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: Gregory Young, RPh, PharmD, PIC Phone No.: 515-247-3262
(include area code)

Address: Mercy Med. Center 1111 Sixth Ave. (license 321)

City: Des Moines State: IA Zip Code: 50314

Petition Information

RECEIVED
APR 18 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.

   Full compliance with USP 797 sterile compounding requirements

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.

   With recent changes in USP 797 requirements, the sterile compounding environment of the Surgery and adult Critical Care area Pharmacy satellite does not meet the new requirements. Construction will be required to meet them. Sterile products prepared within this pharmacy satellite are administered within 24 hours of

preparation, with many being administered immediately after preparation. The infection risk in either case is extremely limited. Having the compounded products available from the pharmacy satellite enhances patient care because of the close proximity to the OR suites, Recovery Room, and adult Critical Care Area. This makes critically needed products available to patients much more expeditiously (compared to preparing and sending the same products from the main inpatient pharmacy area). Necessary changes involving construction are being planned. Funding for the construction is currently being sought (approximately $ 90,000) and additional planning undertaken. An end date for this waiver of May 1, 2017 is requested to allow for completion of this project. I've also included a copy of the estimate that I've received for the required construction.

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 rule doesn't pose an undue hardship long-term, but short-term (until May 1, 2017) it does due to the need to plan, obtain funding for, and complete the necessary construction. If our waiver isn't granted, we will need to close our pharmacy satellite which would have a more significant negative impact on patients being cared for in the Mercy Medical Center Surgery Dept, Recovery Room, and adult critical care areas (as described in 4. above).

   Thank you for considering this request for a waiver. Please let me know if additional information would be helpful.

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.

   My understanding is that the Board of Pharmacy understands the challenges posed by the new USP797 reqs. and is considering waivers with a reasonable timeframe to allow for compliance.

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.

Education and communication provided by Jennifer O'Toole and other BOP compliance officers related to the new USP797 reqs. This has been greatly appreciated!

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

April 15, 2016
Date

Mercy - Des Moines (License # 321)

SME Mechanical

Date: 4/15/2016

Job: Sat. Pharmacy

JOB #:

Cost Breakdown for: Sat. Pharmacy					
DESCRIPTION			**Qty. or Lump Sum**	**COST**	**TOTALS**
Major Equipment Cost					
VAV			L.S.	600.00	
Back-draft Dampers			L.S.	300.00	
Fan Moduals			L.S.	5,500.00	
			L.S.		
			L.S.		
			L.S.		
			L.S.		
material subtotal				**6,400.00**	
sales tax on material				384.00	
Total Material & Equipment Cost				**6,784.00**	**6,784.00**
Field Labor: **REGULAR RATE:**					
General Foreman	$	66.15	0.00	0.00	
Foreman	$	63.95	0.00	0.00	
Journeyman	$	61.67	75.00	4,625.25	
Apprentice	$	43.16	75.00	3,237.00	
OVERTIME RATE:					
General Foreman	$	99.23	0.00	0.00	
Foreman	$	95.93	0.00	0.00	
Journeyman	$	92.51	0.00	0.00	
Apprentice	$	64.74	0.00	0.00	
Total Labor Hours & Cost			**150.00**	**7,862.25**	**7,862.25**
Shop Labor: **REGULAR RATE:**					
General Foreman	$	70.56	0.00	0.00	
Foreman	$	68.21	8.00	545.68	
Journeyman	$	65.78	14.00	920.92	
Apprentice	$	48.81	14.00	683.34	
OVERTIME RATE:					
General Foreman	$	105.84	0.00	0.00	
Foreman	$	102.32	0.00	0.00	
Journeyman	$	98.67	0.00	0.00	
Apprentice	$	73.22	0.00	0.00	
Total Labor Hours & Cost			**36.00**	**2,149.94**	**2,149.94**
Management Labor: **REGULAR RATE:**					
Supervision	$	69.00	8.00	552.00	
Project Management/Detailing	$	69.00	40.00	2,760.00	
Engineer	$	80.00	12.00	960.00	
Drafting	$	55.00	0.00	0.00	
Total Labor Hours & Cost				**4,272.00**	**4,272.00**
Subcontracts:					
Insulator			L.S.	3,500.00	
Electrical			L.S.	8,750.00	

Plumbing		L.S.	10,750.00	
Controls		L.S.	0.00	
Graham Construction		L.S.	35,000.00	
Total Subcontract Cost		**L.S.**	**58,000.00**	**58,000.00**
Job Expense:				
Stock Material		L.S.	1,400.00	
General Conditions		L.S.	650.00	
Travel Pay		L.S.	0.00	
Equipment Rental		L.S.	0.00	
Delivery		L.S.	240.00	
Total Job Expense Cost		**L.S.**	**2,290.00**	**2,290.00**
RECAP				
Sub-Total Cost				**81,358.19**
Overhead		10.0%		1,657.42
Profit		10.0%		1,657.42
Equipment Mark-up		10.0%		678.40
Subcontracts Mark-up		8.0%		4,640.00
TOTAL COST (rounded)				***90,000.00***