

## 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 section 272C.3, the Board of Pharmacy hereby gives Notice of Intended Action to rescind Chapter 30, “Impaired Pharmacy Professional and Technician Recovery Program,” and adopt new Chapter 30, “Iowa Monitoring Program for Pharmacy Professionals,” Iowa Administrative Code.

The amendment was approved at the June 30, 2016, regular meeting of the Board of Pharmacy.

The proposed amendment rescinds current Chapter 30 regarding the Impaired Pharmacy Professional and Technician Recovery Program and adopts new Chapter 30 establishing the Iowa Monitoring Program for Pharmacy Professionals. The program and committee established pursuant to the new chapter are intended to support the evaluation and monitoring of licensees who are impaired as a result of alcohol or drug abuse, dependency, or addiction, or by any mental or physical disorder or disability, while protecting the health, safety and welfare of the public. The program will provide an alternative to formal disciplinary actions against pharmacists, pharmacist-interns, and pharmacy technicians who recognize their impairment and seek assistance and monitoring under the guidance of the program committee. The proposed rules identify the members of the program committee, the organization of the committee, and the length of appointment terms.

Impaired professionals’ eligibility requirements and terms for participation and continued monitoring under the program are established. The proposed rules define actions that constitute noncompliance with the terms of participation in the program and the consequences of noncompliance. The proposed rules identify the circumstances under which program participant records and information may be disclosed to parties other than members of the committee. The proposed rules also authorize the committee to enter into 28E agreements with other health professional licensing boards to share administrative personnel to evaluate, assist, and monitor eligible program participants and to report noncompliant participants to the appropriate licensing board for appropriate action.

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

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on August 30, 2016. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to [terry.witkowski@iowa.gov](mailto:terry.witkowski@iowa.gov).

A public hearing will be held on August 30, 2016, from 3 to 4 p.m. in the large conference room, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309. Persons attending the hearing may present their views either orally or in writing. Persons will be asked to give their names and addresses for the record and to confine their remarks to the content of the proposed amendment.

After analysis and review of this rule making, the Board has determined that the effect of this proposed rule making on jobs cannot be accurately predicted. One of the goals of the Iowa Monitoring Program for Pharmacy Professionals is to encourage pharmacists, pharmacist-interns, and pharmacy technicians who recognize their impairment and who seek assistance and monitoring under the terms of the program to remain in practice within the profession. The continued employment and professional practice afforded these individuals, under the guidance and monitoring provided by this program, should have a positive impact on jobs in Iowa.

This amendment is intended to implement Iowa Code section 272C.3(1)“k.”

The following amendment is proposed.

Rescind 657—Chapter 30 and adopt the following **new** chapter in lieu thereof:

CHAPTER 30  
IOWA MONITORING PROGRAM FOR PHARMACY PROFESSIONALS

**657—30.1(272C) Iowa monitoring program for pharmacy professionals committee.** Pursuant to the authority of Iowa Code section 272C.3(1)“k,” the board establishes the committee for the Iowa monitoring program for pharmacy professionals. The purpose of the committee is to provide a program to support the evaluation and monitoring of licensees who are impaired as a result of alcohol or drug abuse, dependency, or addiction, or by any mental or physical disorder or disability, while protecting the health, safety and welfare of the public.

**657—30.2(272C) Definitions.** For purposes of these rules, the following definitions shall apply:

“*Board*” means the Iowa board of pharmacy.

“*Committee*” means the Iowa monitoring program for pharmacy professionals committee.

“*Contract*” means the written document executed by an applicant or licensee and the committee after the committee receives a report from an approved treatment provider, which establishes the terms for participation in the program.

“*Impairment*” means an inability, or significant potential for inability, to practice with reasonable safety and skill as a result of a diagnosed substance use disorder or any diagnosed mental or physical health condition.

“*Initial agreement*” means the written document establishing the initial terms for participation in the program.

