

PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby amends Chapter 39, “Expanded Practice Standards,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in 2021 Iowa Acts, Senate File 296.

State or Federal Law Implemented

This rule making implements, in whole or in part, 2021 Iowa Acts, Senate File 296.

Purpose and Summary

The amendment updates a Board rule relating to collaborative pharmacy practice agreements between pharmacists and Iowa-licensed prescribers. The rule making identifies the minimum required elements of such agreements.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on November 3, 2021, as **ARC 6012C**.

A public hearing was held on November 24, 2021, at 10:30am at the offices of the Iowa Board of Pharmacy as well as via Zoom. Four individuals attended the hearing by Zoom with none providing oral comments. The board received three written comments; the comments suggested more broad reference to the prescribers with which pharmacists could enter into a collaborative agreement, inclusion of physician assistants as authorized prescribers, and recognition of a hospital system’s Pharmacy & Therapeutics committee in establishing such agreements.

As it relates to the suggestions for extending authority to enter into collaborative agreements to physician assistants, the Board declined as a physician assistant does not have independent prescribing authority. Additionally, to provide broad language allowing any practitioner with “independent prescribing authority” could cause confusion on exactly which types of prescribers that includes. As it relates to the suggestion to recognize the pharmacy and therapeutics (P&T) committees in health systems, the Board agreed that collaborative pharmacy

practice agreements in a health system setting would be developed and monitored by such committee. As such, the rule making was edited to recognize the health system P&T committee. One comment also suggested that requiring each pharmacist to review the agreement, including each update, would be onerous for health system pharmacies. The Board recognizes the challenge, but believes it is imperative each pharmacist reviews the agreement and that attestation to that effect need not be terribly complicated; as such, 39.13(2)"e" was edited to remove the requirement that the pharmacy maintain the documentation, allowing the documentation to be maintained by a human resources department instead.

Adoption of Rule Making

This rule making was adopted by the Board on _____, 2022.

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 _____, 2022.

The following rule-making action is adopted:

Rescind rule 657—39.13(155A) and adopt the following **new** rule in lieu thereof:

657—39.13(155A) Collaborative pharmacy practice.

39.13(1) Definitions. For the purpose of this rule, the following definitions shall apply:

“*Collaborative pharmacy practice*” means a practice of pharmacy whereby one or more pharmacists provides patient care and drug therapy management services not otherwise permitted to be performed by a pharmacist to patients under a collaborative pharmacy practice agreement with one or more practitioners which defines the nature, scope, conditions, and limitations of the patient care and drug therapy management services to be provided by the pharmacist(s) in order to ensure that a patient achieves the desired outcomes.

“*Practitioner*” means a physician, dentist, podiatric physician, veterinarian, optometrist, or advanced registered nurse practitioner who holds an active license to practice in Iowa.

39.13(2) Collaborative practice agreement.

a. Pursuant to these rules, a pharmacist or pharmacy may engage in collaborative pharmacy practice under a collaborative pharmacy practice agreement with one or more practitioners, or as established by a health system pharmacy and therapeutics committee, to provide patient care and drug therapy management services to one or more patients.

b. A collaborative pharmacy practice agreement shall include:

(1) The identification of the parties to the agreement, including the name(s) or category of the pharmacist(s), including registered pharmacist-intern(s) under the supervision of a pharmacist, who are authorized to perform delegated activities under the agreement and the name(s) or category of the practitioner(s) who are delegating activities under the agreement;

(2) The establishment of the delegating practitioner’s scope of practice authorized in the agreement and a description of the permitted activities and decisions to be performed by the pharmacist(s);

(3) The protocol, formulary, or clinical guidelines that describe or limit the pharmacist’s authority to perform the patient care or drug therapy management services and, as applicable, the drug name, class or category provided under drug therapy management;

(4) A description of the process to monitor compliance with the agreement and clinical outcomes of patients;

(5) The effective date;

(6) A provision addressing termination of the agreement; and

(7) The signatures of the parties to the agreement and dates of signing, unless established by a

health system pharmacy and therapeutics committee.

c. Parties to the collaborative pharmacy practice agreement shall review and revise such agreement as appropriate, but no less than every two years.

d. Any collaborative pharmacy practice agreement shall be maintained by the pharmacist(s) or pharmacy and be available upon request or inspection.

e. Prior to engaging in patient care or drug therapy management services under a collaborative pharmacy practice agreement, including when the agreement is updated, each pharmacist practicing under the agreement shall attest that the pharmacist has read and understands the agreement. Documentation of pharmacist attestation shall be maintained for at least two years from the attestation date and be available upon request or inspection.