ARC 6077C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to five-year review of rules

The Board of Pharmacy hereby amends Chapter 21, "Electronic Data and Automated Systems in Pharmacy Practice," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 124.308 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

These amendments are the result of an overall five-year review of Chapter 21 as required by Iowa Code section 17A.7(2). These amendments update processes relating to the submission and review of petitions for an exemption to the electronic prescription transmission mandate, as well as provide conforming language with other Board administrative rules.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on August 11, 2021, as **ARC 5836C**. A public hearing was held on September 2, 2021, at 2:30 p.m. in the Health Professions Board Room, 400 S.W. 8th Street, Suite H, Des Moines, Iowa, as well as via Zoom. Three individuals attended the public hearing with no public comment provided.

The Board received one written comment, which recommended the rules include that a pharmacist is not required to verify the exemption status of a practitioner or prescription. The Board also identified two clarifying edits that were needed.

The Board agreed with the commenter's suggestion and updated subrule 21.8(2) to reflect the suggestion. The Board also updated paragraph 21.9(2)"d" to clarify that an exemption for college or university student health centers would apply to noncontrolled substances only and paragraph 21.9(2)"e" to include an exemption for dental mouthwashes.

Adoption of Rule Making

This rule making was adopted by the Board on November 10, 2021.

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.

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).

Effective Date

This rule making will become effective on January 19, 2022.

The following rule-making actions are adopted:

ITEM 1. Amend rule 657—21.6(124,155A) as follows:

657—21.6(124,155A) Electronic prescription applications. ~~Beginning January 1, 2020, each~~ 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 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~~ section 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.* ~~Beginning January 1, 2020, a~~ A prescription prepared pursuant to this rule shall be transmitted electronically to a pharmacy, 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.* A prescription ~~electronically generated prior to January 1, 2020, or a prescription~~ that is exempt from the electronic prescription mandate 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. to *c.* No change.

ITEM 2. Amend rule 657—21.7(124,155A) as follows:

657—21.7(124,155A) Facsimile transmission of a prescription. A pharmacist may dispense noncontrolled and controlled drugs, including Schedule II controlled substances only as provided in this rule, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the practitioner's agent. The means of transmission via facsimile shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription. The faxed prescription shall serve as the original record, except as provided in subrule 21.7(1), shall be maintained for a minimum of two years from the date of the last activity on the prescription, and shall contain all information required by Iowa Code ~~sections~~ section 155A.27 ~~and 147.107(5)~~, including the prescriber's signature. If the prescription is transmitted by an agent of the prescriber, the facsimile transmission shall include the first and last names and title of the agent responsible for the transmission. The pharmacist shall be responsible for verifying the authenticity of the prescription as to the source of the facsimile transmission.

21.7(1) and **21.7(2)** No change.

21.7(3) *Schedule II controlled substances—~~long-term~~ care facility patients.* A prescription for any Schedule II controlled substance for a resident of a ~~long-term~~ care facility, as ~~"long-term care facility" is~~ defined in rule 657—23.2(155A), may be transmitted by the prescriber or the prescriber's agent to a pharmacy via facsimile. The prescription shall identify that the patient is a resident of a ~~long-term~~ care facility.

21.7(4) No change.

ITEM 3. Amend rule 657—21.8(124,155A) as follows:

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

21.8(1) No change.

21.8(2) *Prescriber, medical group, institution, or pharmacy exemption.* A prescriber, medical group, institution, or pharmacy ~~which~~ that has been granted an exemption to the electronic prescription mandate pursuant to rule 657—21.9(124,155A) shall be exempt from the electronic prescription mandate only for the duration of the approved exemption, and the exemption shall not apply retroactively to prescriptions issued prior to approval. Upon expiration of an approved exemption, the prescriber, medical group, institution, or pharmacy shall either comply with the electronic prescription mandate or timely petition the board for renewal of the exemption pursuant to rule 657—21.9(124,155A). A prescriber, medical group, institution or pharmacy that has been granted an exemption to the electronic prescription mandate pursuant to rule 657—21.9(124,155A) shall identify the exemption on each prescription issued and transmitted by any nonelectronic means. A pharmacist shall not be required to verify that the prescription or prescriber is subject to an exemption.

ITEM 4. Amend rule 657—21.9(124,155A) as follows:

657—21.9(124,155A) Exemption from electronic prescription mandate—petition. A prescriber, medical group, institution, or pharmacy that is unable to comply with the electronic prescription mandate 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 the electronic prescription mandate shall include, but not be limited to, all of the following:

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 shall be maintained by the petitioner for the duration of any approved exemption and shall not be required to be submitted with the petition.

b. and *c.* No change.

d. The reason, such as economic hardship, technological limitations, or other exceptional circumstances, the petitioner is seeking exemption, including any supporting documentation to justify the reason.

~~*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.*~~ *e.* Anticipated date of compliance with the electronic prescription mandate.

~~*g.*~~ *f.* If the petition seeks renewal of a previously approved exemption, information relating to the petitioner's actions during the previous exemption period to work toward compliance with the electronic prescription mandate or an explanation as to 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 prescription mandate and shall approve or deny a petition for exemption based on ~~the following criteria:~~ whether there is a compelling reason to justify the exemption and the nature and volume of prescriptions impacted. Except for petitions citing the exceptional circumstances listed below, which will be administratively reviewed for approval, each petition will be reviewed on a case-by-case basis.

~~*a.* If the reason for exemption is economic hardship, whether the cost of compliance with the electronic prescription mandate would exceed 5 percent of the petitioner's annual income as reported on the petitioner's 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, whether the petitioner is a free or low-income clinic, whether the petitioner had a bankruptcy in the previous year, whether the petitioner intends to discontinue practice in Iowa prior to December 31, 2020, and whether 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 prescription mandate, the number of exemptions previously granted and updated information as it relates to the petitioner working toward compliance with the electronic prescription mandate or the explanation as to why no progress has been made.~~

a. A free or low-income clinic where health care is provided at no cost or at a reduced cost to the patient without reimbursement from a third-party payer that requests an exemption for noncontrolled substances only.

b. A licensed prescriber who issues no more than 50 noncontrolled substance prescriptions per year who requests an exemption for noncontrolled substances only.

c. The department of veterans affairs for prescriptions that are not filled at a veterans affairs pharmacy.

d. A prescriber at a student health center based at a college or university for noncontrolled substances only.

e. A dentist seeking an exemption for prescriptions limited to toothpastes and mouthwashes.

f. A compounding pharmacy that dispenses no more than 50 prescriptions for commercially available prescription medications per year that requests an exemption for noncontrolled substances only.

21.9(3) No change.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/15/21.