby authorized to approve or deny the pharmacy's alternative weekly reporting schedule.~~

ITEM 3. Adopt the following **new** subrule 37.4(9):

37.4(9) *Medical examiner or medical examiner investigator.* A medical examiner or medical examiner investigator may obtain PMP information when the information requested by the examiner or investigator relates to an investigation being conducted by the examiner or investigator.