

BEFORE THE PHARMACY BOARD OF THE STATE OF IOWA

<p>In the Matter of the Petition for Waiver by:</p> <p>Ritedose Pharmaceuticals, LLC</p> <p>Petitioner.</p>	<p>ORDER DENYING WAIVER REQUEST</p>
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Pursuant to Iowa Code section 17A.9A and 481 Iowa Administrative Code (“IAC”) 6, the Iowa Board of Pharmacy (“Board”) makes the following ruling on the Petition for Waiver submitted by Ritedose Pharmaceuticals, LLC (“Petitioner”).

FINDINGS OF FACT

1. Petitioner is seeking an Iowa wholesaler license.
2. Petitioner stated in their Petition for Waiver that they seek to waive 481 IAC 551.13(1)(a)(2) which states: To be eligible for licensure as a wholesale distributor, each application will include evidence of:
 - (2) Current drug distributor accreditation by NABP, NCDQS, or another accreditation body approved by the board. New applicants located in Iowa that undergo an opening inspection will not be obligated to provide evidence of accreditation for initial licensure.
3. Petitioner is specifically seeking to not be required to obtain NABP accreditation prior to obtaining an Iowa license.
4. Petitioner states that requiring NABP accreditation in order to obtain Iowa licensure is an undue hardship because, they assert, that NABP mandates that state licensure must be issued before an accreditation application can be submitted. They maintain that since they do not yet have an Iowa license, they are ineligible to apply for NABP accreditation, and they must received NABP accreditation before they can receive an Iowa license.
5. The Board considered the Petition for Waiver at a board meeting on September 23, 2025.

APPLICABLE LAW

6. Pursuant to Iowa Administrative Code chapter 481—6.1(3), the Board may in its sole discretion issue an order waiving in whole or in part the requirements of a rule if the board finds, based on clear and convincing evidence, all of the following:
 - a. The application of the rule would impose an undue hardship on the person for whom

- the waiver is requested;
- b. The waiver from the requirements of the rule in the specific case would not prejudice the substantial legal rights of any person;
 - c. The provisions of the rule subject to the petition for waiver are not specifically mandated by statute or another provision of law; and
 - d. Substantially equal protection of public health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the waiver is requested.
7. “The burden of persuasion rests with the petitioner to demonstrate by clear and convincing evidence that the board should exercise its discretion to grant a waiver from a board rule.” 481 IAC 6.1(8)(b).
 8. The Board's rules provide “The final decision on whether the circumstances justify the granting of a waiver is at the discretion of the department upon consideration of all relevant factors. Each petition for a waiver will be evaluated by the department based on the unique, individual circumstances set out in the petition.” 481 IAC 6.1(8)(a).
 9. “A waiver, if granted, shall provide the narrowest exception possible to the provisions of a rule.” 481 IAC 6.1(8)(f).

ANALYSIS OF WAIVER CRITERIA

Whether the application of the rule would create an undue hardship on the person for whom the waiver is requested:

10. Application of the rule would not create an undue hardship on Petitioner as it merely requires them to obtain the accreditation as is required by rule for every entity that wishes to obtain an Iowa wholesale license and puts no additional burden on them.

Whether the waiver from the requirements of the rule in the specific case would prejudice the substantial legal rights of any person:

11. Waiving the requirements of the rule would not prejudice the substantial legal rights of any person.

Whether the provision of the rule subject to the petition for waiver is not specifically mandated by another provision of law:

12. The requirement found in the Board’s administrative rule is not specifically mandated by statute.

Whether substantially equal protection of the public health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the waiver

is requested:

13. The public health, safety, and welfare will be not be afforded by other means if this waiver is granted because it is meant to ensure the safety of the entity that wishes to have an Iowa wholesale license and that they are abiding by all pertinent state and federal rules and regulations before such licensure is granted.

CONCLUSIONS OF LAW

For the reasons set forth above and upon review of the Petition, the Board finds that Petitioner has not satisfied the four criteria for waiver set forth in 481 IAC 6.1(3).

ORDER

IT IS THEREFORE ORDERED the Petition for Waiver of 481 Iowa Administrative Code chapter 551.13(1)(a)(2) is DENIED.

Issued September 23, 2025.



Erik Maki, PharmD
Chairperson
Iowa Board of Pharmacy

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