ARC 4205C

PHARMACY BOARD[657]

Notice of Intended Action

Proposing rule making related to prescription monitoring program and providing an opportunity for public comment

The Pharmacy Board hereby proposes to rescind Chapter 37, "Iowa Prescription Monitoring Program," Iowa Administrative Code, and adopt a new Chapter 37 with the same title.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 124.554.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 124.550 to 124.558.

Purpose and Summary

During the 2018 Legislative Session, changes were made to the Iowa Code which affect the Iowa Prescription Monitoring Program (PMP), including a requirement that prescribing practitioners register with the PMP simultaneous to Iowa uniform controlled substance Act (CSA) registration, authorization for the Board to assess up to a 25 percent surcharge on CSA registrations to be deposited into the PMP fund, a requirement that dispensing of controlled substances by prescribers be reported to the PMP, and a requirement that administration of an opioid antagonist by a first responder be reported to the PMP.

The Board and the PMP Advisory Council also took the opportunity to conduct an overall review of the chapter as required by Iowa Code section 17A.7(2) and made changes as reflected in the new chapter to provide clarity where needed and to reorganize and simplify where appropriate.

To further the goal of program utilization, the Board and the PMP Advisory Council propose that pharmacists who are involved in direct patient care shall also be required to register with the PMP simultaneous to licensure or renewal. Also, the specific number of authorized delegates has been removed from the proposed rules to allow practitioners the ability to designate delegates according to their individual practice settings.

Fiscal Impact

The Board is in the process of seeking a format by which first responders can submit data relating to the administration of an opioid antagonist. As stated in the Fiscal Note on 2018 Iowa Acts, House File 2377, this change is anticipated to cost upwards of $75,000. With respect to the surcharge, the Board is not anticipating implementation of the surcharge at this time.

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 written 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 January 22, 2019. Comments should be directed to:

Sue Mears
Board of Pharmacy
400 S.W. 8th Street, Suite E
Des Moines, Iowa 50309
Email: sue.mears@iowa.gov

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:

Rescind 657—Chapter 37 and adopt the following **new** chapter in lieu thereof:

CHAPTER 37
IOWA PRESCRIPTION MONITORING PROGRAM

657—37.1(124) Purpose and scope. These rules establish a prescription monitoring program (PMP) that compiles a central database of reportable prescriptions dispensed to patients in Iowa. An authorized health care practitioner shall access PMP information when mandated by the practitioner's licensing authority regarding the practitioner's patient to assist in determining appropriate treatment options and to improve the quality of patient care. The PMP is intended to provide a practitioner with a resource for information regarding a patient's use of controlled substances and to serve as a tool to assess a prescriber's prescribing practices. This database will assist the practitioner in identifying any potential diversion, misuse, or abuse of controlled substances without impeding the appropriate medical use of controlled substances.

657—37.2(124) Definitions. For the purposes of this chapter, the following definitions shall apply.

"Board" means the Iowa board of pharmacy.

"Controlled substance" means a drug in Schedules II through IV set forth in Iowa Code chapter 124, division II.

"Council" means the PMP advisory council established pursuant to Iowa Code section 124.555 to provide oversight and to co-manage PMP activities with the board.

"CSA registration" means registration with the board under the Iowa uniform controlled substances Act pursuant to 657—Chapter 10.

"DEA number" means the registration number issued to an individual or pharmacy by the U.S. Department of Justice, Drug Enforcement Administration (DEA), authorizing the individual or pharmacy to engage in the prescribing, dispensing, distributing, or procuring of a controlled substance.

"Dispenser" means a pharmacy or prescriber, regardless of location, who delivers to the ultimate user a substance required to be reported to the PMP. "Dispenser" does not include a person exempt from reporting pursuant to subrule 37.7(2).

"First responder" means an emergency medical care provider, a registered nurse staffing an authorized service program under Iowa Code section 147A.12, a physician assistant staffing an authorized service program under Iowa Code section 147A.13, a firefighter, or a peace officer as defined in Iowa Code section 801.4 who is trained and authorized to administer an opioid antagonist.

"Health care professional" means a person who, by education, training, certification, or licensure, is qualified to provide and is engaged in providing health care to patients. "Health care professional" does not include clerical or administrative staff. A health care professional shall be licensed, registered, certified, or otherwise credentialed in a manner that permits verification of the health care professional's credentials.

