Case No. or State ID No.
Rec'd:
(FOR PHARMACY BOARD USE ONLY)

IOWA BOARD OF PHARMACY
Petition for [X] Waiver [ ] Variance

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: Grundy County Memorial Hospital - UnityPoint Health Phone No.: 319-824-4135
Pharmacy License #55
Barry Westbrook, RPh - Pharmacist in Charge

Address: 201 East J Ave

City: Grundy Center State: IA Zip Code: 50638

Petition Information

1. Chapter Number and Title.

   657 - Chapter 20 - Compounding Practices
   USP39-NF34 General Chapter <797> Pharmaceutical Compounding - Sterile Preparations

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

   657—20.4(124,126,155A) Sterile compounding. Iowa-licensed pharmacies that compound sterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 797 standards. Additional USP chapters incorporated by reference into USP Chapter 797 shall also be followed.
   [ARC 2194C, IAB 10/14/15, effective 11/18/15]

3. Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.

   Routine sterile compounding may occur only if standards are met under USP <797> which include preparing sterile compounds in an ISO 5 or better environment.

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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.

Grundy County Memorial Hospital (GCMH) pharmacy department currently does not have a primary engineering control that maintains an ISO class 5 environment for preparing sterile compounds. Grundy County Memorial Hospital is petitioning for a waiver to begin on May 18, 2016. The waiver is being asked to be in place until GCMH completes renovation of the pharmacy department to meet USP <797> standards. Renovation of the pharmacy department is anticipated to be completed by December 31, 2017.

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.

Current practice at GCMH is that nursing will compound sterile preparations just prior to administration to the patient. This is due to pharmacy lacking equipment and environmental controls to prepare doses in advance for patient use. Nursing is only allowed to prepare low risk sterile compounds. In order to deliver better patient care, and advanced patient care, GCMH pharmacy department will undergo a renovation. The pharmacy department renovation includes creation of a ISO Class 7 buffer room with an attached ISO class 8 ante room. The primary engineering control to maintain ISO Class 5 environment will be a laminar air flow workbench placed within the buffer room. Creating the needed ISO classified environments will enhance patient care and make GCMH pharmacy department compliant with current state and USP standards. Renovation is planned to also meet proposed changes to USP <797> making GCMH compliant for the future. Until GCMH has completed its renovation project, we are petitioning the Iowa Board of Pharmacy for a waiver exempting compliance with Rule 20.4 - Sterile Compounding and allowing current sterile compounding practice to continue. GCMH will utilize premixed sterile preparations, proprietary bag and vial systems to our fullest extent possible to limit sterile compounding by nursing.

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.

Jennifer O'Toole
Pharmacist, Compliance Officer
Iowa Board of Pharmacy
400 SW 8th St, Suite E
Des Moines, IA 50309
jennifer.otoole@iowa.gov
Phone 515.729.2465

Sharon Meyer, PharmD, MS
Director of Pharmacy Management
UnityPoint Health Consolidated Services
4488 112th Street
Urbandale, Iowa 50322
Office: 515-252-2647
Sharon.Meyer@unitypoint.org

Jennifer Havens
Chief Executive Officer
Director of Nursing
Grundy County Memorial Hospital - UnityPoint Health
201 East J Avenue
Grundy Center, IA 50638
(319) 824-5080 - office
jennifer.havens@unitypoint.org

