

JILL STUECKER, MPA, MA INTERIM EXECUTIVE DIRECTOR



November 8, 2023

U of I Community HomeCare License/Reg No. 1068 2949 Sierra Ct SW Iowa City, IA 52240 ssedenka@uihealthsystem.org

RE: Petition for Waiver

On November 7, 2023, the Board **granted** your request to waive rule 657 IAC 20.4, requiring compliance with the provisions of USP General Chapter 797, specifically as it relates to the certification of a primary engineering control device used in the compounding of sterile hazardous preparations. The waiver authorizes the facility to continue utilization of the facility's existing MIC unit until the facility construction is complete, providing the pharmacy with a BSC system with open unidirectional air flow.

The Board determined that application of the rule would impose an undue hardship by prohibiting the pharmacy from providing home infusion chemotherapy for its oncology patients. The Board determined that granting the waiver would not prejudice the legal rights of another person. The Board determined that the provisions of the rule being waived are not specifically mandated by statute or another provision of law. The Board determined that substantially equal protection of the health, safety, and welfare of the public can be assured with the pharmacy's strong record of staff and patient safety with MIC utilization and implementation of other Chapter 797 standards.

The waiver is approved and will expire November 1, 2024.

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Sue Mears, RPh, Compliance Officer IOWA BOARD OF PHARMACY