Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 481—Chapter 552
"Standards—Practice of Pharmacy"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 124.303, 147.76 and 155A

State or federal law(s) implemented by the rulemaking: Iowa Code sections 124.302 and 147.76 and chapter 155A

Public Hearing

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

August 29, 2024	6200 Park Avenue, Suite 100
1:30 p.m.	Des Moines, Iowa

Virtual participation for the public hearing will be available on the Department of Inspections, Appeals, and Licensing website.

Public Comment

Any interested person may submit written comments concerning this Regulatory Analysis. Written comments in response to this Regulatory Analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed rulemaking is intended to establish the minimum requirements for the practice of pharmacy regardless of the practice setting. The rules provide the minimum standards for a pharmacy relating to facilities, security, personnel, patient care services, prescription handling and processing, technology, quality improvement, and records. Citations to 481—Chapters 550 and 551 refer to those chapters as proposed in Regulatory Analyses published herein (IAB 8/7/24).

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

Pharmacy owners will bear the costs of compliance with the proposed rulemaking. The extent to which a pharmacy owner will incur expenses to comply with the proposed rulemaking will depend, in part, on the choice of the pharmacy owner to engage in the particular activity. For example, a pharmacy that opts to not provide compounding services or initiate a technician product verification program will not bear the costs associated with the requirements for those activities.

- Classes of persons that will benefit from the proposed rulemaking:

Iowa patients will benefit from the proposed rulemaking in multiple ways. Through the labeling requirements, Iowa patients will be provided with sufficient information on product packaging that allows them to utilize their medications as prescribed and intended; through compounding and therapeutic substitution, patients will be able to obtain medications that are formulated unique to meet

their specific needs or that are equally effective but may cost less; through delegated technical functions, technician product verification programs, contract pharmacy services, and automated medication dispensing systems, pharmacists will be able to focus more of their time on clinical patient services such as prospective drug use review and patient counseling; and through telepharmacy, statewide protocols, and collaborative pharmacy practice, patients will have expanded access to health care services that may not be readily available in the patients' local area from another practitioner.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

The impact of the proposed rulemaking is varied and depends on the extent to which a pharmacy licensee would engage in one or more of the pharmacy services or technologies identified in the rules. The costs associated with pharmacy security would vary depending on the type of security a pharmacy licensee would choose or depending on the length of time to retain access to video surveillance, for example. The costs associated with pharmacy compounding services would depend on the type of compounding performed (i.e., nonsterile vs. sterile and whether the compounding includes hazardous drugs).

- Qualitative description of impact:

The impact to patient safety is paramount for the Board of Pharmacy. The requirements for security and patient confidentiality ensure that prescription drugs, including controlled substances, and patient records are secure from unauthorized access and diversion for illegal or inappropriate purposes. The requirements for adequate education, training and supervision of nonpharmacist personnel will ensure the delegated functions are completed accurately, which will allow pharmacists to focus on clinical patient care activities, improving the health of Iowans. The provision of prospective drug utilization, patient counseling, statewide protocols, and collaborative pharmacy practice provides patients with clinical care from a pharmacist who has completed the education and training to provide such services, which will provide high-quality patient care in Iowa.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

There are no specific implementation costs to the Board since most standards are in place already. Enforcement costs remain the same with the employment of 8.0 full-time equivalent (FTE) positions for compliance officers to conduct routine inspections and investigate complaints.

- Anticipated effect on state revenues:

An anticipated effect on state revenues cannot be determined at this time. In the event that a complaint leads to formal public discipline that includes an assessed civil penalty, such civil penalty is deposited into the State's General Fund. Since 2010, the Board has assessed an average of approximately $75,000 per year in civil penalties.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

The Board believes that the minimum requirements for the practice of pharmacy are justified to prevent the burden and cost of patient harm by ensuring minimum standards for the practice as it relates to security of patient records and prescription drugs, including controlled substances; provision of clinical patient care services; and the utilization of nonpharmacist personnel and technology in the practice of pharmacy.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

