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 [☒] 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? [☒] Initial Request [☐] Request for Renewal
If a request for renewal, explain below why the renewal is necessary.

I. Petitioner Information (include licensee/registrant name and name of contact person, i.e. pharmacist in charge)
Name: Grinnell Regional Medical Center #929 (George Papineau #19950 PIC) Phone No.: 641-236-2360
Address: 210 4th Ave
City: Grinnell State: IA Zip Code: 50112

II. Petition Information

1. Chapter Number and Title.
   Chapter 20 Compounding Practices

2. Rule Number(s) and Title(s).
   657—20.4(124, 126, 155A) Sterile Compounding
   657—20.5(126,155A) Delayed compliance

3. Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.
   A. Personnel training and evaluation in aseptic manipulation skills, USP <797> revision 2008.
   B. Facility Design and environmental controls, USP <797> revision 2008.

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.

A. The 2008 revision of USP <797> requires personnel who prepare CSPs to be trained by expert personnel through audio-visual instructional resources and professional publications on the skills required for aseptic manipulations. These personnel shall also pass written and media fill testing of aseptic manipulation skills initially and annually for low risk compounding. Gloved fingertip sampling is also to be completed annually.

1. Including anesthesia staff and RN's, GRMC has nearly 65 staff members that will need training and validation.
2. While pharmacy staff currently uses ASHP training videos and books for training, I don't think this is the correct media for nursing/anesthesia staff. I would like to find a video resource that is more in line with immediate use compounding and write or purchase a training guide for this type of compounding.
3. Because training material needs to be put together, and there are so many staff that need training and validation I am requesting a variance on this until April 1, 2017.

B. GRMC currently utilizes a CAI for non-hazardous compounding and a CACI vented outside for hazardous compounding. Neither of these isolators is located in an ISO class 7 cleanroom, and we have waivers from the manufacturers stating that placement in such a room is not required to maintain and ISO class 5 environments inside the isolators during dynamic operation. However, the rooms that these isolators are in lack appropriate facility design and environmental controls, including:

1. There are exterior windows in both rooms which prevent the walls from being free of crevices and windowsills which makes cleaning these areas difficult and may lead to dust collection.
2. We are in the planning stages of either remodeling the existing pharmacy or moving the pharmacy to the old physical therapy space which is vacant. As part of the remodel we will be installing either modular clean rooms and anterooms or "brick and mortar" clean rooms anterooms that are compliant with the current USP <797> revision and the pending 2016 revision. Additionally, the hazardous compounding rooms will be compliant with USP <800>. Due to the planning, engineering and cost considerations for this project I am requesting a variance until April 1, 2017.

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.

A. Training and aseptically validating the nursing and anesthesia staff will take time because training material has to be developed, and we have a large number of staff that needs to go through the training. I anticipate a fair amount of resistance to this training, this will consume valuable time in getting staff scheduled and trained.

B. Constructing new anterooms and cleanrooms for our CAI and CACI will take time due to planning, engineering, budgeting and actual construction. This is not something that can be done on short notice. I feel that our current isolators provide a safe, germ free environment for sterile compounding as evidenced by our staffs' negative aseptic validations and negative viable sampling with our volumetric impaction sampling device (1050 liters of air is sampled).

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

[☒] Yes [☐] No [☐] Do not know

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

Curt Gerhold, Compliance Officer, Iowa Board of Pharmacy, 319-310-8870

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

[☐] Yes [☒] 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 [☒] 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 [☒] No

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

C. 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.

George Papineau
Petitioner's Signature

4/5/2016
Date