CHAPTER 39
EXPANDED PRACTICE STANDARDS

657—39.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standards for the programs and activities identified in this chapter. These rules shall apply to all licensed pharmacists, other registered pharmacy personnel, and all pharmacies, including owners, engaged in the state of Iowa in the programs and activities identified in this chapter. These rules are in addition to rules of the board relating to the practice of pharmacy unless otherwise indicated by rule.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.2 and **39.3** Reserved.

657—39.4(155A) Pharmaceutical care. Pharmaceutical care is a comprehensive, patient-centered, outcomes-oriented pharmacy practice in which the pharmacist accepts responsibility for assisting the prescriber and the patient in optimizing the patient's drug therapy plan and works to promote health, to prevent disease, and to optimize drug therapy. Pharmaceutical care does not include the prescribing of drugs without the consent of the prescriber.

39.4(1) *Drug therapy problems.* In providing pharmaceutical care, the pharmacist shall strive to identify, resolve, and prevent drug therapy problems.

39.4(2) *Drug therapy plan.* In providing pharmaceutical care, the pharmacist shall access and evaluate patient-specific information, identify drug therapy problems, and utilize that information in a documented plan of therapy that assists the patient or the patient's caregiver in achieving optimal drug therapy. In concert with the patient, the patient's prescribing practitioner, and the patient's other health care providers, the pharmacist shall assess, monitor, and suggest modifications of the drug therapy plan as appropriate.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.5 Reserved.

657—39.6(155A) Statewide protocols. To the extent authorized in Iowa Code section 155A.46, a pharmacist may, pursuant to statewide protocols developed by the board in consultation with the department of public health and available on the board's website at pharmacy.iowa.gov, order and dispense medications pursuant to the requirements identified in the statewide protocols. For the purpose of this rule, the order shall constitute a prescription.
[**ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter; **ARC 4387C**, IAB 4/10/19, effective 4/5/19; **ARC 4583C**, IAB 7/31/19, effective 9/4/19; **ARC 6076C**, IAB 12/15/21, effective 1/19/22]

657—39.7(135,147A) Opioid antagonist dispensing by pharmacist—standing order. An authorized pharmacist may dispense an opioid antagonist pursuant to a standing order established by the department, which standing order can be found via the board's website, or pursuant to a standing order authorized by an individual licensed health care professional in compliance with the requirements of this rule. An authorized pharmacist may only delegate the dispensing of an opioid antagonist to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. Nothing in this rule prohibits a prescriber or facility from establishing and implementing standing orders or protocols under the authority granted to the prescriber or facility.

39.7(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Authorized pharmacist" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized Iowa-licensed pharmacist.

"Department" means the Iowa department of public health.

"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.

"Licensed health care professional" means a person licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, an advanced registered nurse practitioner licensed under Iowa Code chapter 152 or 152E and registered with the board of nursing, or a physician assistant licensed to practice under the supervision of a physician as authorized in Iowa Code chapters 147 and 148C.

"Opioid antagonist" means the same as defined in Iowa Code section 147A.1.

"Opioid-related overdose" means the same as defined in Iowa Code section 147A.1.

"Person in a position to assist" means a family member, friend, caregiver, health care provider, employee of a substance abuse treatment facility, or other person who may be in a position to render aid to a person at risk of experiencing an opioid-related overdose.

"Recipient" means an individual at risk of an opioid-related overdose or a person in a position to assist an individual at risk of an opioid-related overdose.

"Standing order" means a preauthorized medication order with specific instructions from the licensed health care professional to dispense a medication under clearly defined circumstances.

39.7(2) *Authorized pharmacist training.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to opioid antagonist utilization prior to dispensing opioid antagonists pursuant to a standing order.

39.7(3) *Additional supply.* Notwithstanding a standing order to the contrary, an authorized pharmacist shall only dispense an opioid antagonist after completing an eligibility assessment and providing training and education to the recipient.

39.7(4) *Assessment.* An authorized pharmacist shall assess an individual for eligibility to receive an opioid antagonist pursuant to a standing order. In addition to the criteria identified in a standing order, an authorized pharmacist shall also take into consideration the following criteria to determine the eligibility of the recipient to receive and possess an opioid antagonist:

a. The person at risk of an opioid-related overdose for which the opioid antagonist is intended to be administered has no known sensitivity or allergy to naloxone, unless the person at risk is not known to the recipient, including but not limited to a first responder or member of law enforcement.

b. The recipient is oriented to person, place, and time and able to understand and learn the essential components of opioid-related overdose, appropriate response, and opioid antagonist administration.