The proposed rules provide for less intrusive methods to achieve the purpose of protecting patient safety when compared to the Board's current rules. The proposed rules defer business decisions to the impacted parties (e.g., contents of a contract between two pharmacies for shared services, components of policies and procedures, etc.) and pharmacy services to pharmacists to provide based on a standard

of care that would be provided by other pharmacists similarly situated with the same level of education and training.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

Besides the modifications and simplifications that were already undertaken in these proposed rules compared to current rules, the Board contemplated the requirements for pharmacy security and drug compounding and ultimately determined these areas to be critical to ensuring the safety and welfare of the public.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

As the requirements relate to pharmacy security (primarily with controlled substances) and drug compounding, the Board determined that the proposed minimum requirements are necessary to ensure security and accountability of prescription drugs, including controlled substances, and patient records as well as to ensure that drug compounding is performed at the same level as the national minimum standards established by the United States Pharmacopoeia.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

While not specifically identified in this proposed rulemaking, any licensee is authorized to petition the Board for a waiver of Board rules that are not also required by the Iowa Code (in accordance with 481—Chapter 6). This opportunity is available to any business entity regardless of its size. A petition for waiver of one or more Board rules will include information that would demonstrate how the petitioner would continue to protect the public by alternative means if the rule is waived, in whole or in part.

Text of Proposed Rulemaking

ITEM 1. Adopt the following **new** 481—Chapter 552:

CHAPTER 552
STANDARDS—PRACTICE OF PHARMACY

481—552.1(124,155A) Definitions. The definitions found in 481—Chapter 550 are incorporated by reference into these rules.

481—552.2(155A) Pharmacy department.

552.2(1) *Standards.* Each pharmacy will maintain:

a. Adequate drug storage areas to ensure that drug products are maintained under sanitary conditions and in accordance with package labeling standards.

b. References and drug information as needed to meet the needs of the patients served.

c. Policies and procedures for all aspects of the pharmacy's operation that ensure that all drugs and patient records are secure from unauthorized access, maintain accountability and protect patient confidentiality.

d. Equipment as needed to meet the needs of the patients served that is maintained in accordance with manufacturer recommendations.

e. Drug storage and handling areas in compliance with USP General Chapter 800 (2019) for hazardous drug handling.

552.2(2) *Notice of remodel.* A pharmacy will provide written notice to the board at least 30 days prior to any remodel involving a change to or addition of a primary engineering device or cleanroom suite.

481—552.3(155A) Security.

552.3(1) *Physical security.* Each pharmacy will maintain adequate security to ensure the confidentiality of patient information and the prevention of theft of, diversion of, or unauthorized access to prescription drugs or records, including when prescription drugs or records are stored outside the pharmacy department pursuant to federal law or regulation or these rules. Pharmacy staff personal items allowed in the pharmacy will be stored away from drug storage areas and monitored. Security will include a basic alarm system and video surveillance system, unless the pharmacy is located within a facility that provides equivalent monitoring.

552.3(2) *Processing systems security.* Each pharmacy will maintain adequate security of any electronic device or system that is used to maintain or process patient, practitioner, drug, or prescription records to prevent and detect unauthorized access, modification, or manipulation of such records. Authentication credentials will be securely maintained by the individual to whom the credentials are issued and may not be shared with or disclosed to any other individual.

552.3(3) *Access when pharmacy department is closed.* When the pharmacist is absent from the facility, the pharmacy department will be closed and secured to prevent unauthorized access. Policies and procedures will identify individuals, by title or designation, who are authorized to access the pharmacy department and the specific activities that are authorized.

481—552.4(155A) Pharmacy personnel standards.

552.4(1) *Pharmacy personnel.* Each pharmacy will employ personnel who:

a. Are licensed or registered pursuant to 481—Chapter 551.

b. Have documented training or education for the activities within their scope of practice.

552.4(2) *Identification.* When open to the public, pharmacy personnel will wear visible identification to provide the individual's first name and title.

552.4(3) *Telepharmacy certified pharmacy technicians.* Prior to working in a telepharmacy under remote pharmacist supervision, a certified pharmacy technician will have:

a. Worked at least 1,000 hours in an Iowa-licensed pharmacy.

b. Completed at least 160 hours of training in a managing pharmacy, at another pharmacy using the same audiovisual technology system, or at the telepharmacy site under the direct supervision of an on-site pharmacist.