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

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

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

[ ] Yes [X] No

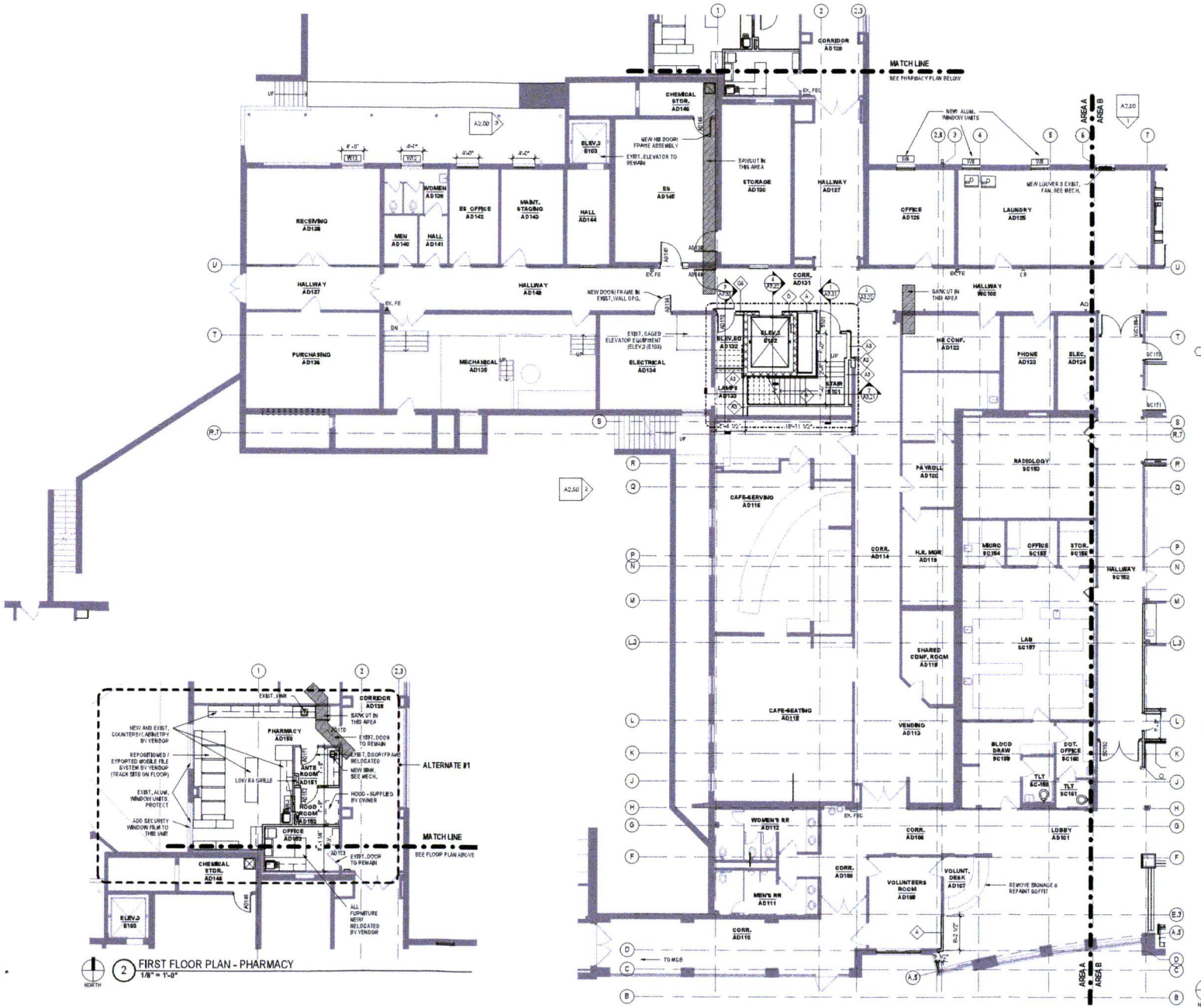
9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

[ ] Yes [X] 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.

Barry Westbrook Rph. 4-12-16

Petitioner's Signature Date



1 FIRST FLOOR PLAN - AREA A
1/8" = 1'-0"

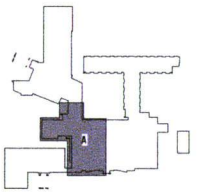
2 FIRST FLOOR PLAN - PHARMACY
1/8" = 1'-0"

GENERAL FLOOR PLAN NOTES:

1. REFER TO ADDITIONAL NOTES AND REQUIREMENTS ON ALL OTHER DOCUMENTS, OTHER DISCIPLINES AND SPECIFICATIONS.
2. REFER TO G0.01 FOR GENERAL CONSTRUCTION NOTES.
3. ALL SITE INFO, FIXTURES AND EQUIPMENT SHOWN ON THIS SHEET IS PROVIDED FOR COORDINATION PURPOSES ONLY. THE LAYOUT IS CONSIDERED CONFIDENTIAL. REFER TO CIVIL, MECHANICAL, ELECTRICAL, PLUMBING, FIRE SPRINKLER, LIFE-SAFETY, ETC. DOCUMENTS FOR SPECIFIC DESIGN INFORMATION.
4. NO OBSTRUCTIONS SHALL PREVENT A FINISHED CEILING HEIGHT NOTED ON THE DRAWINGS IN THOSE AREAS RECEIVING CEILING TREATMENT. PLACEMENT COORDINATION BETWEEN TRADES IS REQUIRED.
5. INSTALL VERTICAL EXPANSION JOINT MINIMAL AT COLUMN GRID LINES AND AT THE HEAD OF DOOR JAMB/OPENINGS OR AS OTHERWISE NOTED OR WHERE REQUIRED PER STANDARD MATERIAL PRACTICE TO REDUCE STRESS CRACKING. NO CONTROL JOINT/EXPANSION JOINT AT MAIN STRUCTURAL BEARING. KEEP AWAY 2'-4" MIN.
6. CAULK & SEAL ALL CONTROL/EXPANSION/SAWCUT JOINTS AT ALL INTERIOR & EXTERIOR MASONRY & CONCRETE.
7. REFER TO FINISH SCHEDULE, PLANS AND INTERIOR ELEVATIONS FOR FINISH INFORMATION.
8. REFER TO A0.02 FOR DOOR SCHEDULE
9. REFER TO A2 SERIES FOR FLOOR FINISHES
10. REFER TO A0.20 FOR WALL TYPES. WALL TYPE A IS TYPICAL UNLESS NOTED OTHERWISE
11. PATCH EXISTING FLOORS AND WALLS AS NEEDED DUE TO DEMOLITION
12. SEE A0.42C FOR ADDITIONAL INFORMATION ON EXTERIOR WALL/WINDOW MODIFICATIONS.
13. EXISTING ALUM. WINDOW: APPLY SECURITY WINDOW FILM TO MATCH CURRENT GLAZING FILM APPLIED.

