

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: Greene County Medical Center
Hospital Pharmacy License #258
Bonnie Orris, R.Ph
Pharmacist in Charge

Phone No.: 515-386-0174
(include area code)

Address: 1000 W Lincolnway

City: Jefferson

State: IA

Zip Code: 50129

Petition Information

1. Chapter Number and Title.

657 Chapter 20 Pharmacy Compounding Practices
Sterile Compounding USP<797>

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.

Our hospital pharmacy needs to perform sterile compounding in a compliant environment following 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.

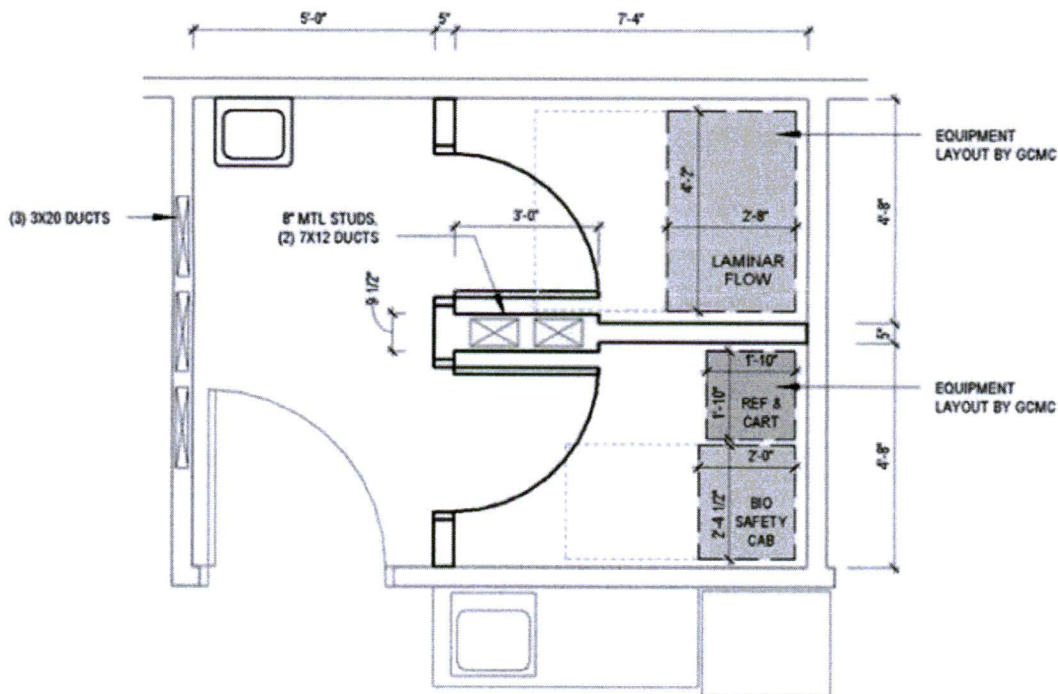
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MAY 20 2016

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A waiver is requested until 12-01-16. The engineering/architectural firm of HGA has completed the preliminary design plan for our USP <797> compliant clean-room that would allow preparation of both hazardous and non-hazardous sterile products of low and medium risk. The final plan will be complete in the next 30 days. The General Contractor Stockton and Associates will oversee the remodeling and modification of the current Greene County Medical Center Pharmacy anteroom and buffer area. Work is expected to commence by July 2016 or sooner. The preliminary plan is shown.



- 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.

Greene County Medical Center completed a multi-million dollar building expansion in August 2015. The architect and general contractor for the \$22 million project are the same firms chosen for this remodel. They have a firsthand knowledge of our present pharmacy. The 2015 expansion included a new pharmacy with compounding area. Board of Pharmacy Compliance Officer Jennifer Tiffany came onsite prior to the pharmacy moving into the new space. In November 2015, the Board of Pharmacy adopted more stringent sterile compounding rules. Time is needed and requested to modify our new space to carry us forward in compliance with 657-20.4 (124,126,155A). Jennifer Tiffany conducted an inspection of our new area as part of a Voluntary USP <797> Assessment in February 2016. She made recommendations for features in our new space that would need modification to be fully compliant with USP <797>. Discussion began immediately with the leadership of the medical center. They authorized structural modifications that will fully align the anteroom and buffer area with USP <797> standards. Jennifer Tiffany was included in an informational conference call between the architect, GCMC Pharmacist in Charge, Bonnie Orris, R.Ph. and Chief Nurse

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Executive Katie Heldt prior to the plan approval. The plan has received executive approval to move forward as soon as possible.

An interim plan for sterile compounding has been formulated. A new A2 Biological Safety Cabinet (BSC) will be placed in a dedicated segregated room near the present pharmacy. After certification of the new unit, all sterile compounding will occur in this temporary location during the construction phase. It is our policy to utilize manufacturer's premix solutions as much as possible. We also utilize proprietary Closed system Transfer Devices manufactured by Bag2Vial and PhaSeal. As such, sterile compounding will be held to a minimum during the interim period. All sterile compounds will be prepared by the pharmacist with beyond use dating less than 12 hours until USP<797> standards are fully in place.

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.

Jennifer Tiffany, R.Ph.
Compliance Officer
Iowa Board of Pharmacy
400 SW 8th St, Suite E
Des Moines, IA 50309
Mobile: 515-729-2462

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

Yes No Do not know

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

Yes No

If yes, describe below how similar situations were handled.

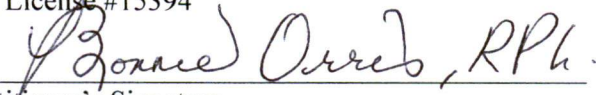
Conversations with Jennifer Tiffany, R.Ph. following the May 2016 Board of Pharmacy monthly meeting indicated that similar waiver requests had been approved. Jennifer advised that we move forward with construction.

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

Yes No

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.

Bonnie Orris, R.Ph.
Pharmacist in Charge
IA License #15394


Petitioner's Signature

05-18-16
Date