481—552.5(155A) Standard of care. Each licensee and registrant will provide the accepted standard of care within the individual's scope of practice that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training and experience.

481—552.6(155A) Patient confidentiality. In the absence of express consent from the patient or an order or direction of a court, except where the best interests of the patient require, pharmacy personnel will not divulge or reveal to any person other than the patient or the patient's authorized representative, the prescriber or other licensed practitioner then caring for the patient, a licensed pharmacist, or a person duly authorized by law to receive such information any information contained

in a patient's record relating to any prescription for, medical information about, or pharmacy service provided to the patient.

481—552.7(155A) Pharmacist-interns. An internship will include no fewer than 1,500 hours of pharmacy practice experience that, at a minimum, includes community, institutional and clinical pharmacy practice settings that are licensed in the state in which they are located. A student who has been awarded a pharmacy degree from an ACPE-accredited college of pharmacy located in the United States is deemed to have satisfied this requirement.

481—552.8(155A) Supervision of nonpharmacist personnel.

552.8(1) *Temporary absence of pharmacist.*

a. Pharmacist is not on site. Pharmacy policies and procedures may designate pharmacy personnel who may be present in the pharmacy department to perform delegated functions in accordance with subrule 552.3(3), with the exception of dispensing filled prescriptions, when the pharmacy is closed and, excluding institutional practice settings, a pharmacist is not on site for a period of time not to exceed two hours.

b. Pharmacist is on site and absent from the pharmacy department. Pharmacy policies and procedures may designate pharmacy personnel who may be present in the pharmacy department to perform delegated functions.

552.8(2) *Remote supervision.* Pharmacist supervision of certified pharmacy technicians performing delegated functions at a location other than the licensed location will ensure that:

a. Patient information is secure and confidential.

b. The pharmacist has real-time access to the system used or record processed.

c. The technician has real-time access to the pharmacist.

552.8(3) *Telepharmacy.* Notwithstanding subrules 552.8(1) and 552.8(2), a pharmacist may provide remote supervision of pharmacy personnel in a licensed telepharmacy.

481—552.9(155A) Delegation of functions.

552.9(1) *Technicians and pharmacy support persons.* A supervising pharmacist may delegate any nonclinical function to a pharmacy technician or pharmacy support person in accordance with the individual's registration, training, and education.

552.9(2) *Pharmacist-interns.* A preceptor or supervising pharmacist is responsible for the professional oversight of a pharmacist-intern and may delegate any task in accordance with the education and training of the pharmacist-intern.

481—552.10(155A) Technician product verification. A pharmacy may establish a technician product verification program in accordance with this rule for the purpose of redirecting pharmacist time to clinical services.

552.10(1) *Policies and procedures.* A pharmacy will establish policies and procedures prior to initiation of a program that will include but not be limited to:

a. Utilization of barcode scanning and prohibition of technician overrides,

b. Training of checking technicians and pharmacists,

c. Authorization of checking technicians,

d. Medications that will be excluded from the program, and

e. Documentation of each technician involved in filling or verifying prescriptions in a program.

552.10(2) *Quality assurance.* A pharmacy utilizing a technician product verification program will establish and utilize a quality assurance program to ensure ongoing compliance with its policies and procedures.

481—552.11(155A) Unprofessional conduct. Acts or practices that constitute unprofessional conduct contrary to public interest include but are not limited to:

552.11(1) Unethical conduct that includes but is not limited to fraud, misrepresentation, negligence, concealment, negating the patient's freedom of choice for pharmacy services, or breaching the public trust with respect to the practice of pharmacy.

552.11(2) Discrimination against a patient or group of patients.

552.11(3) Unprofessional behavior that includes but is not limited to verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, theft, or refusal to provide reasonable information or answer reasonable questions for the benefit of a patient.

481—552.12(155A) Manner of issuance of prescriptions.