FLOOR PLAN KEYNOTE LEGEND

1 INFILL OPENING FROM DEMOLITION. WALL TYPE AND THICKNESS TO MATCH EXISTING WALL CONSTRUCTION
8 CASEWORK- REFER TO INTERIOR ELEVATION
9 PROJECTOR SCREEN- OFCI



KEY PLAN - FIRST FLOOR AREA A
NOT TO SCALE

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BISHOP ENGINEERING
CONSTRUCTION MANAGER
GRAHAM CONSTRUCTION

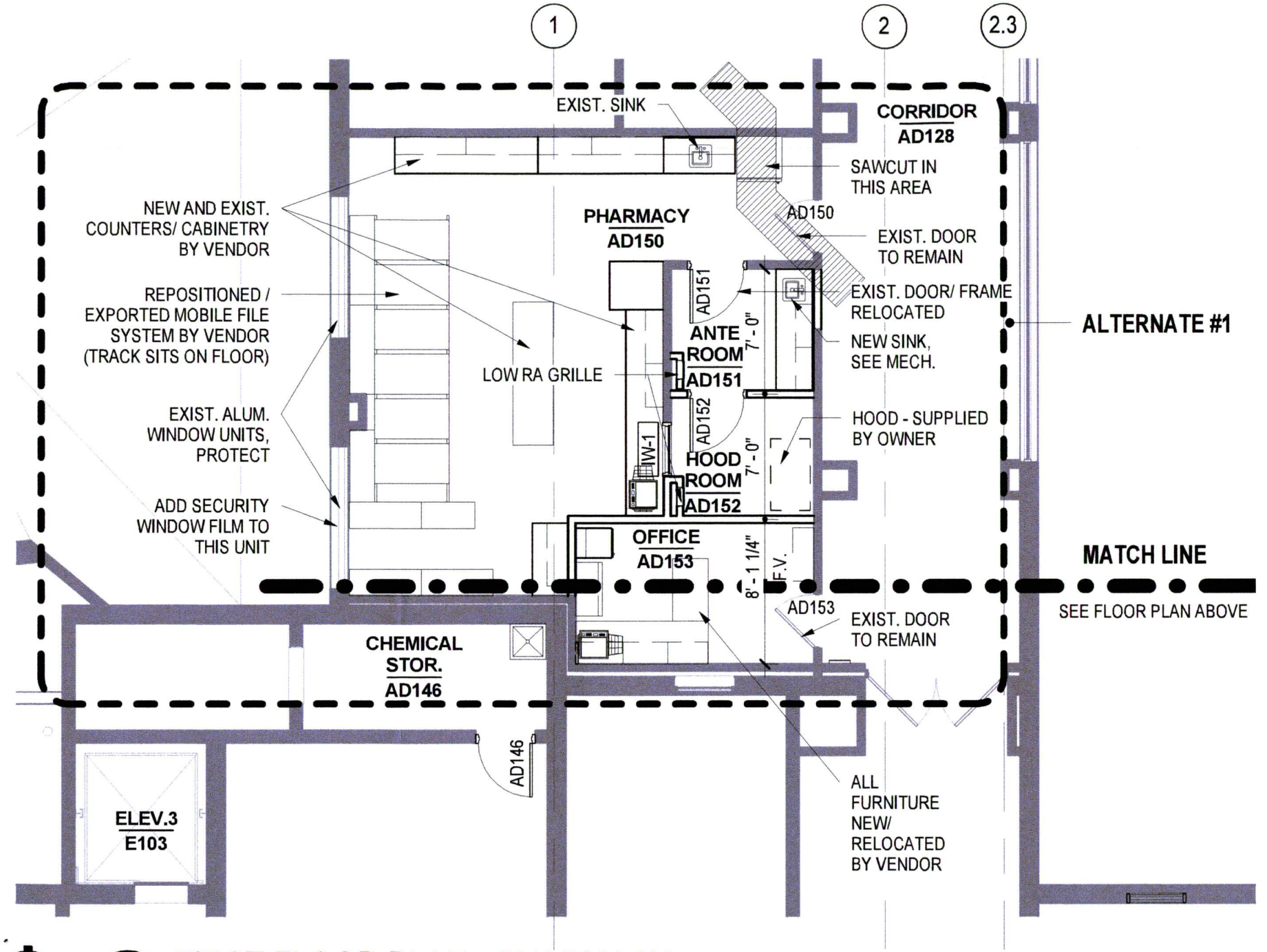
REVISIONS:

Description	Date	No.

OWNER SIGN-OFF:
DATE NAME

GRUNDY COUNTY MEMORIAL HOSPITAL
SPECIALTY CLINIC EXPANSION
201 East J Avenue, Grundy Center, IA 50638

PROJECT NO: 15047
DATE: 03.17.2016
SHEET SET: BID DOCUMENTS
SHEET NAME: FIRST FLOOR PLAN - AREA A
SHEET: A1.11



NORTH

2 FIRST FLOOR PLAN - PHARMACY

1/8" = 1'-0"