PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend Chapter 8, "Universal Practice Standards," Chapter 10, "Controlled Substances," and Chapter 21, "Electronic Data and Automated Systems in Pharmacy Practice," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 124.301, 124.308, 147.176, and 155A.27.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 124.308 and 155A.27.

Purpose and Summary

During the 2018 Legislative Session, the Iowa Code was amended to require the electronic transmission of all prescriptions as of January 1, 2020. The Code amendments provided exemptions for prescriptions which will not be required to be transmitted electronically. The Code amendments provided that a prescriber, medical group, institution, or pharmacy that is unable to comply with the electronic transmission mandate may petition the board for an exemption. The Code amendments required the board to adopt rules to establish the form and specific information to be included in a request for such an exemption and the specific criteria to be considered by the board in determining whether to approve a request for exemption.

Fiscal Impact

This rule making may have minimal fiscal impact to the state of Iowa. As noted in the legislation's fiscal note submission, the board anticipates an extra two days of meetings to review petitions for exemption to the mandate. This would result in an estimated $2,500 expense to the board for the initiation of the mandate.

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 _____, 2019. Comments should be directed to:

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

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

_____, 2019	Shared Conference Room, Suite E
9 a.m.	400 S.W. 8th Street
	Des Moines, Iowa

Persons who wish to make oral comments at the public hearing may be asked to state their names for the record and to confine their remarks to the subject of this proposed rule making.

Any persons who intend to attend the hearing and have special requirements, such as those related to hearing or mobility impairments, should contact the Board and advise of specific needs.

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 proposed:

ITEM 1. Adopt the following **new** rule(s) 657—8.18(124,155A):

657—8.18(124,155A) Electronic prescription requirement. Beginning January 1, 2020, all prescriptions shall be transmitted electronically to a pharmacy pursuant to rule 657—21.6(124,155A), except as provided in rule 657—21.8(124,155A). A pharmacist who receives a

written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exception provided in rule 657—21.8(124,155A) and may dispense a prescription drug pursuant to an otherwise valid written, oral, or facsimile prescription pursuant to rule 657—8.19(124,126,155A).

ITEM 2. Amend rule 657—8.19(124,126,155A) as follows:

657—8.19(124,126,155A) Manager of issuance of a prescription drug or medication order. A prescription drug order or medication order issued prior to January 1, 2020, or that is exempt from the electronic prescription requirement pursuant to rule 657—21.8(124,155A) may be transmitted from a prescriber or a prescriber's agent to a pharmacy in written form, orally including telephone voice communication, by facsimile transmission as provided in rule ~~657—21.9(124,155A)~~ 657—21.7(124,155A), or by electronic transmission in accordance with applicable federal and state laws, rules, and regulations. Any prescription drug order or medication order provided to a patient in written or printed form shall include the original, handwritten signature of the prescriber except as provided in rule ~~657—21.7(124,155A)~~ 657—21.6(124,155A).

8.19(1) *Requirements for a prescription.* A valid prescription drug order shall be based on a valid patient-prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors and in subrule 8.19(8) for opioid antagonists.

a. No change.

b. *Written prescription.* In addition to the requirements of paragraph 8.19(1)*"a,"* a written prescription shall be manually signed, with ink or indelible pencil, by the prescriber. The requirement for manual signature shall not apply when an electronically prepared and signed prescription for a noncontrolled substance is printed on security paper as provided in 657—paragraph ~~21.7(3)"*b.*"~~ 21.6(2)"*b.*"

c. and *d.* No change.

8.19(2) to **8.19(8)** No change.

ITEM 3. Amend rule 657—10.24(124,126,155A) as follows:

657—10.24(124,126,155A) Prescription requirements. All prescriptions for controlled substances shall be dated as of, and signed on, the day issued. Controlled substances prescriptions shall be valid for six months following date of issue. A prescription for a Schedule

III, IV, or V controlled substance may include authorization to refill the prescription no more than five times within the six months following date of issue. A prescription for a Schedule II controlled substance shall not be refilled. Beginning January 1, 2020, all prescriptions for controlled substances shall be transmitted electronically to a pharmacy pursuant to rule 657—21.6(124,155A), except as provided in rule 657—21.8(124,155A).

10.24(1) *Form of prescription.* All prescriptions for controlled substances shall bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; and the name, address, and DEA registration number of the prescriber. All prescriptions for controlled substances issued by individual prescribers shall include the legibly preprinted, typed, or hand-printed name of the prescriber as well as the prescriber's written or electronic signature. A prescription for a controlled substance issued prior to January 1, 2020, or a prescription for a controlled substance that is exempt from the electronic prescription requirement pursuant to rule 657—21.8(124,155A), may be transmitted via non-electronic methods as described in this rule.

a. to *e.* No change.

