After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.

Case No. or State ID No.

Rec'd:

(FOR PHARMACY BOARD USE ONLY)

IOWA BOARD OF PHARMACY
Petition for [☐] Waiver [X] Variance
(check the appropriate box)

PLEASE PRINT OR TYPE ALL INFORMATION IN INK

A waiver excuses the petitioner from the requirements of a rule in its entirety or from a part of a rule; a variance does not. Instead, a variance is a modification to the requirements of a rule or a part of a rule. Example: A rule requires the fencing of certain property and further requires that the fence be at least 6 feet in height. A waiver of that rule would excuse the petitioner from the requirement for fencing the property. A variance would require the property be fenced but would allow the petitioner to maintain the current fencing configuration of 5 feet in height (perhaps the fence was constructed prior to the height requirement). When replacement of the current fence becomes necessary as a consequence of normal wear and tear, the variance would terminate and the petitioner would be required to comply with the 6-foot height requirement.

Note: Statutory requirements that have been repeated in administrative rules are not subject to consideration for a waiver or variance.

Is this petition an initial request or is it a request for renewal? [X] Initial Request [☐] Request for Renewal
If a request for renewal, explain below why the renewal is necessary.

Petitioner Information (include licensee/registrant name and name of contact person, i.e. pharmacist in charge)

Name: Megan A. Kramer, Marengo Memorial Hospital Phone No.: 319 642-8039
(include area code)

Address: 300 West May Street

City: Marengo State: IA Zip Code: 52301

Petition Information

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APR 21 2016
IOWA BOARD OF PHARMACY

1. Chapter Number and Title.

   657-20.4 (124,126,155A) and Sterile Compounding USP 797

2. Rule Number(s) and Title(s).

   657-20.4 (124,126,155A) and Sterile Compounding USP 797

3. Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.

   Compounding Sterile IVs for chemotherapy and non-chemotherapy are to be compounded in separate IV hoods or biological safety cabinets.

4. Describe the specific nature and scope of your petition. In your description, include the anticipated time period (beginning and ending) for which the petition would apply. A waiver or variance may not be requested or granted on a permanent basis; the petition must identify an end date.

   Request that both non-chemotherapy and chemotherapy sterile IVs be prepared in the same biological safety cabinet. Over the past years and currently at this Hospital, both types of sterile IV preparations have been

prepared in the same biological safety cabinet: Envirco BSC Model # 10448 laminal flow externally vented ISO class V type A, Type A/B3 cabinet. We need this waiver until February to June or 2019 for project completion.

5. Describe the relevant facts and reasons that, in your opinion, justify and provide "clear and convincing evidence" as to why this petition merits consideration for waiver or variance. In your description, explain why the rule(s) poses an undue hardship. If there is a public health, safety and welfare issue associated with this rule(s), or if this rule(s) addresses security or confidentiality issues, also explain how equal protection will be maintained if this petition were granted.

   The current pharmacy, IV room and ante-room have limited space and cannot accommodate two different style devices. The pharmacy will be expanded and remodeled starting approximately the fall of 2016 which will include separate IV rooms for chemotherapy and for non-chemotherapy. As per the manufacturer, the current biological safety cabinet is ISO class V rated for both chemotherapy and non-chemotherapy sterile IV preparations as a laminar circular flow vertically vented hood. Cleaning between the different types of sterile IV preparations is extensive and chemotherapy is only performed on Thursdays each week.

6. Does anyone else (inside or outside state government) possess knowledge relevant to this petition?

   [☐] Yes [X] No [☐] Do not know

   If yes, list their names, addresses and phone numbers below.

7. Would anyone (inside or outside state government) be adversely affected if this petition were granted?

   [☐] Yes [X] No [☐] Do not know

   If yes, list their names, addresses and phone numbers below.

8. Do you know how the Board of Pharmacy has treated similar situations?

   [☐] Yes [X] No

   If yes, describe below how similar situations were handled.

9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

   [☐] Yes [X] No

   If yes, describe below the issue involved and the outcome.

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I authorize any person with knowledge of the relevant or important facts relating to this petition to release any pertinent information to the Iowa Board of Pharmacy. I hereby attest to the accuracy and truthfulness of the information contained herein.

Megan A. Kramer
Petitioner's Signature

4/19/2016
Date