

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: Allen Memorial Hospital Pharmacy Phone No.: 319-235-3510
License #354 *(include area code)*
Pharmacist in Charge Timothy Schmidt

Address: 1825 Logan Ave.

City: Waterloo State: IA Zip Code: 50703

Petition Information

- Chapter Number and Title.
Chapter 20 COMPOUNDING PRACTICES
- Rule Number(s) and Title(s).
20.4 Sterile compounding.
- Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.
USP Chapter 797
Hazardous Drugs as CSPs
All hazardous drugs shall be prepared in a BSC placed in an ISO Class 7 area.
- 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.

RECEIVED
JUN 08 2016
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The BSC is not in an ISO Class 7 area. The BSC is in an area that meets the USP<800> definition of a containment segregated compounding area. The BSC meets ISO Class 5 in the existing area. A waiver is requested to follow USP<800> environmental control rules instead of current USP<797> rules until USP Chapter 797 is updated.

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.

The briefing for USP Chapter 800 from http://www.usp.org/sites/default/files/usp_pdf/EN/m7808_pre-post.pdf states:

Facility requirements that differ from Pharmaceutical Compounding—Sterile Preparations <797> and this chapter will be harmonized through an upcoming revision of <797>, which will include the following: ...

- Addition of an allowance in <800> for a Containment Segregated Compounding Area (C-SCA), a separate, negative pressure room with at least 12 air changer per hour (ACPH) for use when compounding HDs. Low- and medium-risk HD compounded sterile preparation (CSP) may be prepared in a BSC or compounding aseptic containment isolator (CACI) located in a C-SCA, provided the beyond-use date of the CSP does not exceed 12 hours.

2016 USP Compounding Compendium Chapter 800 5.3.2 Sterile Compounding states:

The C-PEC must be located in a C-SEC, which may either be an ISO Class 7 buffer room with an ISO Class 7 ante-room (preferred) or an unclassified containment segregated compounding area (C-SCA). If the C-PEC is placed in a C-SCA, the beyond-use date (BUD) of all compounded sterile preparations (CSPs) prepared must be limited as described in <797> for CSPs prepared in a segregated compounding area.

Proposed USP Chapter 797 (http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/usp-gc-797-proposed-revisions-sep-2015.pdf) 4.2 Facility Design and Environmental Controls states:

A BSC used to prepare only Category 1 CSPs can be placed in an unclassified area. If used to prepare Category 2 CSPs, the BSC must be located within a restricted access buffer area with an ISO Class 7 or better air quality. If a BSC is used to prepare hazardous drugs, see <800>.

Proposed USP Chapter 797 defines segregated compounding area as “A designated, unclassified space, area, or room that contains a PEC and is suitable for preparation of Category 1 CSPs only.”

Current USP Chapter 797 defines Segregated compounding area as “A designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 (see Table 1) air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.”

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.

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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.

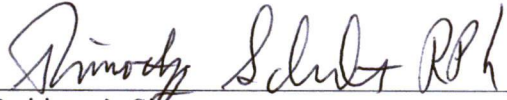
9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

Yes No

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

May 4th 2016 Iowa Board of Pharmacy Meeting item 13 Request for Waiver 657 IAC 20.4 Sterile
Compounding – Allen Memorial Hospital Pharmacy, Waterloo
Clarification of waiver requested for June board meeting.

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

6-6-2016
Date