10.24(2) *Verification by pharmacist.*

a. The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber's agent in each case when a written or oral prescription for a Schedule II controlled substance is presented for filling and neither the prescribing individual practitioner issuing the prescription nor the patient or patient's agent is known to the pharmacist. The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber's agent in any case when the pharmacist questions the validity of, including the legitimate medical purpose for, the prescription. The pharmacist is required to record the manner by which the prescription was verified and include the pharmacist's name or unique identifier.

b. A pharmacist who receives a written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exception provided in rule 657—21.8(124,155A) and may dispense a prescription drug pursuant to an otherwise valid written, oral, or facsimile prescription pursuant to this rule.

10.24(3) and **10.24(4)** No change.

10.24(5) *Facsimile transmission of a controlled substance prescription.* With the exception of an authorization for emergency dispensing as provided in rule 657—10.26(124), a

prescription for a controlled substance in Schedules II, III, IV and V may be transmitted via facsimile from a prescriber to a pharmacy only as provided in rule ~~657—21.9(124,155A)~~ 657—21.7(124,155A).

ITEM 4. Amend subrule 10.29(3) as follows:

10.29(3) *Dates and instructions.* Each prescription issued pursuant to this rule shall be dated as of and manually or electronically signed by the prescriber on the day the prescription is issued. Each separate prescription, other than the first prescription if that prescription is intended to be filled immediately, shall contain written instructions indicating the earliest date on which a pharmacist may fill each prescription.

ITEM 5. Amend rule 657—10.32(124) as follows:

657—10.32(124) Schedule III, IV, or V prescription. No prescription for a controlled substance listed in Schedule III, IV, or V shall be filled or refilled more than six months after the date on which it was issued nor be refilled more than five times. Beginning January 1, 2020, all prescriptions for controlled substances shall be transmitted electronically to a pharmacy pursuant to rule 657—21.6(124,155A), except as provided in rule 657—21.8(124,155A).

10.32(1) to **10.32(4)** No change.

ITEM 6. Adopt the following **new** definition of "CSA" in rule **657—21.2(124,155A)**:

"*CSA*" means the Iowa uniform controlled substances Act.

ITEM 7. Adopt the following **new** definition of "CSA registration" in rule **657—21.2(124,155A)**:

"*CSA registration*" means the registration issued by the board pursuant to the CSA that signifies the registrant's authorization to engage in registered activities with controlled substances.

ITEM 8. Amend rule 657—21.6(124,155A) as follows:

657—21.6(124,155A) Electronic prescription applications. Beginning January 1, 2020, each prescription for a controlled substance shall be transmitted electronically to a pharmacy except as provided in rule 657—21.8(124,155A). Prior to January 1, 2020, ~~A~~ a prescriber may, but shall not be required to, initiate and authorize a prescription drug order utilizing an electronic prescription application that has been determined to maintain security and confidentiality of patient information and records and, if prescribing controlled substances via an electronic

prescribing system, certified compliant with DEA regulations for electronic prescribing of controlled substances. The prescription drug order shall contain all information required by Iowa Code sections 155A.27 and 147.107(5). The receiving pharmacist shall be responsible for verifying the authenticity of an electronically prescribed prescription pursuant to rule 657—8.19(124,126,155A). A prescription that is electronically generated prior to January 1, 2020, or subject to exemption as provided in rule 657—21.8(124,155A), may be transmitted to a pharmacy via electronic or facsimile transmission or printed in hard-copy format for delivery to the pharmacy. A prescription that is transmitted by a prescriber's agent via electronic or facsimile transmission shall include the first and last names and title of the agent responsible for the transmission.

21.6(1) *Electronic transmission.* ~~A~~ Beginning January 1, 2020, a prescription prepared pursuant to this rule ~~may~~ shall be transmitted electronically to a pharmacy ~~via electronic transmission~~, unless exempt pursuant to rule 657—21.8(124,155A). A pharmacy shall be certified compliant with DEA regulations relating to electronic prescriptions prior to electronically receiving prescriptions for controlled substances. The electronic record shall serve as the original record and shall be maintained for two years from the date of last activity on the prescription. Any annotations shall be made and retained on the electronic record.

a. to *e.* No change.

21.6(2) *Printed (hard-copy) prescriptions.* ~~An electronically generated~~ A prescription electronically generated prior to January 1, 2020, or a prescription that is exempt from the electronic prescription requirement as provided in rule 657—21.8(124,155A), may be printed in hard-copy format for facsimile transmission or delivery to the pharmacy.

a. A prescription for a controlled substance shall include the prescriber's manual or electronic signature. Printed or hard-copy prescriptions for Schedule II controlled substances shall not be transmitted to a pharmacy via facsimile transmission, except as authorized in rule 657—21.7(124,155A).

b. to *c.* No change.

ITEM 9. Adopt the following **new** rule(s) 657—21.8(124,155A):

657—21.8(124,155A) Electronic prescription mandate and exemptions. Beginning January 1, 2020, all prescriptions shall be transmitted electronically to a pharmacy except as provided in this rule.

