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: Mercy Medical Center North IA/David B. Blaha, Pharm.D. Phone No.: 641-428-6874 *(include area code)*

Address: 1000 4th Street SW

City: Mason City State: IA Zip Code: 50401

Petition Information

1. Chapter Number and Title.

   657 – Pharmacy Board

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

   7.8 (8) – Drug Distribution and Control

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

   Samples. The use of drug samples within the institution shall be eliminated to the extent possible. Sample use is prohibited for hospital inpatient use. If the use of drug samples is permitted for hospital outpatients, that use of samples shall be controlled and the samples shall be distributed through the pharmacy or through a process developed in cooperation with the pharmacy and the institution's appropriate patient care committee, subject to oversight by the pharmacy.

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.

Requesting to be allowed to administer "initiation doses" of long-acting antipsychotic medications (ie. Invega Sustenna, Abilify Maintenna, etc) as part of the manufacturer's inpatient hospital pharmacy initiation trial programs for a period of 3 years.

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.

   Psychiatric illness is a major public health/safety issue that needs to be addressed. These patients are commonly uninsured or are on Medicaid, and do not attend scheduled appointments. The ability to treat them with a long-acting antipsychotic medication while captive as an inpatient has benefits to the patients and the public. These medications are very expensive and are not reimbursed in the inpatient arena, so a few manufacturers have developed "inpatient hospital trial programs." These trial programs are being used throughout the state, but the medications could be considered samples, which is in violation of the above Board rule.

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.

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.

   I have contacted and discussed with our Compliance Officer, Jennifer O'Toole.

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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

4/19/16
Date