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 [X] 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? [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: CHI Health Mercy Corning (Amy Wetzel) Phone No.: 641-322-6242 *(include area code)*

Address: 603 Rosary Drive

City: Corning State: IA Zip Code: 50841

RECEIVED
APR 15 2016
IOWA BOARD OF PHARMACY

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

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

   To prepare sterile compounds for administration per USP 797 standards

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.

   We are asking for a waiver to give our facility time to become compliant with USP 797 standards in regards to sterile compounding. We already have a negative pressure Compounding Aseptic Containment Isolator (CACI) which we utilize for hazardous medication preparation but we need to obtain a positive

pressure isolator/biological safety cabinet (BSC) for use in sterile compounding. To accomplish this, our plan is to create a separate positive pressure room that will house our BSC/isolator and a separate negative pressure room that our current CACI resides in. This will require a wall being constructed to divide the existing room. We are working with APEX to provide us with a blueprint of the proposed remodeling to accomplish our plan. We are also working with HVAC contractors to complete the necessary duct work/ventilation. We anticipate that this work may commence in July with an estimated completion date of November 30th, 2016. If there are any major changes that impact the completion date, the Board of Pharmacy will be notified.

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.

   There is anticipated construction and HVAC work that must be completed prior to establishing a positive pressure room that will contain the isolator/BSC that is separate from the negative pressure area in which our CACI resides. This construction is not feasible to be accomplished by the enforcement date of Chapter 20. We are currently working with contractors to complete this work and obtain a second CAI for use.

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

   [X] Yes [☐] No [☐] Do not know

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

   Jean Rhodes, Iowa Board of Pharmacy Compliance Officer

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.

Petitioner's Signature

4/13/16
Date