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Petition for [X] Waiver [D] Variance (check the appropriate box)

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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. <u>Example:</u> 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 <u>not</u> 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: Mindi Jorgenson Phone No.: 641-628-6616 (include area code) PIC Pella Regional Health Center Hospital Pharmacy

Kent BreemsPhone No.: 641-628-1214PIC Pella Regional Health Center Retail Pharmacy

Address: 404 Jefferson St and 802 Washington St

City: Pella State: IA Zip Code: 50219

Petition Information

1. Chapter Number and Title.

155A.13 Pharmacy license 124.303 Controlled Substances, Registration

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

N/A radius for the first state of the first state

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

Chapter 155A.13 Pharmacy license requires that a license is obtained to start, run and maintain a pharmacy business in the state of Iowa. Chapter 124.303 is the same requirement for controlled substances.

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.

Pella Regional Health Center critical access hospital operates with 3 different pharmacy licenses. License #1520 is a general pharmacy license for our retail pharmacy in the community at 802 Washington St., License #268 is a Hospital Pharmacy License at 404 Jefferson St. and License #1136 is a General Pharmacy License to operate our Instymeds machine in the Emergency Department, also at 404 Jefferson St. All pharmacies serve the Pella and the surrounding communities.

Pella Regional Health Center also operates a clinic in Pella, attached to our Critical Access Hospital. This clinic creates anywhere between 110 and 115 thousand prescriptions a year.

Pella Regional Health Center would like to start and maintain a First Fill Pharmacy in this attached clinic utilizing General Pharmacy License #1520 from our community retail pharmacy, thereby allowing us to utilize the community pharmacy's computer system, Premier Retail Contract pricing and inventory, but to fill and dispense at a satellite location in the Pella Regional Clinic. We would like to trial this for a period of 2 years to July 2017 - July 2019 to assess the effectiveness of this business model.

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.

It is well documented and publicized in a number of journals that nearly 1/3 of all prescriptions are never picked up from the pharmacy. With the physicians in our clinic prescribing nearly 115,000 prescriptions, that gives us an estimated 38,000 scripts never picked up at the pharmacy. This can be due to prescription cost, the need for prior authorization and/or lack of time to go to the pharmacy after a clinic visit to pick up the prescription. Pella Regional Health Center would like to address this issue by implementing a First Fill Pharmacy in our clinic setting. By employing a pharmacist in this clinic to work with our Pella Regional Health Center employed physicians, we can focus our attention on getting initial prescriptions filled and providing extra assistance on compliance issues, cost, prior authorization, and education. Picking up a prescription prior to leaving the clinic is also saving time for the patient. Unfortunately, cost to start a new pharmacy is a limiting factor for us to address these issues. As a small facility, we are limited in funding to purchase the computer system (\$625/month, \$7500/year, not including computers needed), Pharmacy Licensing (\$135), CSA registration (\$90), DEA registration (\$1523), and point of sale system (\$15,000 for equipment).

We propose creating a satellite pharmacy of our current retail pharmacy that will be manned by licensed pharmacists and certified and registered technicians employed by Pella Regional Health Center at a location inside our Pella Clinic. Prescriptions will be scanned into our retail pharmacy system and order entry and insurance adjudication will be performed at our retail pharmacy. There is a provision in our software for a remote fill site, so we would be able to set up a printer at our clinic pharmacy for a label to print. Prescriptions will be filled at the clinic pharmacy location, from an inventory kept as an extension of the retail pharmacy's inventory which will then be checked and dispensed as per Iowa Administrative Code 657, Chapter 8 Universal Practice Standards.

Pella Regional Health Center would be willing to pilot this project as per Iowa Administrative Code 657-8.40 (155A 84GA, ch63) Iowa pharmacy pilot or demonstration research projects. By allowing this as a demonstration we would test our theory that by having this pharmacy nearby to the physicians in the physical clinic, we can decrease the number of first fill prescriptions that are never picked up at the pharmacy. We can track the medication classes being prescribed and pharmacy interventions made to prescriptions. We could also potentially track patient savings by pharmacist interventions in the clinic.

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

[X] Yes [D] No

[D] Do not know

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

Jean Rhodes and Terri Witkowski of the Iowa Board of Pharmacy

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

[D] Yes

[[]] Do not know

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

[X] No

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

[D] Yes [X] No

If yes, describe below how similar situations were handled.

Not aware of any similar situations.

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

[D] Yes [X] 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.

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