MINUTES

AUGUST 2025 MEETING
ADMINISTRATIVE RULES REVIEW COMMITTEE

MEMBERS PRESENT

Senator Mike Klimesh, Vice Chair	Representative Chad Ingels, Chair
Senator Mike Bousselot	Representative Amy Nielsen
Senator Dan Dawson	Representative Rick L. Olson
Senator Sarah Trone Garriott	Representative Michael V. Sexton
Senator Cindy Winckler	Representative David E. Young

EX OFFICIO, NONVOTING MEMBER: Stan Thompson, Administrative Rules Coordinator, Office of the Governor

LSA CONTACTS: Organizational staffing provided and minutes prepared by Jack Ewing, Administrative Code Editor, 515.281.6048, and Natalie Sherman, Legal Counsel, 515.725.2299

BULLETINS NEEDED FOR THIS MEETING: 6/11/25, 7/9/25, 7/23/25

Procedural Business

Representative Ingels convened the regular, statutory meeting of the Administrative Rules Review Committee (ARRC) at 10 a.m. on Monday, August 11, 2025, in Room 116, State Capitol, Des Moines, Iowa. The minutes of the June 16, 2025, meeting were approved. The next meeting was scheduled for Monday, September 8, 2025, at 10 a.m. Mr. Ewing noted the meeting would cover three bulletins. The meeting was adjourned at 11:40 a.m.

Fiscal Overview

Mr. Nathan Moore, Fiscal Legislative Analyst, presented the LSA fiscal report.

IOWA FINANCE AUTHORITY

Representing the agency: Lisa Connell, Terri Rosonke

ARC 9407C (AF), Shelter Assistance Fund, Ch. 41

Committee members asked Ms. Connell to comment on some of the public comments received, and if the rulemaking was affected by the comments. She responded that many of the public comments regarded proposed changes to the eligibility of facilities for the program, including a new requirement that a facility must comply with applicable zoning regulations to receive program assistance. Ms. Rosonke added that the new requirement added to the definition of "homeless shelter" or "shelter"; would require a shelter to comply with all local, state, and federal laws and ordinances; and may exclude some new entities that intended to apply to the program.

Members asked how many shelters would be impacted by the rulemaking. Ms. Rosonke responded that one shelter in particular would be impacted.

No action taken on ARC 9407C.

Rulemaking type is indicated in parentheses following the ARC number. The acronyms have the following meanings: Notice of Intended Action (**NOIA**), Amended Notice of Intended Action (**ANOIA**), Notice of Termination (**NOT**), Adopted and Filed Emergency (**AFE**), Filed Emergency After Notice (**FEAN**), and Adopted and Filed (**AF**).

IOWA PUBLIC EMPLOYEES' RETIREMENT SYSTEM

Representing the agency: Elizabeth Hennessey

ARC 9414C (NOIA), Contribution Rates — Sheriffs, Deputy Sheriffs, Protection Occupations, Ch. 4, also Filed Emergency ARC 9417C

No discussion on ARC 9414C or ARC 9417C.

PUBLIC HEALTH DEPARTMENT

Representing the agency: Victoria Daniels, Jill Myers Geadelmann

ARC 9411C (ANOIA), Child Protection Center Grant Program, Ch. 94

No discussion on ARC 9411C.

ARC 9418C (NOIA), Iowa Care for Yourself (IA CFY) Program, Ch. 8

Committee members asked if the program was previously entirely dependent on federal funding. Ms. Myers Geadelmann responded that the program relied primarily on federal funding, as well as some state funds. Members asked how much state funding had previously been allocated. She responded $300,000. Members asked how many Iowans had been served through the program. She responded that just under 4,000 individuals had been screened in the prior fiscal year.

Committee members asked if the federal government had communicated whether the program would receive funding in the coming years. Ms. Myers Geadelmann responded that the program currently had funding for next year as part of a five-year cooperative agreement. Members asked whether there would be a decrease in funding for the coming year due to state funds no longer being allocated for the program. She responded that the program has state and federal funds appropriate for what was requested in order to serve the anticipated number of people through the program.

No action taken on ARC 9418C.

ARC 9419C (NOIA), Outpatient Diabetes Education Programs, Ch. 9

Committee members asked if the department intended rulemaking authority for the program to be included in legislation. Ms. Daniels responded that the legislative proposals for the upcoming legislative session would need to be discussed with the department's government relations team. She stated that if key stakeholders contacted the department regarding rulemaking authority the department would take it under consideration.

No action taken on ARC 9419C.

