PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend Chapter 10, "Controlled Substances," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 124.301.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 124.301.

Purpose and Summary

The proposed rulemaking clarifies the expectation that a registrant's perpetual inventory must at all times accurately reflect the actual on-hand inventory of the substance(s) as well as simplifies the rule relating to the purchase of schedules I or II controlled substances. Federal regulations were recently amended to now allow a single page order form for the purchase of schedule I and II substances, but continues to allow the use of the prior triplicate order form for a period of time in addition to the electronic ordering process.

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.

Public Comment

Any interested person may submit comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on _____, 2020. Comments should be directed to:

Sue Mears, RPh
Iowa Board of Pharmacy
400 SW 8th Street, Suite E
Des Moines, IA 50309

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)*"b,"* an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

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).

The following rule-making action is proposed:

ITEM 1. Rescind rule 657—10.17(124) and adopt the following **new** rule in lieu thereof:

657—10.17(124) Ordering or distributing Schedule I or II controlled substances. A registrant authorized to order or distribute schedule I or II controlled substances shall do so only pursuant to and in compliance with DEA regulations via a DEA Form 222 or via the DEA Controlled Substances Ordering System (CSOS).

ITEM 2. Amend rule 657—10.18(124) as follows:

657—10.18(124) Schedule II perpetual inventory. Each registrant located in Iowa that maintains Schedule II controlled substances shall maintain a perpetual inventory system for all Schedule II controlled substances pursuant to this rule. All records relating to the perpetual inventory shall be maintained at the registered location and shall be available for inspection and copying by the board or its representative for a period of two years from the date of the record. The perpetual inventory shall accurately reflect the on-hand inventory of schedule II substances and the registrant is responsible for ensuring that the perpetual inventory record is accurate and matches the actual on-hand inventory at all times.

10.18(1) to **10.18(4)** No change

ITEM 3. Rescind rule 657—11.27(124,147A,155A) and adopt the following **new** rule in lieu thereof:

657—11.27(124,147A,155A) Ordering Schedule II controlled substances—medical director-based service programs. A registrant authorized to order or distribute schedule II controlled substances shall do so only pursuant to and in compliance with DEA regulations via a DEA Form 222 or via the DEA Controlled Substances Ordering System (CSOS).