"Health care system" means an organization that includes at least one hospital or at least one group of practitioners that provides comprehensive care who are connected with each other through common ownership or management.

"HIPAA" means the Health Insurance Portability and Accountability Act.

"Law enforcement" means an entity or agency with jurisdiction to investigate or prosecute violations of criminal law. "Law enforcement" includes, but is not limited to, such agencies as police departments, United States attorneys, the DEA, county attorneys, and the Medicaid fraud control unit.

"Licensing authority" means an agency that licenses or registers health care professionals and has jurisdiction to enforce governing laws over those individuals who are licensed or registered. "Licensing authority" includes, but is not limited to, professional licensing boards and the DEA.

"NarxCare" means an analytics tool and care management platform that helps practitioners analyze real-time data from the PMP. The platform analyzes patient data and history to provide a patient risk score and usage patterns to help practitioners identify potential risk factors.

"NDC number" means the universal product identifier used in the United States to identify a specific human drug.

"PMP administrator" means staff persons designated to manage and administer the PMP under the direction and oversight of the board and the council.

"Practitioner" means a prescriber or a pharmacist.

"Practitioner's delegate" means a health care professional who is under the supervision of a PMP-registered practitioner and who is authorized by the practitioner to access PMP information on the practitioner's behalf.

"Prescriber" means an individual with an active CSA registration who has the authority to prescribe controlled substances. For the purposes of this chapter, "prescriber" does not include a licensed veterinarian.

"Prescription monitoring program" or *"PMP"* means the program established pursuant to these rules for the collection and maintenance of PMP information and for the provision of PMP information to authorized individuals.

"Reportable prescription" means the record of a controlled substance administered or dispensed by a practitioner and the record of an opioid antagonist dispensed by a practitioner or administered by a first responder. "Reportable prescription" shall not include records identified in subrule 37.7(1). "Reportable prescription" shall include, but not be limited to:

1. The dispensing of a controlled substance to an emergency department patient;
2. The administration of a controlled substance to an emergency department patient at the discretion of the treating practitioner;
3. The administration or dispensing of an opioid antagonist to an emergency department patient;
4. The dispensing of a controlled substance sample; and
5. The dispensing of a controlled substance or opioid antagonist to a patient upon discharge from a hospital or care facility.

657—37.3(124) Registration. Registration for the PMP pursuant to this rule shall be via the Iowa PMP AWARxE website at iowa.pmpaware.net.

37.3(1) *Prescribers.* A prescriber shall register for the PMP at the same time the prescriber registers or renews a CSA registration pursuant to 657—Chapter 10. A licensed veterinarian with an active CSA registration may register for the PMP.

37.3(2) *Pharmacists.* A pharmacist who is involved in patient care shall register for the PMP at the same time the pharmacist becomes licensed or renews a license pursuant to 657—Chapter 2.

37.3(3) *Practitioner's delegates.* A practitioner may authorize an adequate number of health care professionals who actively work with the practitioner to act as the practitioner's delegates for the purpose of requesting PMP information. A practitioner's delegate shall be licensed, registered, certified, or otherwise credentialed as a health care professional in a manner that permits verification of the health care professional's credentials. The practitioner shall be responsible for the PMP information access of the practitioner's delegates.

37.3(4) *Law enforcement officials.* A law enforcement official may register for the PMP to access information by order, subpoena, or other means of legal compulsion relating to a specific investigation and supported by a determination of probable cause.

37.3(5) *Licensing authority.* A licensing authority official may register for the PMP to access information by order, subpoena, or other means of legal compulsion relating to a specific investigation and supported by a determination of probable cause.

37.3(6) *Medical examiners and medical examiner investigators.* A medical examiner or a medical examiner investigator may register for the PMP to access information when the information relates to an investigation being conducted by the examiner or investigator.

657—37.4 and **37.5** Reserved.

657—37.6(124) Security of PMP credentials. Each user registered to access PMP information shall securely maintain and use the login and password and any other secured credentials assigned to the individual user. Except in an emergency when a patient would be placed in greater jeopardy by restricting PMP information access to the user, a registered user shall not share the user's secure login and password information.

657—37.7(124) PMP reporting—exemptions.