ARC 9420C (NOIA), Iowa Get Screened: Colorectal Cancer Program, Ch. 10

Committee members asked how many Iowans had been served under the program in the past year, if there had been a state appropriation for the program, and would there be a state appropriation in the future. Ms. Myers Geadelmann responded that the program was awaiting the award of a new five-year cooperative agreement, and the state had appropriated $97,000 for the program. She stated that in the past year the program screened 112 individuals for colorectal cancer.

No action taken on ARC 9420C.

WORKFORCE DEVELOPMENT DEPARTMENT

Representing the agency: Rebecca Stonawski

ARC 9427C (NOIA), Iowa Industrial New Jobs Training Program, Ch. 62

Committee members asked if the program had been used more or less frequently, and about the development or use of the program and its importance. Ms. Stonawski responded that she would put the members in contact with someone from the department to discuss the policy behind the rulemaking.

No action taken on ARC 9427C.

NATURAL RESOURCES DEPARTMENT

Representing the agency: Denise Roberg, Tamara McIntosh

ARC 9426C (ANOIA), Special Nonresident Deer and Turkey Licenses, Ch. 12

Committee members asked the department to explain the rulemaking creating a new type of organization that could qualify for a special license, and what the organization would entail. Ms. Roberg responded that the rulemaking includes a statewide signature event organization. The organization may qualify for a conservation organization tag auctioned off as part of a fundraising event that raises money for the organization, with half of the proceeds going to the state. Members asked if the rulemaking targeted a specific organization. She responded that the rulemaking was intended for the Blue Ribbon Foundation.

No action taken on ARC 9426C.

ARC 9433C (AF), Rules of Practice in Contested Cases, Ch. 7

No discussion on ARC 9433C.

INSPECTIONS AND APPEALS DEPARTMENT

Representing the agency: Sue Mears

ARC 9337C (AF), Definitions; Licenses, Registrations, and Permits, Chs. 550, 551

Note: ARC 9337C, 9338C, 9339C, 9340C, 9341C, 9342C, 9343C, and 9346C were reviewed and discussed collectively.

Mr. Aaron McDonough, co-owner of Towncrest Pharmacy, and Mr. Adam Jones, acute care pharmacy manager at University of Iowa Health Care, spoke in support of the rulemaking and offered to answer questions from the committee.

Committee members asked Mr. Jones the volume of compounded medications distributed or utilized by the hospital network. He responded that more than 20,000 medications are compounded per month for patients throughout the hospital.

Committee members asked what the impact would be on patients and the pharmacy industry if the rulemaking did not move forward. Mr. Jones responded that almost all compounded medications are specific for in-patient dosages. Mr. McDonough stated that for the seven pharmacies owned by Towncrest Pharmacy, less than 5 percent of medications are compounded, and compounding is typically used for very specific orders that are not commercially available, the active ingredient must be removed due to a sensitivity, or the exact prescription does not exist.

Committee members asked to what extent compounding is reconstituting a medication with a short shelf life, or is creating a custom medication based on a doctor's prescription. Mr. Jones responded that his practice involves both, and a medication is not typically compounded until a prescription is received because ingredients are premade and combined to create the medication. He stated that because he works in a hospital setting the pharmacy is continually looking at patient safety, and compounds medications in a clean room using techniques to avoid contamination and reduce risk for patients. He also stated that standards of care for staff members had been increased to require staff to be tested every six months in order to compound medications. He explained that roughly 80 percent of the compounding at his practice involves reconstituting or combining medications, including thawing medications that arrive frozen. He further explained that approximately 20 percent of prescriptions, such as chemotherapy medications, are more complex and require intricate compounding.

Committee members asked how frequently a long-term prescription medication is compounded, and whether the bulk of compounded medications are dispensed on site. Mr. Jones replied that roughly 95 percent of compounded medications are dispensed for a patient in the hospital, and in a rare case that a medication does not exist or requires a unique formula, the medication will be compounded for long-term use.

Committee members asked about the difference between the proposed rules and the current rules, and whether the ability to send a compounded medication home with a patient is different than current practices. Mr. Jones responded that if a pharmacy is unable to provide a prescription medication a patient would suffer the effects if they did not have access to a compounded medication. Mr.

McDonough added that compounding for the state as a whole is limited and involves a subset of the rulemaking. Mr. Matt Pitlick, CEO of the Iowa Pharmacy Association, stated that with the new rules all compounding occurs pursuant to a patient-specific medication order, and pharmacies are not sending patients home with a medication a pharmacist did not see or a provider did not order. Members asked if the rulemaking is a change from current practice. Mr. Pitlick responded that the rulemaking includes small changes in wording, but current practices would not change and the rulemaking aligns with federal Food and Drug Administration (FDA) guidelines.

