

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 and 39.6** Reserved.

**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 and 39.9** Reserved.

**657—39.10(155A) Vaccine administration by pharmacists.** An authorized pharmacist may administer vaccines pursuant to protocols established by the CDC in compliance with the requirements of this rule. An authorized pharmacist may only delegate the administration of a vaccine to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

**39.10(1) Definitions.** For the purposes of this rule, the following definitions shall apply:

“ACIP” means the CDC Advisory Committee on Immunization Practices.

“ACPE” means the Accreditation Council for Pharmacy Education.

“Authorized pharmacist” means an Iowa-licensed pharmacist who has met the requirements identified in subrule 39.10(2).

“Authorized pharmacist-intern” means an Iowa-registered pharmacist-intern who has met the requirements for an authorized pharmacist identified in paragraphs 39.10(2) “a” and “c.”

“CDC” means the United States Centers for Disease Control and Prevention.

“Immunization” shall have the same meaning as, and shall be interchangeable with, the term “vaccine.”

“Protocol” means a standing order for a vaccine to be administered by an authorized pharmacist.

“Vaccine” means a specially prepared antigen administered to a person for the purpose of providing immunity.

**39.10(2) Authorized pharmacist training and continuing education.** An authorized pharmacist shall document successful completion of the requirements in paragraph 39.10(2) “a” and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 39.10(2) “b.”

*a. Initial qualification.* An authorized pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an ACPE-accredited continuing education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol for health care providers.

(2) Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current CDC guidelines, and provides instruction and experiential training in the following content areas:

1. Standards for immunization practices;
2. Basic immunology and vaccine protection;
3. Vaccine-preventable diseases;
4. Recommended immunization schedules;
5. Vaccine storage and management;
6. Informed consent;
7. Physiology and techniques for vaccine administration;
8. Pre- and post-vaccine assessment, counseling, and identification of contraindications to the vaccine;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

*b. Continuing education.* During any pharmacist license renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of continuing education related to vaccines.

*c. Certification maintained.* During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol for health care providers.

**39.10(3) Protocol requirements.** A pharmacist may administer vaccines pursuant to a protocol based on CDC recommendations. A protocol shall be unique to a pharmacy. The pharmacy shall comply with the parameters of the protocol. The prescriber who signs a protocol shall identify within the protocol, by name or category, those pharmacists or other qualified health professionals that the prescriber is authorizing to administer vaccines pursuant to the protocol. A protocol:

*a.* Shall be signed by an Iowa-licensed prescriber practicing in Iowa.

*b.* Shall expire no later than one year from the effective date of the signed protocol.

*c.* Shall be effective for patients who wish to receive a vaccine administered by an authorized pharmacist, who meet the CDC recommended criteria, and who have no contraindications as published by the CDC.

*d.* Shall require the authorized pharmacist to notify the prescriber who signed the protocol within 24 hours of a serious complication, and the pharmacist shall submit a Vaccine Advisory Event Reporting System (VAERS) report.

*e.* Shall specifically indicate whether the authorizing prescriber agrees that the administration of vaccines may be delegated by the authorized pharmacist to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

**39.10(4) Influenza and other emergency vaccines.** An authorized pharmacist shall only administer via protocol, to patients six years of age and older, influenza vaccines and other emergency vaccines in response to a public health emergency.

**39.10(5) Other adult vaccines.** An authorized pharmacist shall only administer via protocol, to patients 18 years of age and older, the following vaccines:

*a.* A vaccine on the ACIP-approved adult vaccination schedule.

*b.* A vaccine recommended by the CDC for international travel.

**39.10(6) Vaccines administered via prescription.** An authorized pharmacist may administer any vaccine pursuant to a prescription or medication order for an individual patient. In case of a serious complication, the authorized pharmacist shall notify the prescriber who authorized the prescription within 24 hours and shall submit a VAERS report.

**39.10(7) Verification and reporting.** The requirements of this subrule do not apply to influenza and other emergency vaccines administered via protocol pursuant to subrule 39.10(4). An authorized pharmacist shall:

*a.* Prior to administering a vaccine identified in subrule 39.10(5) or 39.10(6), consult the statewide immunization registry or health information network.

*b.* Within 30 days following administration of a vaccine identified in subrule 39.10(5) or 39.10(6), report the vaccine administration to the statewide immunization registry or health information network and to the patient's primary health care provider, if known.