37.7(1) *Exempted dispensing or administration.* The dispensing or administration of a controlled substance as described in this subrule shall not be considered a reportable prescription. A pharmacy engaged in the distribution of controlled substances solely pursuant to one or more of the practices identified in this subrule shall notify the PMP administrator of the exempted practice, and the pharmacy shall not be required to report to the PMP.

a. The dispensing by a licensed hospital pharmacy for the purposes of inpatient hospital care.

b. The dispensing by a licensed pharmacy for a patient residing in a long-term care or inpatient hospice facility.

c. The administration by a prescriber of a controlled substance for the purposes of outpatient procedures.

37.7(2) *Exempted practitioners.* The following entities or individuals shall not be required to report to the PMP and shall not be required to notify the PMP administrator of their exempted status:

a. A licensed pharmacy that does not have a CSA registration and does not dispense controlled substances in Iowa.

b. A licensed veterinarian who administers or dispenses a controlled substance in the normal course of the veterinarian's professional practice.

c. A DEA-registered narcotic treatment program which is subject to the record-keeping provisions of 21 CFR Section 1304.24.

657—37.8(124) PMP reporting—dispensing prescribers. Each dispensing prescriber, unless exempt pursuant to rule 657—37.7(124), shall submit to the PMP a record of each reportable prescription dispensed during a reporting period pursuant to subrule 37.12(2). For purposes of prescriber dispensing, the prescriber shall also be identified as the dispenser or pharmacy.

657—37.9(124) PMP reporting—pharmacies. Each pharmacy, unless exempt pursuant to rule 657—37.7(124), shall submit to the PMP either a record of each reportable prescription dispensed or administered during a reporting period pursuant to subrule 37.12(2) or a zero report pursuant to subrule 37.12(4), as appropriate.

657—37.10 and **37.11** Reserved.

657—37.12(124) Reporting requirements.

37.12(1) *Data elements.* The information submitted to the PMP for each reportable prescription shall be accurate and shall include, at a minimum, the following data elements:

a. Dispenser DEA number.
b. Date the prescription is dispensed or administered.
c. Prescription number or unique identification number.
d. NDC number of the drug dispensed or administered.
e. Quantity of the drug dispensed or administered.
f. Number of days of drug therapy provided by the drug dispensed or administered.
g. Patient legal first and last names.
h. Patient address including street address, city, state, and ZIP code.
i. Patient phone number.
j. Patient date of birth.
k. Patient gender.
l. Prescriber name and DEA number.
m. Date the prescription was issued by the prescriber.
n. Method of payment.
o. Form of transmission of prescription origin.
p. Refill number.
q. Number of refills authorized.
r. Indication as to whether the prescription is new or a refill.

37.12(2) *Reporting periods.* A record of each reportable administration or prescription dispensed shall be submitted by each dispenser no later than the next business day following administration or dispensing.

37.12(3) *Transmission.* Prescription dispensing and administration information shall be transmitted via the PMP's current version of data upload or electronic submission.

37.12(4) *Zero reports.* If a pharmacy did not dispense or administer any reportable prescriptions during a reporting period, the dispenser shall submit a zero report no later than the next business day.

657—37.13(124) Opioid antagonist administration by first responders.

37.13(1) The administration of an opioid antagonist by a first responder shall be reported to the PMP, unless such administration was reported to the Iowa department of public health bureau of emergency and trauma services.

37.13(2) The reporting of the administration of an opioid antagonist by a first responder shall include the following data elements:

a. Patient first and last names.
b. First and last names of the individual who administered the opioid antagonist.
c. Date of administration.
d. Quantity of the opioid antagonist administered.

657—37.14 and **37.15** Reserved.

657—37.16(124) Access to PMP information. All information contained in the PMP is confidential and shall only be accessed as provided in this rule. All requests for PMP information must comply with the format specified by the board for the particular type of request. Once information is accessed, further dissemination or use of that information is governed by applicable federal and state laws governing the person who accessed the information. The board may charge a fee to recover the actual costs associated with responding to any request by a person other than a practitioner or a practitioner's delegate. Any fees or costs assessed by the board shall be considered repayment receipts as defined in Iowa Code section 8.2.

37.16(1) *Prescribers.* A prescriber may access a patient's prescription history report; the prescriber's report card; proactive alerts or system user notes, such as peer-to-peer communication; and NarxCare reports.

