

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy  
400 SW 8<sup>th</sup> Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on  
Board's agenda is three weeks prior to Board meeting.

**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: Mike Zadina

Phone No.: 712-328-5094 | 402-350-5404  
*(include area code)*

Address: 800 Mercy Drive

City: Council Bluffs

State: IA

Zip Code: 51503

**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.

Our current negative pressure room that includes the BSA that we use for hazardous sterile compounding has an unsealed drop down ceiling. If we seal the ceiling, the pressure in the room will no longer be in an acceptable range. We will need to do significant construction with HVAC changes in order to be compliant

*Case No. or State ID No.*

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*Rec'd:*

*(FOR PHARMACY BOARD USE ONLY)*

RECEIVED

MAY 04 2016

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which will not be completed by May 18<sup>th</sup>. We are currently in the planning stages and weighing our different options. We hope to have everything completed by December 31<sup>st</sup> 2016. If there are 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.

We will need to do construction and HVAC work which will not be completed by May 18<sup>th</sup>. Our current setup does maintain an ISO 7 environment even without the correct type of ceiling. Also, all of our environmental sampling done in this area has been within acceptable ranges. We only compound an average of one to two hazardous sterile compounds per week.

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, Iowa Board of Pharmacy Compliance Officer 515-729-2462  
Mike Tiesi, Senior Regional Pharmacy Director, CHI Health 402-717-2614

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.

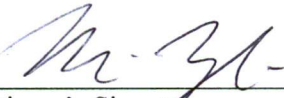
9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

Yes       No

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

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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

4-28-16  
\_\_\_\_\_  
Date

I am available by phone if any questions arise during the review of this request.  
Office: 712-328-5094  
Cell: 402-350-5404