

BEFORE THE PHARMACY BOARD OF THE STATE OF IOWA

<p>In the Matter of the Petition for Waiver by:</p> <p>Medicap Pharmacy License #5971</p> <p>Petitioner.</p>	<p>ORDER GRANTING 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 Medicap Pharmacy (“Petitioner”).

FINDINGS OF FACT

1. Petitioner is an Iowa pharmacy that dispenses investigational compounded medications for IRB-approved clinical research studies.
2. Petitioner stated in their Petition for Waiver that they seek to waive 481 IAC 552.21(1)(d) which states “the required labeling elements for a prescription dispensed for an ambulatory patient include: d. product name, strength, dosage form, and quantity.”
3. Petitioner stated in their Petition for Waiver that they also seek to waive 481 IAC 552.21(4)(a) which states: 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.”
4. Petitioner is specifically seeking to be permitted to dispense prescriptions for blinded IRB-approved clinical trials without requiring disclosure of product identity or active ingredient information that would compromise blinding.
5. The Board considered the Petition for Waiver at a board meeting on May 5, 2026.

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 create an undue hardship on Petitioner as it would require labeling of compounded prescriptions that are being used in blind studies and would compromise the purpose and integrity of the blind study.

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 afforded by other means if this waiver is granted because the rule is meant to protect the public and is not meant to apply to compounded prescriptions that are involved in blind investigational

studies.

CONCLUSIONS OF LAW

For the reasons set forth above and upon review of the Petition, the Board finds that Petitioner has 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 552.21(1)(d) and 552.21(4)(a) is GRANTED.

Issued May 5, 2026.



Erik Maki, PharmD
Chairperson
Iowa Board of Pharmacy

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