“*Licensee*” means a pharmacist licensed by the board, a pharmacist-intern registered with the board, or a pharmacy technician registered with the board.

“*Participant*” means an applicant or licensee who does any of the following: self-reports an impairment to the program, is referred to the program by the board, signs an initial agreement with the committee, or signs a contract with the committee.

“*Program*” means the Iowa monitoring program for pharmacy professionals.

“*Self-report*” means that an applicant or licensee provides written notification to the committee that the applicant or licensee has been, is, or may be impaired. Information related to impairment or a potential impairment which is provided on a license application or renewal form may be considered a self-report.

**657—30.3(272C) Organization of the committee.** The board shall appoint the members of the Iowa monitoring program for pharmacy professionals committee.

**30.3(1) Membership.** The membership of the committee includes, but is not limited to:

- a. The executive director of the board or the director’s designee from board staff;
- b. One representative from the Drake University College of Pharmacy and Health Sciences;
- c. One representative from the University of Iowa College of Pharmacy;
- d. One board of pharmacy licensee who has maintained sobriety for a period of no less than two years following successful completion of a recovery program;
- e. One health care professional with expertise in substance use disorders;
- f. One health care professional with expertise in mental health; and
- g. One public member.

**30.3(2) Officers.** At the last meeting of each calendar year, the committee shall elect a chairperson and a vice chairperson, each of whom will begin serving a one-year term on January 1.

a. The chairperson is responsible for offering guidance and direction to staff between regularly scheduled committee meetings, including guidance and direction concerning program descriptions, interim restrictions on practice, and negotiation and execution of initial agreements and contracts on behalf of the committee. The committee retains authority to review all interim decisions at its discretion.

b. The vice chairperson is responsible for providing guidance and direction to staff between regularly scheduled committee meetings if the chairperson is unavailable or unable to assist in a particular matter.

**30.3(3) Terms.** Committee members, except the executive director or designee, shall be appointed for three-year terms and shall serve for a maximum of three terms. Each term shall expire on December 31 of the third year of the term.

**657—30.4(272C) Eligibility.**

**30.4(1) Self-report.** An applicant or a licensee shall self-report an impairment or potential impairment directly to the program.

**30.4(2) Board referral.** The board may refer an applicant or licensee to the program if a complaint or investigation reveals an impairment or potential impairment and the board determines that the individual is an appropriate candidate for review by the committee. The board may refer a licensee to the program in a public disciplinary order or other public order.

**30.4(3) Review by the committee.** The committee will determine on a case-by-case basis whether an applicant or licensee who self-reports or is referred by the board is an appropriate candidate for participation in the program. Several factors may lead to the committee's determination that an applicant or licensee is ineligible to participate in the program, including but not limited to if the committee finds sufficient evidence that the applicant or licensee:

- a. Diverted drugs for distribution to third parties or for personal profit;
- b. Adulterated, misbranded, or otherwise tampered with drugs intended for a patient;
- c. Provided inaccurate, misleading, or fraudulent information or failed to fully cooperate with the committee;
- d. Participated in the program, or a similar program offered by another state, without success; or
- e. Failed to sign an initial agreement or a contract when offered by the committee.

**30.4(4) Discretion.** Eligibility of a person to participate in the program is at the sole discretion of the committee. No person is entitled to participate in the program.

**30.4(5) Authority and jurisdiction.** Participation in the program does not divest the board of its authority or jurisdiction over the participant. A participant with an impairment or potential impairment may be eligible to participate in the program while being subject to investigation or discipline by the board for matters other than the alleged impairment.