21.8(1) *Prescriptions exempt*. Prescriptions which shall be exempt from electronic transmission include:

a. A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.

b. A prescription authorized by a licensed veterinarian.

c. A prescription for a device.

d. A prescription dispensed by a department of veterans affairs pharmacy.

e. A prescription requiring information that makes electronic transmission impractical, such as complicated or lengthy directions for use or attachments.

f. A prescription for a compounded preparation containing two or more components.

g. A prescription issued in response to a public health emergency in a situation where a non-patient specific prescription would be permitted.

h. A prescription issued for an opioid antagonist pursuant to Iowa Code section 135.190 or a prescription issued for epinephrine pursuant to Iowa Code section 135.185.

i. A prescription issued during a temporary technical or electronic failure at the location of the prescriber or pharmacy, provided that a prescription issued pursuant to this paragraph shall indicate on the prescription that the prescriber or pharmacy is experiencing a temporary technical or electronic failure.

j. A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol.

k. A prescription issued in an emergency situation pursuant to federal law and regulation and rules of the board.

21.8(2) *Prescriber, medical group, institution, or pharmacy exemption.* A practitioner, medical group, or pharmacy which has been granted an exemption to the electronic prescribing requirements pursuant to rule 657—21.9(124,155A) shall be exempt from the electronic prescribing requirements only for the duration of the approved exemption. Upon expiration of an approved exemption, the practitioner, medical group, or pharmacy shall either comply with the electronic prescribing requirements or timely petition the board for renewal of the exemption pursuant to rule 657—21.9(124,155A).

ITEM 10. Adopt the following **new** rule(s) 657—21.9(124,155A):

21.9(124,155A) Exemption from electronic prescribing mandate – petition. A prescriber, medical group, institution, or pharmacy that is unable to comply with the electronic prescribing requirement in rule 657—21.8(124,155A) prior to January 1, 2020, may petition the board, on forms provided by the board, for an exemption from the requirements based upon economic hardship, technical limitations that the prescriber, medical group, institution, or pharmacy cannot control, or other exceptional circumstances. A prescriber, medical group, institution, or pharmacy seeking an exemption beginning January 1, 2020, shall submit a completed petition no later than October 1, 2019. A timely petition for renewal of a previously approved exemption shall be submitted at least 60 days in advance of the expiration of the previously approved exemption.

21.9(1) *Petition information.* A petition for exemption from electronic prescribing requirement shall include all of the following, but not be limited to:

a. The name and address of the prescriber, medical group, institution or pharmacy seeking the exemption. For medical groups and institutions, a list of the names, professional license numbers, and CSA registration numbers of all prescribers who would be covered by the exemption.

b. Whether the petitioner is seeking an exemption for controlled substance prescriptions, non-controlled substance prescriptions, or both.

c. The petitioner's current electronic prescribing capabilities.

d. The reason, such as economic hardship, technological limitations, or other exceptional circumstances, the petitioner is seeking exemption.

e. Supporting documentation to justify the reason for the exemption, including the following mandatory documentation:

(1) For economic hardship petitions, a copy of the petitioner's most recent tax return showing annual income and at least two quotes documenting the cost of implementing electronic prescribing.

(2) For technological limitation petitions, documentation showing the available internet service providers, the speed and bandwidth available from each provider, and any data caps imposed by the internet service provider, and documentation showing the minimum technological requirements from at least two electronic prescribing platform vendors.

f. Anticipated date of compliance with electronic prescribing requirement.

g. If the petition is seeking renewal of a previously approved exemption, information relating to the petitioner's actions during the previous exemption period to work towards compliance with the electronic prescribing requirement or an explanation for why no progress has been made.

21.9(2) *Criteria for board consideration of a petition.* The board shall consider all information provided in a petition seeking exemption to the electronic prescribing requirement and shall approve or deny a petition for exemption based on the following criteria:

a. If the reason for exemption is economic hardship, whether the cost of compliance with the electronic prescribing requirement would exceed five percent of the petitioner's annual income as reported on the most recent tax return.

b. If the reason for exemption is technological limitations, whether the internet service providers available have the technological capabilities required by the electronic prescribing platform.

c. If the reason for exemption is other exceptional circumstances, examples of exceptional circumstances include, but are not limited to, if the petitioner is a free or low-income clinic, if the petitioner had a bankruptcy in the previous year, if the petitioner intends to discontinue practice in Iowa prior to December 31, 2020, and if the petitioner has a disability that limits the ability to utilize an electronic prescribing platform. All other exceptional circumstances will be evaluated on a case-by-case basis.

d. If the petition seeks renewal of a previous exemption to the electronic prescribing requirement, the number of exemptions previously granted and updated information as it relates to the petitioner working towards compliance with the electronic prescribing requirement or the explanation for why no progress has been made.

21.9(3) *Duration of approved exemption.* The board may approve an exemption, or the renewal of an exemption, to the electronic prescribing requirement for a specified period of time not to exceed one year from the date of approval.