552.12(1) *Legitimate purpose.* Prescriptions will be valid when issued for a legitimate medical purpose by a prescriber acting in the usual course of the prescriber's professional practice to a patient within an established prescriber/patient relationship, except when issued in accordance with Iowa Code section 135.185, 135.190, 139A.41, 147A.18, or 280.16A.

552.12(2) *Security paper.* A prescription for a noncontrolled substance that is authenticated with an electronic signature and printed will be printed on security paper that ensures the prescription information is not obscured or rendered illegible during fax transmission or scanning into an electronic record system.

552.12(3) *Inaccessibility of prescriber.*

a. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient's use of the medication, a prescription loses its validity. Upon becoming aware of the situation, the pharmacist will cancel the prescription and any remaining refills but may exercise prudent judgment in individual circumstances to ensure sufficient patient access to continued treatment until the patient can reasonably obtain the service of another prescriber.

b. In the event that a pharmacist is unable to obtain a response from a prescriber after reasonable attempts, the pharmacist may refill a patient's prescription, excluding controlled substances, when in the pharmacist's judgment the patient may experience undue harm due to the lapse in therapy.

552.12(4) *Therapeutic substitution.*

a. The patient record will include the originally prescribed medication as well as the therapeutic substitution made by the pharmacist.

b. For noninstitutionalized patients, the pharmacist will obtain patient consent prior to substitution and notify the prescriber of the therapeutic substitution within three business days following dispensing.

c. For institutionalized patients, the pharmacist will follow institutional policies and procedures for therapeutic substitution and documentation.

481—552.13(124,155A) Electronic transmission mandate—exemptions and petition.

552.13(1) *Exemptions.* In addition to the exemptions identified in Iowa Code sections 124.308 and 155A.27, the following prescriptions will be exempt from the electronic transmission requirement:

a. Prescriptions issued pursuant to Iowa Code section 280.16A.

b. A prescription issued in an emergency to meet the immediate care need of a patient when a prescriber is unable to access electronic prescribing capabilities. Such prescription will be limited to a quantity sufficient to meet the acute need of the patient with no authorized refills.

552.13(2) *Form.* An exemption from the electronic transmission mandate provided in Iowa Code sections 124.308 and 155A.27 may be requested on a form provided by the board.

552.13(3) *Criteria for board consideration.* Except for petitions citing the exceptional circumstances listed herein, which will be administratively reviewed for approval, each petition will be reviewed on a case-by-case basis.

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.

481—552.14(155A) Manner of issuance of medication orders.

552.14(1) *Required elements.* Each medication order for a hospital patient or for a noncontrolled substance for a care facility or correctional facility patient will include:

a. Patient name.

b. Drug name, strength, dosage form, and quantity or duration of use.

c. Instructions for use.

d. Date of authorization.

e. Prescriber name and signature.

552.14(2) *Pharmacist verification.* Except as provided in facility policies, a pharmacist will review the entry of a new medication order completed by a nonpharmacist prior to the administration of the medication.

481—552.15(155A) Prospective drug use review.

552.15(1) *Prior to dispensing.* Except for prescriptions issued in accordance with Iowa Code section 135.185, 135.190, 139A.41, 147A.18, or 280.16A, a pharmacist will perform a drug utilization review for each prescription dispensed.

552.15(2) *Prior to second administration from stock or emergency supply.* A pharmacist will perform a drug utilization review prior to the administration of a second dose of a new medication order when administered from a stock or emergency supply for an institutional patient.

481—552.16(155A) Transfer of prescriptions. Transfers of prescriptions will be at the request of the patient or patient's caregiver. Individuals authorized to transfer prescriptions include a pharmacist and, except for transfers of controlled substance prescriptions, a certified pharmacy technician and a pharmacist-intern.

552.16(1) *Limitations.* Transfers of controlled substance prescriptions are limited in accordance with 21 CFR §1306 as amended August 28, 2023.

552.16(2) *Documentation.*

a. Controlled substances for initial filling. Documentation of transfers of electronic controlled substance prescriptions for initial filling will be in accordance with 21 CFR §1306.08 as amended August 28, 2023.

b. Controlled substances for refilling. Documentation of transfers of controlled substance prescriptions for refilling will be in accordance with 21 CFR §1306.25 as amended August 28, 2023.

c. Noncontrolled substances. Documentation of transfers of noncontrolled substance prescriptions will include the required elements identified in 21 CFR §1306.25 as amended August 28, 2023, except for the date of original dispensing, location(s) of previous refill(s), and the DEA registration numbers of the pharmacies party to the transfer.