39.7(5) *Recipient training and education.* Upon assessment and determination that an individual is eligible to receive and possess an opioid antagonist pursuant to a standing order, an authorized pharmacist shall, prior to dispensing an opioid antagonist pursuant to a standing order, provide training and education to the recipient including, but not limited to, the information identified in this subrule. An authorized pharmacist shall require the recipient to attest that, if the product will be accessible to any other individual for administration, the recipient will make available to such individual all received training and education materials. An authorized pharmacist may provide to the recipient written materials that include, but may not be limited to, the information identified in this subrule, but the written materials shall not be in lieu of direct pharmacist consultation with the recipient.

a. The signs and symptoms of opioid-related overdose as described in the standing order.

b. The importance of calling 911 as soon as possible and the potential need for rescue breathing.

c. The appropriate use and directions for administration of the opioid antagonist to be dispensed pursuant to the standing order.

d. Adverse reactions of the opioid antagonist as well as reactions resulting from opioid withdrawal following administration.

e. The proper storage conditions, including temperature excursions, of the opioid antagonist being dispensed.

f. The expiration date of the opioid antagonist being dispensed and the appropriate disposal of the opioid antagonist upon expiration.

g. The prohibition of the recipient from further distributing the opioid antagonist to another individual, unless that individual has received appropriate training and education.

h. Information about substance abuse or behavioral health treatment programs.

39.7(6) *Labeling.* Upon the determination that a recipient is eligible to receive and possess an opioid antagonist, an authorized pharmacist shall label the product pursuant to rule 657—6.10(126,155A) and 657—subrule 8.19(8). An authorized pharmacist shall ensure that the labeling does not render the expiration date of the product illegible. The medication shall be dispensed in the name of the eligible recipient.

39.7(7) *Reporting.* A copy of the assessment form shall be submitted to the department as provided on the assessment form within seven days of the dispensing of the opioid antagonist or within seven days of a denial of eligibility.

39.7(8) *Records.* An authorized pharmacist shall create and maintain an original record of each individual assessment on forms provided by the board, regardless of the eligibility determination following assessment, and dispensing of opioid antagonists pursuant to a standing order. These records shall be available for inspection and copying by the board or its authorized agent for at least two years.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.8(155A) Medications administered via prescription.

39.8(1) *Vaccine administration.* A pharmacist who is authorized to administer vaccines pursuant to the statewide protocol may administer, including via delegation to authorized pharmacy personnel, any vaccine pursuant to a prescription or medication order for an individual patient. In case of a serious complication, the pharmacist shall notify the prescriber who authorized the prescription within 24 hours and shall submit a report to the Vaccine Adverse Event Reporting System (VAERS).

39.8(2) *Medication administration.* A pharmacist may administer, including via delegation to authorized pharmacy personnel if so delegated or authorized by the prescriber, any medication pursuant to a prescription or medication order for an individual patient. In case of a serious complication, the pharmacist shall notify the prescriber who issued the prescription within 24 hours and shall submit a report to the United States Food and Drug Administration Adverse Event Reporting System (FAERS).
[**ARC 6076C**, IAB 12/15/21, effective 1/19/22]

657—39.9(155A) Statewide protocol—nicotine replacement tobacco cessation products. Rescinded **ARC 6076C**, IAB 12/15/21, effective 1/19/22.

657—39.10(155A) Vaccine administration by pharmacists—physician-approved protocol. Rescinded **ARC 6076C**, IAB 12/15/21, effective 1/19/22.

657—39.11(155A) Vaccine administration by pharmacists—statewide protocol. Rescinded **ARC 6076C**, IAB 12/15/21, effective 1/19/22.

657—39.12 Reserved.

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.

[**ARC 6174C**, IAB 2/9/22, effective 3/16/22]

657—39.14 and **39.15** Reserved.

657—39.16(155A) Pharmacy pilot or demonstration research projects. The purpose of this rule is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy. In reviewing projects, the board will consider only projects that expand pharmaceutical care services that contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage to a single applicant or group of applicants.

39.16(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Act" means Iowa Code chapter 155A, the Iowa pharmacy practice Act.

"Board" means the Iowa board of pharmacy.

"Practice of pharmacy" means the practice of pharmacy as defined in Iowa Code section 155A.3(37).

"Project" means a pilot or demonstration research project as described in this rule.