Committee members asked what fraction of compounding is patient-specific versus nonpatient-specific. Mr. Jones responded that all compounded medications are patient-specific, except that a pharmacy may receive a supply of compounded medications from a 503B pharmacy, and the supply is only distributed pursuant to patient-specific prescriptions. Mr. McDonough stated that 503A pharmacies cannot compound a medication that is not pursuant to a patient-specific prescription.

Ms. Gabrielle Constantini, speaking on behalf of Novo Nordisk, stated that the rulemaking would change how medications are compounded by 503B pharmacies and which compounded medications could be sold to hospitals, raising public health concerns. She stated changes made to federal law could allow outsourcing facilities to make nonpatient-specific supplies of compounded medications.

Committee members asked whether the rulemaking complies with federal regulations. Ms. Constantini responded that the rulemaking is not aligned with federal law. She stated that the FDA published draft guidance in 2023 that suggested there may be a pathway for medication compounded by outsourcing facilities to be distributed by a pharmacy to a patient. She stated that the rulemaking is getting ahead of an FDA decision and final guidance. She stated that federal law has not changed, and still prohibits reselling and wholesaling compounded medication. She further stated that the rulemaking is premature and risky. Ms. Mears responded that federal law allows compounded medications to be dispensed pursuant to patient-specific prescriptions, and dispensing is not the same as wholesaling or reselling. Members asked whether dispensing a compounded medication is the same as selling a compounded medication. She replied that reselling is the same as wholesaling, which the rules would not allow, but dispensing is giving a patient a medication pursuant to a prescription. Members asked if a hospital or local pharmacy would be purchasing from a 503B pharmacy and then dispensing or selling to a patient. She responded that a pharmacy can buy a stock supply of compounded medications from outsourcing facilities and dispense medications to patients pursuant to patient-specific prescriptions. Ms. Constantini responded that it is incorrect to look at the language on dispensing and interpret it to suggest the entire federal framework and protections are moot.

Ms. Sandy Conlin, speaking on behalf of the Outsourcing Facility Association, stated that not allowing 503B pharmacies to fully implement what is permitted under federal law would hurt patient safety. She noted that 27 states already allow what would be permitted by the rulemaking. Ms. Constantini responded that hospitals and clinics can still get medications from 503B pharmacies, but that federal protections limit broader distribution of compounded medications and did not anticipate mass marketing through telehealth or retail chains. She stated that only a few states have made the changes anticipated by the rulemaking.

Committee members asked what triggers the use of a compounded medication and the ability to compound a medication that already exists in the market. Ms. Constantini responded that there are different pathways permitted by federal law for compounded medications.

Representative Brett Barker, speaking as a pharmacist, added that the rulemaking is consistent with FDA and other federal guidance, and that there is no need for further restrictions. He explained that the use of an outsourcing facility to compound a medication is necessary when a prescription medication is unavailable. He further explained that 503A compounding is less desirable than 503B compounding. He stated the biggest change made by the rulemaking is that 503B medications would be available for patients to use at home. He also stated that dispensing is not the same as reselling or wholesaling, and to conflate such would be to misinterpret federal law. He further stated that patient-specific prescription medications are explicitly excluded from wholesaling or reselling under federal law.

Committee members asked if compounded medications are used due to availability issues, and at what point a compounded medication reverts to the FDA-approved medication. Representative Barker responded that a medication reverts when there is no longer a shortage pursuant to the FDA shortage list. Members asked whether a complaint may be filed if a compounded medication is used after the FDA-approved medication is removed from the FDA shortage list, and asked how many complaints

had been filed. Representative Barker responded that while there have been complaints, he did not have a specific number. Members asked what the cost difference is between a compounded medication and the FDA-approved medication. He responded that the cost of a compounded 503A medication is the cost of the ingredients plus labor. Members asked whether the rulemaking changes current practices, or primarily impacts labeling of compounded medications. He responded that the rulemaking primarily impacts labeling, and loopholes found by pharmacies should be addressed by the Legislature. Members urged affected parties to work together to resolve any issues relating to the rulemaking.

Ms. Constantini expressed concern that action taken based on narrow issues relating to weight loss drugs may impact patient safety for all drugs.

Delay Lifted

A motion to lift the 70-day delay on ARC 9337C, 9338C, 9339C, 9340C, 9341C, 9342C, 9343C, and 9346C carried unanimously on a roll call vote.