481—552.17(155A) Contract pharmacy services. A pharmacy may, via an executed agreement between the entities, utilize the services of another Iowa-licensed pharmacy for prescription processing, filling, or dispensing when:

552.17(1) The entities involved have real-time electronic access to the prescription in process that is secure from unauthorized access and maintains patient confidentiality.

552.17(2) Any prescription processing system utilized documents the identification of each individual involved in each step or function of prescription processing, filling or dispensing.

552.17(3) Patient counseling is provided by a pharmacist or pharmacist-intern in a professional setting that can maintain patient privacy.

552.17(4) The pharmacy that maintains the original prescription record maintains ultimate responsibility to ensure compliance with all laws and rules.

481—552.18(155A) Telepharmacy.

552.18(1) *Managing pharmacy requirement.* Only an Iowa-licensed pharmacy can serve as a managing pharmacy for a telepharmacy site located in Iowa.

552.18(2) *Agreement.* An agreement between a telepharmacy and a managing pharmacy will include:

a. The services to be provided by the managing pharmacy, including by an on-site pharmacist no less than 16 hours per month.

b. The conditions under which the telepharmacy may be operational.

552.18(3) *Requirements.* Notwithstanding other rules of the board, a telepharmacy site will:

a. Maintain a perpetual inventory system in accordance with 481—subrule 553.6(1) for all controlled substances at the telepharmacy site.

b. Maintain documentation of a monthly inspection at the telepharmacy site conducted by an on-site pharmacist in accordance with subrule 552.18(4).

552.18(4) *Monthly inspection.* The monthly inspection will include:

a. Audit and reconciliation of controlled substance perpetual and physical inventories.

b. Verification that the video recording system is functioning properly and that the recordings are available for at least 60 days beyond the recording date.

c. Compilation of data of the previous month to include the number of prescriptions filled, the number of on-site pharmacist hours, and the number of hours the telepharmacy site was open for business.

552.18(5) *Conversion to general pharmacy.* If the average number of prescriptions dispensed per day, calculated as the average number of prescriptions dispensed per day over the previous 90-day period, exceeds 150 prescriptions, the telepharmacy site will provide on-site pharmacist staffing 100 percent of the time the telepharmacy is open for business and will, within 30 days, submit an application for licensure as a general pharmacy.

481—552.19(155A) Packaging. Medications will be packaged to ensure that:

552.19(1) The packaging is appropriate for the medication.

552.19(2) The packaging can be appropriately labeled in accordance with rule 481—552.21(155A).

552.19(3) An assigned beyond-use date is appropriate for the medication and packaging used.

552.19(4) Medications that were co-mingled with other medications or any medication for which storage conditions and product integrity cannot be verified, as described in pharmacy policies and procedures, will not be returned to pharmacy stock.

481—552.20(155A) AMDS.

552.20(1) *Stocking AMDS.* Drug products will be loaded into an AMDS or component via barcode scanning by pharmacy personnel, except pharmacy support persons, as delegated by the supervising pharmacist.

552.20(2) *Pharmacist verification of AMDS-dispensed drugs.*

a. Prepackaged medications that were verified by a pharmacist prior to being stocked in the AMDS and that are not further manipulated will not require additional verification prior to dispensing to a patient.

b. Except as provided in paragraph 552.20(3)*"b,"* a pharmacist will document final verification of any medication manipulated by the AMDS (such as counting or packaging) prior to dispensing to a patient.

552.20(3) *Placement of AMDS.*

a. Except as provided in paragraph 552.20(3)*"b,"* an AMDS may only be placed outside a pharmacist's direct supervision when utilized in an approved telepharmacy or when the AMDS dispenses pharmacist-verified packages in compliance with paragraph 552.20(2)*"a."*

b. A pharmacy may place and maintain an AMDS in an Iowa-licensed institution for administration to institution patients pursuant to policies and procedures.