[ARC 3858C, IAB 6/20/18, effective 7/25/18]

**657—39.11 and 39.12** Reserved.

**657—39.13(155A) Collaborative drug therapy management.** An authorized pharmacist may only perform collaborative drug therapy management pursuant to protocol with an authorized provider pursuant to the requirements of this rule. The authorized provider retains the ultimate responsibility for the care of the patient. The pharmacist is responsible for all aspects of drug therapy management performed by the pharmacist.

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

*“Authorized pharmacist”* means an Iowa-licensed pharmacist whose license is in good standing and who meets the drug therapy management criteria defined in this subrule.

*“Authorized provider”* means an Iowa-licensed prescribing practitioner who is authorized by the practitioner’s professional licensing authority to participate in a collaborative practice agreement with an authorized pharmacist pursuant to these rules and the rules of the practitioner’s professional licensing authority. An authorized provider who executes a written protocol with an authorized pharmacist shall supervise the pharmacist’s activities involved in the overall management of patients receiving medications or disease management services under the protocol. The authorized provider may delegate only drug therapies that are in areas common to the authorized provider’s practice.

*“Board”* means the board of pharmacy.

*“Collaborative drug therapy management”* means participation by an authorized pharmacist and an authorized provider in the management of drug therapy pursuant to a written community practice protocol or a written hospital practice protocol.

*“Collaborative practice”* means that an authorized provider may delegate aspects of drug therapy management for the authorized provider’s patients to an authorized pharmacist through a community practice protocol. *“Collaborative practice”* also means that a P&T committee may authorize hospital pharmacists to perform drug therapy management for inpatients and hospital clinic patients through a hospital practice protocol.

*“Community practice protocol”* means a written, executed agreement entered into voluntarily between an authorized pharmacist and an authorized provider establishing drug therapy management for one or more of the pharmacist’s and authorized provider’s patients residing in a community setting. A community practice protocol shall comply with the requirements of subrule 39.13(2).

*“Community setting”* means a location outside a hospital inpatient, acute care setting or a hospital clinic setting. A community setting may include, but is not limited to, a home, group home, assisted living facility, correctional facility, hospice, or long-term care facility.

*“Drug therapy management criteria”* means one or more of the following:

1. Graduation from a recognized school or college of pharmacy with a doctor of pharmacy (Pharm.D.) degree;
2. Certification by the Board of Pharmaceutical Specialties (BPS);
3. Certification by the Commission for Certification in Geriatric Pharmacy (CCGP);
4. Successful completion of a National Institute for Standards in Pharmacist Credentialing (NISPC) disease state management examination and credentialing by the NISPC;
5. Successful completion of a pharmacy residency program accredited by the American Society of Health-System Pharmacists (ASHP); or
6. Approval by the board of pharmacy.

*“Hospital clinic”* means an outpatient care clinic operated and affiliated with a hospital and under the direct authority of the hospital’s P&T committee.

*“Hospital pharmacist”* means an Iowa-licensed pharmacist who meets the requirements for participating in a hospital practice protocol as determined by the hospital’s P&T committee.

*“Hospital practice protocol”* means a written plan, policy, procedure, or agreement that authorizes drug therapy management between hospital pharmacists and authorized providers within a hospital and the hospital’s clinics as developed and determined by the hospital’s P&T committee. Such a protocol may apply to all pharmacists and authorized providers at a hospital or the hospital’s clinics or only to those pharmacists and authorized providers who are specifically recognized. A hospital practice protocol shall comply with the requirements of subrule 39.13(3).

*“P&T committee”* means a committee of the hospital composed of physicians, pharmacists, and other health professionals that evaluates the clinical use of drugs within the hospital, develops policies for managing drug use and administration in the hospital, and manages the hospital drug formulary system.

*“Therapeutic interchange”* means an authorized exchange of therapeutic alternate drug products in accordance with a previously established and approved written protocol.

**39.13(2) Community practice protocol.**

a. An authorized pharmacist shall engage in collaborative drug therapy management with an authorized provider only under a written protocol that has been identified by topic. Protocols shall be made available upon request of the board or the licensing board of the authorized provider.

b. The community practice protocol shall include:

(1) The name, signature, date, and contact information for each authorized pharmacist who is a party to the protocol and is eligible to manage the drug therapy of a patient. If more than one authorized pharmacist is a party to the agreement, the pharmacists shall work for a single licensed pharmacy and a principal authorized pharmacist shall be designated in the protocol.