**657—30.5(272C) Terms of participation.** A participant shall agree to comply with the program terms of participation established in the initial agreement and the contract. Participants will be responsible for all expenses incurred to comply with the terms imposed by the program. Terms of participation specified in the contract shall include, but not be limited to:

**30.5(1) Duration.** The length of time a participant may participate in the program shall be determined by the committee in accordance with the following:

a. Participation in the program for participants impaired as a result of a substance use disorder is set at a minimum of three years. The committee may offer a contract with a shorter duration to a participant who can demonstrate successful participation in another state's monitoring program, who can document similar experience, or who, as a board referral, has successfully completed a portion of the monitoring period established in the board order.

b. Length of participation in the program for participants with impairments resulting from mental or physical conditions will vary depending upon the recommendations provided by health care providers and the determination of the committee following review of all relevant information.

**30.5(2) Requirements.** The committee shall establish terms of participation designed to meet the specific needs of a participant. The committee shall determine the type of recovery, rehabilitation, or maintenance program required to treat the participant's impairment. The contract shall provide a detailed description of the goals of the program, the requirements for successful participation, and the participant's obligations therein. The committee may establish terms of participation specific to a participant's impairment including, but not limited to, the following: treatment, aftercare, worksite

monitoring, chemical screening, further evaluations, structured recovery meetings, therapy, and medication management.

**30.5(3) Practice restrictions.** The committee may impose restrictions on the license to practice as a term of the initial agreement or contract until such time as the committee receives a report from an approved evaluator, and the committee determines, based on all relevant information, that the participant is capable of practicing with reasonable skill and safety. As a condition of participation in the program, a licensee is required to agree to restricted practice in accordance with the terms specified in the initial agreement or contract. In the event the licensee refuses to agree to or comply with the practice restrictions, the committee shall refer the licensee to the board for appropriate action.

**30.5(4) Noncompliance.** Noncompliance is the failure to adhere to the terms of the initial agreement or contract. Participants shall promptly notify the committee of any instances of noncompliance, including relapse. Any instances of significant noncompliance shall be reported by the committee to the board. The report shall include a description of the noncompliance and the committee's recommendation as to whether the participant should remain in the program.

**657—30.6(272C) Confidentiality.** Information in the possession of the board or the committee shall be subject to the confidentiality requirements of Iowa Code section 272C.6. Information about participants in the program shall not be disclosed except as provided in this rule.

**30.6(1)** The committee is authorized, pursuant to Iowa Code section 272C.6(4), to communicate information about a current or former program participant to the applicable regulatory authorities or licensee monitoring programs in the state of Iowa and in any jurisdiction of the United States or foreign nations in which the participant is currently licensed or in which the participant seeks licensure. Program participants must report their participation to the applicable monitoring program or licensing authority in any state in which the participant is currently licensed or in which the participant seeks licensure.

**30.6(2)** The committee is authorized to communicate information about a program participant to any person assisting in the participant's treatment, recovery, rehabilitation, monitoring, or maintenance for the duration of the contract.

**30.6(3)** The committee is authorized to communicate information about a program participant to the board in the event a participant does not comply with the terms of the contract as set forth in rule 657—30.5(272C). The committee may provide the board with a participant's program file in the event the participant does not comply with the terms of the contract and the committee refers the case to the board for the filing of formal disciplinary charges or other appropriate action. If the board initiates disciplinary action against a licensee for noncompliance with the terms of the contract, the board may include in the public disciplinary documents information about a licensee's participation in the program. The committee is also authorized to communicate information about a participant to the board in the event that the participant is under investigation by the board.

**30.6(4)** The committee is authorized to communicate information about a current or former program participant to the board if reliable information held by the committee reasonably indicates that a significant risk to the public exists. If the board initiates disciplinary action based upon this information, the board may include in the public disciplinary documents information about a licensee's participation if necessary to address impairment issues related to the violations which are the subject of the disciplinary action.

**657—30.7(28E) Authority for 28E agreements.** The committee may enter into 28E agreements with other health professional licensing boards to evaluate, assist, and monitor impaired licensees from other health professions who self-report and to report to those professional licensing boards regarding the compliance of individual licensees. In the event of noncompliance, the licensee may be referred to the appropriate licensing board for appropriate disciplinary action.

These rules are intended to implement Iowa Code section 272C.3(1) "k."