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.

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

Name: Keokuk Area Hospital-
Beth Davis, RPh- PIC
Phone No.: 319-526-8782
(include area code)
Address: 1600 Morgan St

City: Keokuk State: IA Zip Code: 52632

Petition Information

RECEIVED
APR 11 2016
IOWA BOARD OF PHARMACY

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.

   USP <797> states that smoke testing be completed as part of compounding isolator certification. This was not completed by certification provider. Sterile fingertip testing has not been completed as we are not required to garb per our isolator manufacturer (Baker). It was understood here that fingertip testing was to check garbing technique.

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.

Compounding isolator inspection was completed on 3/10/2016. A smoke test was not performed. We petition you to ask for a waiver to allow us to have the smoke testing completed in September 2016, which is the time that our next certification is due. I do not know at this time exactly what day the certification company will arrive so would ask that we have until September 30th of 2016 to be in compliance.

We have 4 Pharmacy personnel and 22 Nursing House Supervisors that will need to complete sterile fingertip testing. I would like to request that we receive a waiver to be able to complete all testing by June 15, 2016.

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.

   Keokuk Area Hospital is being run by Fitch Healthcare, a turn-around management group, in an effort to maintain a hospital here in south Lee county. Finances are extremely tight and incurring the expense of re-certifying our 2 compounding isolators prior to the next regularly scheduled inspection will bring about extra expenses at this time. Keokuk Area Hospital is a small community hospital with an average daily census of 12 patients. We perform mostly low risk sterile compounding with an occasional medium risk compound.

   Scheduling 22 Nursing House Supervisors to come in for training and completion of sterile fingertip testing when a Pharmacist is present and allowing for time to repeat the testing if someone fails will make it challenging to be in total compliance by 5/18/16. Pharmacy staff compound at least 90% of all IV compounding at Keokuk Area Hospital. All Pharmacy staff WILL have sterile fingertip testing completed by 5/18/16.

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.

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?

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[☐] Yes [☒] 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.

Beth Davis
Petitioner's Signature

4/8/16
Date