(2) The name, signature, date, and contact information for each authorized provider who may prescribe drugs and is responsible for supervising a patient's drug therapy management. The authorized provider who initiates a protocol shall be considered the main caregiver for the patient respective to that protocol and shall be noted in the protocol as the principal authorized provider.

(3) The name and contact information of the principal authorized provider and the principal authorized pharmacist who are responsible for development, training, administration, and quality assurance of the protocol.

(4) A detailed written protocol pursuant to which the authorized pharmacist will base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the patient's authorized provider. The protocol shall not authorize the pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the patient's authorized provider for follow-up.

4. Patient activities. The protocol may authorize the pharmacist to monitor specific patient activities.

(5) Procedures for securing the patient's written consent. If the patient's consent is not secured by the authorized provider, the authorized pharmacist shall secure such and notify the patient's authorized provider within 24 hours.

(6) Circumstances that shall cause the authorized pharmacist to initiate communication with the authorized provider including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction.

(7) A detailed statement identifying the specific drugs, laboratory tests, and physical findings upon which the authorized pharmacist shall base drug therapy management decisions.

(8) A provision for the collaborative drug therapy management protocol to be reviewed, updated, and reexecuted or discontinued at least every two years.

(9) A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the authorized provider.

(10) A description of the types of reports the authorized pharmacist is to provide to the authorized provider and the schedule by which the pharmacist is to submit these reports. The schedule shall include a time frame within which a pharmacist shall report any adverse reaction to the authorized provider.

(11) A statement of the medication categories and the type of initiation and modification of drug therapy that the provider authorizes the pharmacist to perform.

(12) A description of the procedures or plan that the pharmacist shall follow if the pharmacist modifies a drug therapy.

(13) Procedures for record keeping, record sharing, and long-term record storage.

(14) Procedures to follow in emergency situations.

(15) A statement that prohibits the authorized pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.

(16) A statement that prohibits an authorized provider from delegating collaborative drug therapy management to any unlicensed or licensed person other than another authorized provider or an authorized pharmacist.

(17) A description of the mechanism for the pharmacist and the authorized provider to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy.

*c.* Collaborative drug therapy management is valid only when initiated by a written protocol executed by at least one authorized pharmacist and at least one authorized provider.

*d.* The collaborative drug therapy protocol shall be kept on file in the pharmacy and be made available upon request of the board or the authorized provider's licensing board.

*e.* An authorized provider may terminate or amend the collaborative drug therapy management protocol with an authorized pharmacist if the authorized provider notifies the authorized pharmacist in writing. Notification shall include the name of the authorized pharmacist, the desired change, and the proposed effective date of the change. Written notification shall be maintained in the pharmacy and be made available upon request of the board or the authorized provider's licensing board.

*f.* The authorized provider or pharmacist who initiates a protocol with a patient is responsible for securing the patient's written consent to participate in drug therapy management and for transmitting a copy of the consent to the other party within 24 hours. The consent shall indicate which protocol is involved. Any variation in the protocol for a specific patient shall be communicated to the other party at the time of securing the patient's consent. The patient's authorized provider shall maintain the patient consent in the patient's medical record.

**39.13(3) Hospital practice protocol.**

*a.* A hospital's P&T committee shall determine the scope and extent of collaborative drug therapy management practices that may be conducted by the hospital's pharmacists.

*b.* Collaborative drug therapy management within a hospital setting or the hospital's clinic setting is valid only when approved by the hospital's P&T committee.

*c.* The hospital practice protocol shall include:

(1) The names or groups of pharmacists and providers who are authorized by the P&T committee to participate in collaborative drug therapy management.

(2) A plan for development, training, administration, and quality assurance of the protocol.

(3) A detailed written protocol pursuant to which the hospital pharmacist shall base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Medication orders and prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the authorized provider. The protocol shall not authorize the hospital pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the hospital pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the authorized provider for follow-up.

(4) Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's authorized provider including but not limited to the need for new medication orders and prescription drug orders and reports of a patient's therapeutic response or adverse reaction.

(5) A statement of the medication categories and the type of initiation and modification of drug therapy that the P&T committee authorizes the hospital pharmacist to perform.

(6) A description of the procedures or plan that the hospital pharmacist shall follow if the hospital pharmacist modifies a drug therapy.

(7) A description of the mechanism for the hospital pharmacist and the patient's authorized provider to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

[ARC 3858C, IAB 6/20/18, effective 7/25/18]

**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 as authorized by 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. 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(34).

“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 drug therapy management protocol established 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]

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.

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