481—552.21(155A) Labeling.

552.21(1) *Ambulatory prescription labeling.* The required labeling elements for a prescription dispensed for an ambulatory patient include:

a. Patient name, except as provided by the Iowa Code.

b. Prescriber name.

c. Pharmacy name, address, and toll-free telephone number.

d. Product name, strength, dosage form, and quantity.

e. Instructions for use.

f. Dispense date.

g. Unique serial number.

h. Manufacturer name or NDC.

i. Beyond-use date.

552.21(2) *Institutional patient-specific prescription labeling.* The required labeling elements for a patient-specific supply of prescription medication dispensed for an institutional patient include:

a. On the immediate container:

(1) Patient name.

(2) Drug name, strength, and dosage form.

b. On outer packaging, if not present on the immediate container:

(1) Prescriber name.

(2) Instructions for use.

(3) Pharmacy name, address, and telephone number, unless the pharmacy is located within the institutional facility.

(4) Dispense date.

(5) Unique serial number.

(6) Beyond-use date.

552.21(3) *Non-patient-specific drug labeling.* The required labeling elements for a non-patient-specific supply of prescription medication include:

a. Drug name, strength, and dosage form.

b. Drug manufacturer or NDC.

c. Expiration or beyond-use date.

552.21(4) *Compounded patient-specific preparation labeling.* In addition to the required labeling identified in subrule 552.21(1) or 552.21(2), as applicable, a label for a compounded preparation will also include:

a. The name and concentration of each active ingredient.

b. The date that the preparation was compounded.

c. Special storage and handling instructions, if applicable.

d. Except in institutional settings, the statement "THIS IS A COMPOUNDED DRUG" or similar statement identifying the product as a compounded preparation, including the term "STERILE" when applicable.

e. The batch identification or control number from which the preparation was dispensed, if applicable.

552.21(5) *Compounded non-patient-specific preparation labeling—batch compounding or veterinary office supply.* The required labeling elements for a non-patient-specific supply of a compounded preparation include the:

a. Preparation name, strength, dosage form, and quantity.

b. Name and concentration of each active ingredient.

c. Pharmacy name, address, and telephone number, except when batch compounding.

d. Preparation date.

e. Beyond-use date.

f. Storage and handling instructions.

g. Lot or batch identification or control number, if applicable.

h. The statement "THIS IS A COMPOUNDED DRUG" or similar statement identifying the product as a compounded preparation, including the term "STERILE" when applicable, except for use within an institutional setting.

i. Statement "NOT FOR REDISTRIBUTION" or similar statement to ensure that use of the compounded preparation is limited to direct patient administration or dispensing pursuant to a patient-specific prescription, except when compounded for use within a health system.

481—552.22(155A) Compounding.

552.22(1) *USP standards—pharmacies.* Preparations compounded pursuant to 21 U.S.C. §353a (Food, Drug, and Cosmetic Act §503A), as amended November 27, 2013, will be prepared in accordance with the standards of USP General Chapter 795 (2023) for nonsterile compounds and USP General Chapter 797 (2023) for sterile compounds.

552.22(2) *Compounding copies of an approved drug.*

a. The compounding of a preparation that is essentially a copy of an FDA-approved drug is prohibited unless:

(1) The compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as documented by the prescriber.

(2) The FDA-approved product is identified as currently in shortage on the FDA drug shortages database.

b. The factors that indicate that a compounded preparation is essentially a copy of an approved drug include:

(1) The compounded preparation has the same active pharmaceutical ingredient(s) as the commercially available drug product;

(2) The active pharmaceutical ingredients have the same, a similar, or an easily substitutable dosage strength; and

(3) The commercially available drug product can be used by the same route of administration as prescribed for the compounded preparation.

c. A prescription issued for a compounded preparation that is essentially a copy of an approved drug will clearly document the relevant change and the significant clinical difference produced for the patient.

