MINUTES

JULY 2025 MEETING
ADMINISTRATIVE RULES REVIEW COMMITTEE

MEMBERS PRESENT

Senator Mike Bousselot	Representative Chad Ingels, Chair
Senator Dan Dawson	Representative Rick L. Olson
Senator Mike Klimesh	Representative Michael V. Sexton
	Representative David E. Young

EX OFFICIO, NONVOTING MEMBER: Stan Thompson, Senior Legal Counsel, 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: 5/28/25, 6/11/25, 6/25/25

Procedural Business

Representative Ingels convened the regular, statutory meeting of the Administrative Rules Review Committee (ARRC) at 10:05 a.m. on Monday, July 14, 2025, in Room 116, State Capitol, Des Moines, Iowa. The next meeting was scheduled for August 11, 2025, at 10 a.m. Mr. Thompson, the new administrative rules coordinator, introduced himself to the committee. The meeting was adjourned at 11:25 a.m.

Fiscal Overview

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

UTILITIES COMMISSION

Representing the agency: Cheyanne Whisner

ARC 9353C (AF), Electric Interconnection of Distributed Generation Facilities, Ch. 45

Committee members asked about public comments regarding meter socket adapters and how the public comments impacted the rulemaking. Ms. Whisner responded that she would provide members with such information at a later date.

No action taken on ARC 9353C.

INSPECTIONS AND APPEALS DEPARTMENT

Representing the agency: Sue Mears, Emily DeRonde

ARC 9338C (AF), Standards—Practice of Pharmacy, Ch. 552

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

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**).

Mr. Jake Ketzner, speaking on behalf of Novo Nordisk, requested a delay of the rulemaking addressing the compounding of prescription medication. He stated he had submitted comments to the Board of Pharmacy that raised concerns regarding patient safety due to where prescription medications were manufactured and lack of FDA approval. He provided members with a letter detailing the concerns of Novo Nordisk.

Committee members asked the department to explain the changes to the compounding section of the rulemaking and any comments the department had received. Ms. Mears explained that compounding of prescription medication can be done in two different ways. Either a pharmacy compounds pursuant to a patient-specific prescription, or a United States Food and Drug Administration (FDA)-registered outsourcing facility operates like a manufacturer and compounds a nonpatient-specific medication. The FDA limits entities that can compound medication, and prohibits compounding of exact copies of FDA-approved medications. The Board of Pharmacy's rules would allow hospitals or practitioners to receive a supply of compounded medication and to dispense the medication to a patient for at-home use, rather than only allow the administration of the compounded medication within the hospital or practitioner's clinic.

Committee members asked what variations are permitted during the compounding process. Ms. Mears explained that there must be enough variation in the components of a compounded medication that there is a significant difference from the FDA-approved medication. Members asked how deviations are handled when compounding a medication, including who makes the determination regarding what is interchangeable and what is a significant enough deviation from the original formulation. She explained that it depends on the practitioner's order, and that the FDA guidance for the difference to be considered clinically significant is 10 percent. She noted that it is the practitioner's responsibility to describe the difference between the FDA-approved medication and the compounded medication. Members asked whether it is necessary to look at the primary ingredient of a prescription medication, and if a compounded medication can contain the same amount of the primary ingredient. She responded that a compounded medication can contain the same amount of the primary ingredient, and other factors may be important such as additional ingredients or dosage. She also noted that an FDA-approved medication and a compounded medication can be exact copies if the FDA-approved medication is not commercially available.

Committee members asked to what extent a search must be conducted by a pharmacy or outsourcing facility for an FDA-approved medication before it is acceptable to make a compounded medication for an extended period. Ms. Mears stated that a pharmacy or outsourcing facility must check for the availability of an FDA-approved medication before creating a copy, unless it is a unique formula. She explained that the first step is to check whether the FDA-approved medication is listed on the FDA shortage list.

Committee members asked if there may be legal recourse as a result of an adverse reaction to a compounded medication, and raised concern about an adverse reaction to a compounded medication administered at home. Ms. Mears responded that the ability to compound is available to practitioners any time that a compounded medication is necessary, and any adverse reaction would be the same whether the compounded medication were administered in a clinic or at home.

Committee members asked what would happen in the case of a prescription refill. Ms. Mears responded that the same requirements apply to refills.

Committee members asked if compounded medications have expiration dates. Ms. Mears responded that compounded medications have the same standards as noncompounded medications. Members asked about the policy for disposing of compounded medications after the expiration date. She responded that the policy is the same for compounded medications and all other medications at a pharmacy. Members asked how frequently compounding occurs. She responded that compounding occurs frequently due to patient-specific formulations and medication shortages.

Committee members asked Mr. Ketzner to explain Novo Nordisk's three biggest concerns regarding the rulemaking. He responded that there are many easily accessible compounded medications on the market that are not FDA-approved and that do not meet the same safety and quality standards as FDA-approved medications.

Committee members asked if the rulemaking would bridge the gap between patient-specific and nonpatient-specific compounded medications for at-home use. Ms. Mears responded that the

rulemaking would allow practitioners to send patients home with a supply of nonpatient-specific compounded medications, similar to what is currently allowed under federal law.

Committee members asked Mr. Ketzner if the part of the letter he provided to the committee that relates back to the FDA draft guidance is compatible with the rulemaking. Ms. Mears responded that the FDA guidance articulated that a supply of compounded medication may be dispensed pursuant to a patient-specific prescription. Mr. Ketzner responded that Novo Nordisk disagrees, and believes that the FDA guidance does not allow for a supply of compounded medication to be taken home.

Committee members asked who has liability if a compounded medication is sent home for at-home administration. Ms. Mears responded that it depends on where in the process a problem with the medication occurs.

Committee members asked if there would be any implications if the rulemaking were delayed for 70 days to allow for the committee to better understand the positions of the parties interested in the rulemaking. Ms. DeRonde responded that all of the rulemaking carried out by the board to fully redraft its rules under Executive Order 10 would be delayed. She noted the delayed rulemaking would include rules implementing 2023 Acts, House File 555, legislation that significantly reformed the state's pharmacy laws. She explained that the provisions relating to compounding could not be delayed separately.

Committee members made a motion to delay the rulemaking and all of the pharmacy rules under the Department of Inspections, Appeals, and Licensing for 70 days, including ARC 9346C. Members explained that they would like to have somebody from the compounding industry discuss compounding at the August meeting.

Members asked what similar rulemaking other states had been working on. Ms. DeRonde responded that a complete assessment had not been completed. The members asked that the assessment be provided to the members prior to the August meeting.

70-Day Delay

A motion for a 70-day delay on ARC 9337C, 9338C, 9339C, 9340C, 9341C, 9342C, and 9343C, as well as 9346C under agency number 657, carried 7-0 on a roll call vote.

MEDICINE BOARD

Representing the agency: Emily DeRonde

ARC 9379C (ANOIA), Physician Supervision of a Physician Assistant, Ch. 21

Ms. Sydney Gangestad, speaking on behalf of the Iowa Physician Assistant Society, stated that the two rulemakings addressing similar subjects are proceeding concurrently, including the joint rules regarding licensure of physician assistants and the joint rules regarding oversight of physicians who supervise physician assistants, and that is an issue. She requested the rules refer to the independent physician assistants that could be supervised. She requested that the board remove the rules provision regarding the maximum number of physician assistants that can be supervised by physicians. She asked for clarification on whether the committee would need to take any action before the board made changes or brought changes to the committee. Mr. Ewing responded that the committee did not need to take any action.

No action taken on ARC 9379C.