37.16(2) *Pharmacists.* A pharmacist may access a patient's prescription history report; proactive alerts or system user notes, such as peer-to-peer communication; and NarxCare reports.

37.16(3) *Practitioner's delegates.* A practitioner's delegate may access a patient's prescription history report; proactive alerts or system user notes, such as peer-to-peer communication; and NarxCare reports.

37.16(4) *Licensing authority officials.*

a. A licensing authority with jurisdiction over a practitioner may obtain the following information, if the request is accompanied by a subpoena compelling disclosure of such information for a specific investigation into the prescribing or dispensing practices of the licensee: prescription history reports; proactive alerts or system user notes, such as peer-to-peer communication; PMP access logs and login records; and NarxCare reports.

b. A licensing authority with jurisdiction over a health care professional may obtain the following information, if the request is accompanied by a subpoena compelling disclosure of such information for a specific investigation into the licensee's misuse of controlled substances: the licensee's prescription history report.

37.16(5) *Law enforcement officials.* A law enforcement official may obtain a patient's prescription history report if the request is accompanied by a subpoena or other means of legal compulsion compelling disclosure of such information for use in a specific investigation.

37.16(6) *Medical examiners and medical examiner investigators.* A medical examiner or medical examiner investigator may obtain a decedent's prescription history report for use in a specific investigation.

37.16(7) *Patients.* A patient or the patient's agent may request the patient's own prescription history report by using the board's patient request form. The request can be personally delivered to the board office where the patient will be required to present current government-issued photo identification at the time of the delivery of the request. A patient who is unable to personally deliver the request to the board office may submit a notarized request, along with a certified copy of the patient's government-issued photo identification, via mail or commercial delivery service. The following agents may submit a request on behalf of a patient: an individual with a medical power of attorney for the patient, a patient's attorney, or an executor of the patient's estate. In addition to the patient's information, the patient's agent shall be identified by name, current address, and telephone number. In lieu of the patient's signature and identification, the patient's agent shall sign the request and the government-issued photo identification shall identify the patient's agent. The patient's agent shall include a copy of the legal document that establishes the agency relationship with the patient.

657—37.17(124) Integrated systems. A practitioner or a health care system may integrate its electronic health record system with the PMP using an application programming interface. Use of an integrated system shall comply with all of the following:

37.17(1) The integrated system shall log each user's access to PMP information. Access logs shall be retained by the practitioner or health care system for a minimum of four years from the date of access and shall be provided to the board upon request.

37.17(2) If the user identified in access logs is not the practitioner, the integrated system shall clearly identify on which practitioner's behalf the user was accessing PMP information. A practitioner's delegate using an integrated system is required to maintain active PMP registration.

37.17(3) The integrated system shall maintain appropriate administrative, technical, and physical security measures to safeguard against unauthorized access, disclosure, or theft of PMP information and shall meet all HIPAA requirements for safeguarding protected health information.

37.17(4) The practitioner or health care system shall notify the PMP administrator of any breach in the electronic health record system that may have included PMP information within 72 hours of making the determination that a breach occurred.

37.17(5) An integrated system shall comply with all requirements in subchapter VI of Iowa Code chapter 124 and all requirements of this chapter.

657—37.18(124) PMP administrator access.

37.18(1) *PMP staff.* The board may designate PMP administrators who may access any PMP information needed to perform the functions of the job.

37.18(2) *Statistical data.* The PMP administrator or designee may provide summary, statistical, or aggregate data to public or private entities for statistical, public research, public policy, or educational purposes. The board may charge a fee to recover the actual costs associated with responding to a request for PMP data pursuant to this subrule. Any fees or costs assessed by the board shall be considered repayment receipts as defined in Iowa Code section 8.2.

657—37.19 and **37.20** Reserved.

657—37.21(124) Record retention. The PMP shall retain all reported prescriptions and all records of access to or query of PMP information for a minimum of four years from the date of the record.

657—37.22(124) Information errors. Any person who believes that PMP information is erroneous shall notify the pharmacy or dispensing practitioner. Upon notification of a potential error in PMP information, the pharmacy or dispensing practitioner shall promptly correct erroneous information in the record.

657—37.23(124) Discipline. Any licensee who fails to comply with the provisions of the law or these rules is subject to disciplinary action by the board.

These rules are intended to implement Iowa Code sections 124.550 to 124.558.