552.22(3) *Use of flavoring agents.* Notwithstanding subrule 552.22(1), a flavoring agent may be added to a drug at the discretion of a pharmacist or upon the request of a prescriber, a patient, or a patient's agent. A pharmacist may add flavoring agents not to exceed 5 percent of the total volume of the drug to which the flavoring agents are added. A beyond-use date of 14 days will be assigned if the drug requires refrigeration, although alternate storage conditions or beyond-use dating may be

indicated if supported by peer-reviewed medical literature. Documentation of the flavoring agent and volume used will be added to the prescription record.

552.22(4) *Compounding for veterinary office use.* A pharmacy may compound preparations for distribution to a veterinarian for office use, which may include direct patient administration or dispensing pursuant to a patient-specific prescription.

552.22(5) *Reporting.* Annually, prior to April 1, each licensed pharmacy located in Iowa that dispensed compounded preparations for human use interstate in the previous calendar year will report compounding data to the NABP information-sharing network.

481—552.23(155A) Patient counseling.

552.23(1) *Counseling required.* Except for institutionalized patients, prior to dispensing a prescription that is a new or changed therapy, a pharmacist or pharmacist-intern will counsel the patient or the patient's caregiver on matters that, in the pharmacist's professional judgment, will enhance or optimize drug therapy. An offer to counsel will not satisfy this requirement.

552.23(2) *Counseling area.* Each pharmacy located in Iowa will maintain an area for patient counseling that is accessible to patients and the pharmacist, prevents patient access to prescription drugs, and ensures the confidentiality and privacy of the pharmacist/patient communication.

552.23(3) *Alternative methods.* If, in the pharmacist's professional judgment or following reasonable attempts, oral counseling is not practicable, the pharmacist may utilize an alternative method for providing prescription educational materials to the patient or the patient's caregiver, including a toll-free mechanism for the patient to contact the pharmacist. "Not practicable" does not include issues relating to pharmacy staffing, prescription volume, or manner of dispensing (by mail or courier).

552.23(4) *Refusal of counseling.* A patient's refusal for counseling will be documented by the pharmacist.

481—552.24(155A) Provision of emergency kits. A pharmacy may provide one or more emergency kits to facilities licensed and authorized to administer medications to patients pursuant to established policies and procedures, ensuring that the drugs are stored in a location that is secure from unauthorized access and maintains product integrity. Each emergency kit will be labeled with the name, strength, and quantity of drugs contained in the kit. A pharmacy will maintain documentation of the contents of each kit provided to an authorized facility as well as the expiration dates of all drugs contained in each kit.

481—552.25(155A) Continuous quality improvement program. Each pharmacy will utilize a continuous quality improvement or similar program to timely detect, identify, evaluate and prevent medication errors.

552.25(1) *Reportable program events.* Medication errors resulting in the incorrect dispensing of a prescribed drug received by or administered to a patient that require documentation include but are not limited to:

a. An incorrect drug strength or dosage form.
b. A drug received by the wrong patient.
c. Inadequate or incorrect packaging, labeling or directions.
d. Any error that results in or has the potential to result in serious patient harm.

552.25(2) *Documentation.* Events will be documented, with the initiation of the program record, within three days following the discovery of the event, and will include:

a. A description of the event.
b. The dates of the event and its discovery.
c. The names of individuals involved in the event, the discovery, and the event review.
d. The root cause of and contributing factors to the event.
e. Remediation to prevent similar future events.

f. Review of events with all pharmacy personnel.

481—552.26(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 health and human services and available on the board's website at dial.iowa.gov, order and dispense medications pursuant to the requirements identified in the statewide protocols. For the purpose of this rule, the order constitutes a prescription.

481—552.27(155A) Collaborative pharmacy practice.

552.27(1) *Agreement.* A pharmacist or pharmacy may engage in collaborative pharmacy practice under a collaborative pharmacy practice agreement with one or more practitioners who are authorized to independently prescribe, 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.

552.27(2) *Standards.*

a. A collaborative pharmacy practice agreement will be reviewed and updated as necessary by all parties every two years and will 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.

b. Any agreement will be maintained by the pharmacist(s) or pharmacy and be available upon request or inspection.

c. Prior to engaging in activities provided by the agreement, each pharmacist will document attestation that the pharmacist has read and understands the agreement.

