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)

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: Van Buren County Memorial Hospital; Mathew Porepp, PIC Phone No.: 319-293-3171 ext 1125

Address: 304 Franklin Street

City: Keosauqua State: IA Zip Code: 52565

Petition Information

1. Chapter Number and Title.

Chapter 20: Compounding Practices

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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.

The essence of rule 657—20.4(124,126,155A) Sterile compounding is to reduce risk of patient harm associated with compounded sterile products (CSPs). USP 797 guidelines offer direction to assure proper conditions and procedures are met during the compounding process. Observation of these guidelines improves quality of care and limits potential for adverse events.

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.

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USP 797 guidelines preclude medium risk products from being compounded as immediate use CSPs. Additionally, immediate use CSPs are intended only for emergency situations. As Van Buren County Memorial Hospital (VBCH) does not currently use a primary engineering control, a variance is requested to allow for medium risk products to be compounded as immediate use CSPs and that immediate use CSPs may be used for non-emergent situations. The proposed waiver would apply beginning May 18th, 2016 and remain in effect for 24 months. Included in this time frame are planning, funding, construction, and education to assure proper implementation of guidelines.

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.

Historically, VBCH contracted with a local retail pharmacy to provide hospital pharmacy services. Due to the nature of the service agreement, pharmacist presence on site was limited. Thus, movement toward compliance with USP 797 was not aggressively pursued. Beginning in January 2016, VBCH contracted with the University of Iowa Hospitals and Clinics (UIHC) and has been working to bring the pharmacy into compliance with all Iowa Board of Pharmacy rules. Due to the short time frame since UIHC partnering, the wide scope of this complex project, staff education and required culture change, the need for proper budget allocations for equipment/remodel, and to conduct a thorough review of pharmacy physical space, additional time is required to safely develop plans for full compliance with 657—20.4 (124,126,155A) Sterile compounding. An interim plan will be enacted to minimize patient risk during VBCH's system and structure modifications. Notably, the pharmacy contains a laminar airflow workbench. After recertification, this device will be used for all CSP preparation and an immediate use expiration date will be used for all products. Additionally, staff will be reeducated on proper aseptic technique to further minimize patient risk. Nurses will undergo media fill and fingertip testing to assure proper adherence to best practices. Reeducation and testing of staff will be targeted for completion within 6 months. Increased use of alternative products such as Vial-Mate and other ready-to-use commercially available products will be implemented immediately to minimize need for preparation of CSPs. If VBCH were not able to prepare medium risk CSPs or non-emergent CSPs, patient care would be significantly compromised resulting in increased morbidity and mortality.

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

   [☐] Yes [☐] No [x] 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 [☐] No [x] 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?

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[☐] 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.

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

4-11-16
Date