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 [X] 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? [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: Lucas County Health Center
Ann Moon PIC
Address: 1200 N Seventh St.

Phone No.: (641) 774-3212
(include area code)

City: Chariton State: IA Zip Code: 50049

Petition Information

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APR 13 2016
IOWA BOARD OF PHARMACY

1. Chapter Number and Title.

   USP 797 Sterile Compounding

2. Rule Number(s) and Title(s).

   657-20.5(126,155A)

3. Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.
   USP chapter 797 has been adopted by the Iowa Board of Pharmacy to regulate all sterile compounding done by pharmacies in the state.

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 hospital pharmacy currently does not meet the USP 797 requirements for our clean room and we need the waiver if granted to be effective immediately. I am unsure on the end date—we have requests for bids on different vendors' CAIs and CACIs. We also are having a contractor currently working at our site draw up

plans for an ante room as well as adjacent clean rooms for the appropriate hoods. This process is very time consuming. I would expect it to take a few months for the new CAI and CACI to arrive after purchased, so we may be looking at a year.

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.
Our pharmacy has been operating as an immediate use pharmacy since the early 2000's because we have such a low census and only one R.Ph. employed because of budget restraints. We have always purchased as many pre-made products and advantage system antibiotics as possible, and the med surge nurse prepares her IV solution immediately before hanging. Nothing we prepare is stored or saved for later but hung as soon as it is made. The R.Ph. would prepare in our LAF any preparations requiring more than 3 ingredients but when pharmacy is closed the nurse would have to make any new order until the pharmacy was open again.. We prepare a very small volume of chemotherapy in our Biologic Safety cabinet (an average of 20 solutions per month) and each of these solutions is prepared after patient has arrived and is ready to receive it.
Compliance Officer Rhodes informed us at her invaluable information session we are not an immediate use facility. Our hardship is we sincerely felt we were immediate use, and were planning to purchase the CACI to meet the needs of USP 800 since we felt we were 797 compliant. USP 797 is a budget buster for any small facility. Even if we could outsource some solutions, a few of the chemotherapy preparations must be administered within one hour of preparation;

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

[X] Yes [ ] No [ ] Do not know

If yes, list their names, addresses and phone numbers below.
Jean Rhodes

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

[ ] Yes [X] 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?

[X] Yes [ ] No

If yes, describe below how similar situations were handled.
I know that waivers have been granted to aid in pharmacies becoming compliant with USP 797.

9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?NO

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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.

Ann C. Moon RPh. PIC 4-11-16

Petitioner's Signature Date

Pat. #	Patient Name	Room	Adm. Date	Age	Weight LB /KG	Height IN /CM	Creatinine Serum	Creatinine Date	Creatinine Clearance
505192	WHITE MIRANDA M	119-1	04/10/16	19	240/108	64.00/162			* NA *
505009	WHITE KAREN A	136-1	04/07/16	66	233/105	66.00/167			* NA *
505130	FUNK GEORGE MURRAY	138-1	04/08/16	88	181/ 82	71.00/180			* NA *
504448	ROBISON CAROL E	139-1	03/28/16	87	117/ 53	63.00/160	.81	04/08/16	40.09
505186	WADLE DARRELL	140-1	04/10/16	84	162/ 73	69.00/175	1.22	04/10/16	45.07