481—552.28(155A) Pharmacy pilot or demonstration research projects. In accordance with Iowa Code section 155A.47, a pharmacy may submit a pilot or demonstration research project ("pilot project") to the board for approval.

552.28(1) *Petition.* A petition for a pilot project, including for renewal of a previously approved project, will include:

a. The name, email address, and pharmacist license number of each pharmacist responsible for overseeing the project.

b. The name, address, and telephone number of each specific location, including the pharmacy license number if the location is a pharmacy where the project will be conducted.

c. A detailed summary of the pilot project that includes:

(1) The goals, hypothesis, and objective(s) of the pilot project.

(2) An explanation of the project, including background information or literature review to support the project, and how it will be conducted.

(3) The time frame for the project, including the start date and study length.

(4) The rule(s) to be waived for the project and a petition for waiver of the rule(s).

(5) Procedures to be used during the project to ensure that public health and safety are not compromised.

552.28(2) *Board decision.* Upon review of a petition for a pilot project, the board may approve or deny a petition. Project approval:

a. Will be specific for the project requested.

b. Will identify a time period for the project.

c. May include conditions to be satisfied.

552.28(3) *Final project report.* A final project report will include a written summary of the result(s) of the project and the conclusion(s) drawn from those result(s), which will be submitted to the board within three months of the conclusion or termination of the project.

481—552.29(155A) Nuclear pharmacy.

552.29(1) *Personnel and training.*

a. An authorized nuclear pharmacist will meet all applicable requirements of the United States Nuclear Regulatory Commission pursuant to 10 CFR (2023).

b. Notwithstanding rule 481—552.9(155A), pharmacy personnel registered as a pharmacy support person trained in nuclear pharmacy operations may engage in technical functions as delegated by an authorized nuclear pharmacist.

552.29(2) *Supervision.* An authorized nuclear pharmacist is responsible for all operations of the pharmacy and, except in emergency situations, will be on-site during the pharmacy's hours of operation.

552.29(3) *Preparation standards.* Radiopharmaceuticals will be prepared in accordance with the standards identified in USP General Chapter 825 (2020). Compounded radiopharmaceuticals will be prepared in accordance with the standards identified in USP Chapter 795 for nonsterile preparations (2023) or USP Chapter 797 for sterile preparations (2023), as applicable.

481—552.30(155A) Records.

552.30(1) *Types of records.* Each pharmacy will maintain the following records, if applicable to the pharmacy's operation:

a. Patient records, including demographic information, prescription or medication order information and all information needed to conduct drug utilization review pursuant to rule 481—552.15(155A).

b. Prescriber records, including demographic and prescription information.

c. Prescription or medication order records, including the unique identification number assigned, information about each fill including product NDC, and identification of the individuals(s) responsible for prescription preparation and product verification.

d. Prescription drug inventory records, including transaction records for the receipt and distribution of prescription drugs.

e. Documentation of the current license or registration of each pharmacy staff member working in the pharmacy. The current pharmacist license certificate will be posted within view of the public when a pharmacist is working on-site and the pharmacy is open to the public.

f. Documentation of the initials or unique credentials used in pharmacy records and systems for each pharmacy employee.

g. Documentation of temporary pharmacy staffing, including the individual's name, license or registration number, unique credentials used in pharmacy records and systems, and date and shift worked.

h. Documentation of pharmacy personnel training for delegated functions within the individual's scope of practice.

552.30(2) *Retention of records.*

a. Security. Records will be maintained in a secure fashion, ensuring that the records protect patient confidentiality and prevent unauthorized access.

b. Duration. All records will be retained for at least two years from the date of the last activity on the record.

c. Method. When not prohibited by federal law or regulation, records may be maintained as follows:

(1) At an alternate site in compliance with paragraph 552.30(2)*"a"* if a legible electronic copy is immediately available for inspection and copying by the board or its authorized agent.

(2) Via legible electronic copy if immediately available for inspection and copying by the board or its authorized agent.

552.30(3) *Provision of records.* Records will be provided to the board or its authorized agent within three business days of a request.

These rules are intended to implement Iowa Code sections 124.302 and 147.76 and chapter 155A.