39.16(2) *Scope of project.* A project may not expand the definition of the practice of pharmacy. A project may include therapeutic substitution or substitution of medical devices used in patient care if such substitution is included under a collaborative pharmacy practice agreement pursuant to rule 657—39.13(155A).

39.16(3) *Board approval of a project.* Board approval of a project may include the grant of an exception to or a waiver of rules adopted under the Act or under any law relating to the authority of prescription verification and the ability of a pharmacist to provide enhanced patient care in the practice of pharmacy. Project approval, including exception to or waiver of board rules, shall initially be for a specified period of time not exceeding 18 months from commencement of the project. The board may

approve the extension or renewal of a project following consideration of a petition that clearly identifies the project, that includes a report similar to the final project report described in paragraph 39.16(6)*"a,"* that describes and explains any proposed changes to the originally approved and implemented project, and that justifies the need for extending or renewing the term of the project.

39.16(4) *Applying for approval of a project.* A person who wishes the board to consider approval of a project shall submit to the board a petition for approval that contains at least the following information:

a. Responsible pharmacist. Name, address, telephone number, and pharmacist license number of each pharmacist responsible for overseeing the project.

b. Location of project. Name, address, and telephone number of each specific location and, if a location is a pharmacy, the pharmacy license number where the proposed project will be conducted.

c. Project summary. A detailed summary of the proposed project that includes at least the following information:

(1) The goals, hypothesis, and objectives of the proposed project.

(2) A full explanation of the project and how it will be conducted.

(3) The time frame for the project including the proposed start date and length of study. The time frame may not exceed 18 months from the proposed start date of the project.

(4) Background information or literature review to support the proposed project.

(5) The rule or rules to be waived in order to complete the project and a request to waive the rule or rules.

(6) Procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver.

39.16(5) *Review and approval or denial of a proposed project.*

a. Staff review. Upon receipt of a petition for approval of a project, board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for board consideration, board staff shall return the petition to the requestor with a letter explaining the reason the petition is being returned. A petition that has been returned pursuant to this paragraph may be amended or supplemented as necessary and submitted for reconsideration.

b. Board review. Upon review by the board of a petition for approval of a project, the board shall either approve or deny the petition. If the board approves the petition, the approval:

(1) Shall be specific for the project requested;

(2) Shall approve the project for a specific time period; and

(3) May include conditions or qualifications applicable to the project.

c. Inspection. The project site and project documentation shall be available for inspection and review by the board or its representative at any time during the project review and the approval or denial processes and, if a project is approved, throughout the approved term of the project.

d. Documentation maintained. Project documentation shall be maintained and available for inspection, review, and copying by the board or its representative for at least two years following completion or termination of the project.

39.16(6) *Presentation of reports.* The pharmacist responsible for overseeing a project shall be responsible for submitting to the board any reports required as a condition of a project, including the final project report.

a. Final project report. The final project report shall include a written summary of the results of the project and the conclusions drawn from those results. The final project report shall be submitted to the board within three months after completion or termination of the project.

b. Board review. The board shall receive and review any report regarding the progress of a project and the final project report at a regularly scheduled meeting of the board. The report shall be an item on the open session agenda for the meeting.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 6076C**, IAB 12/15/21, effective 1/19/22]

These rules are intended to implement Iowa Code sections 135.190, 147.76, 147A.18, 155A.2, 155A.3, 155A.13, 155A.33, and 155A.44; and 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, chapter 1113, section 31, and by 2013 Iowa Acts, chapter 138, section 128.

[Filed ARC 3858C (Notice ARC 3509C, IAB 12/20/17), IAB 6/20/18, effective 7/25/18]

[Filed ARC 4270C (Notice ARC 4096C, IAB 10/24/18), IAB 1/30/19, effective 3/6/19][1]
[Filed Emergency ARC 4387C, IAB 4/10/19, effective 4/5/19]
[Filed Emergency After Notice ARC 4555C (Notice ARC 4450C, IAB 5/22/19), IAB 7/17/19, effective 7/1/19]
[Filed ARC 4583C (Notice ARC 4388C, IAB 4/10/19), IAB 7/31/19, effective 9/4/19]
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[Filed ARC 6174C (Notice ARC 6012C, IAB 11/3/21), IAB 2/9/22, effective 3/16/22]

[1] March 6, 2019, effective date of ARC 4270C [amendments to ch 39] delayed 70 days by the Administrative Rules Review Committee at its meeting held February 8, 2019; delay lifted at the meeting held April 5, 2019.