

BEFORE THE IOWA BOARD OF PHARMACY

Re:)
THE APPLICATION FOR)
NONRESIDENT PHARMACY) **PRELIMINARY NOTICE OF**
LICENSE OF) **INTENT TO DENY LICENSE**
)
Z-Stat Medical, LLC,)
Applicant.)

TO: Z-Stat Medical, LLC
d/b/a Oldsmar Pharmacy
34911 US Hwy 19N, Ste 525A
Palm Harbor, FL 34684

YOU ARE HEREBY NOTIFIED that on March 12, 2014, the Iowa Board of Pharmacy voted to deny your application for a nonresident pharmacy license. The intent to deny licensure is based upon the following:

LEGAL GROUNDS

The applicant applied for an Iowa nonresident pharmacy license in accordance with Iowa Code section 155A.13A(1) and 657 Iowa Administrative Code rule 19.2. The Board has authority to deny an application for licensure in accordance with Iowa Code sections 155A.13A(1)(d) and 155A.13A(3) and 657 Iowa Administrative Code rules 8.11, 19.10, and 36.1(4)(a).

FACTUAL CIRCUMSTANCES

Z-Stat Medical, LLC, d/b/a Oldsmar Pharmacy submitted an application for an Iowa nonresident pharmacy license to the Iowa Board of Pharmacy. The applicant indicated on its application that it did not dispense controlled substances. The applicant also indicated that it did not employ any pharmacy technicians or pharmacy support persons. A compliance officer with the Board contacted the applicant and asked if the pharmacy could fill a prescription for topical testosterone, which is a controlled substance. A pharmacy technician returned the call and stated the pharmacy would be happy to fulfill the order if it was submitted to them by one of their "contracted physicians."

NOTICE OF APPEAL RIGHTS

Pursuant to the provisions of 657 Iowa Administrative Code rule 36.16, you may appeal the Board's preliminary notice of denial of licensure by serving a written notice of appeal and request for hearing upon the board not more than thirty (30) days following the date of mailing of this notice. The request for hearing shall specifically describe the facts to be contested and determined at the hearing. The hearing shall be held pursuant to the process outlined at 657

Iowa Administrative Code rules 35.19 and 36.8. If an appeal is not filed within this time period, this preliminary notice of intent to deny licensure will become final.

Dated: March 12, 2014



EDWARD MAIER, Chairperson
Iowa Board of Pharmacy
400 SW Eight Street, Suite E
Des Moines, Iowa 50309-4688

cc: Laura Cathelyn
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF THE
APPLICATION FOR A NONRESIDENT
PHARMACY LICENSE FILED BY:

Z-STAT MEDICAL, LLC,
d/b/a OLDSMAR PHARMACY

DIA NO: 14PHB021

FINDINGS OF FACT,
CONCLUSIONS OF LAW,
DECISION AND ORDER

On April 29, 2014, a hearing was held before the Iowa Board of Pharmacy (Board) on the Request for Reconsideration, which was filed by Z-Stat Medical, LLC d/b/a Oldsmar Pharmacy (Applicant), from the Board's Notice of Intent to Deny its application for a nonresident pharmacy license. The following members of the Board presided at the hearing: Edward Maier, Chairperson; Susan Frey; James Miller; Edward McKenna; LaDonna Gratiyas; and Judith Trumpy. The Applicant was self-represented by its owner Larry Smith and by its pharmacist-in-charge Dorothy Vinson. Mr. Smith and Ms. Vinson appeared for hearing by telephone, and the exhibits were mailed to them prior to hearing. Assistant Attorney General Laura Cathelyn represented the state. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing. The hearing was open to the public, pursuant to Iowa Code section 272C.6(1)(2013), and was recorded by a certified court reporter. After hearing the testimony and examining the exhibits, the Board convened in closed executive session, pursuant to Iowa Code section 21.5(1)(f), to deliberate its decision. The administrative law judge was instructed to prepare the Board's Findings of Fact, Conclusions of Law, Decision and Order, in conformance with the Board's deliberations.

THE RECORD

The record includes the testimony of Compliance Officer Andrew Funk, Larry Smith, and Dorothy Vinson and State Exhibits 1-8 (See Exhibit Index for description).

FINDINGS OF FACT

Submission and Review of Initial Application

On October 21, 2013, Z-Stat Medical, LLC, d/b/a Oldsmar Pharmacy (hereinafter "Oldsmar Pharmacy") of Palm Harbor, Florida submitted an application to the Iowa

Board of Pharmacy (Board) for a new nonresident Iowa pharmacy license. Applicants for a nonresident pharmacy license are required to provide:

- ownership, staffing, and contact information for the pharmacy;
- a copy of their current home state license, permit or registration;
- the most recent inspection report from the home state and evidence of correction of any noncompliance;
- policies and procedures regarding the records to be maintained for controlled substances delivered, dispensed, or distributed to ultimate users in Iowa;
- policies and procedures evidencing that the pharmacy provides toll-free telephone service to facilitate communication with ultimate users in Iowa and a pharmacist who has access to the ultimate user's records in the pharmacy. Policies and procedures shall include evidence that such pharmacist is available at least 6 days and at least 40 hours per week;
- A prescription label including the toll-free number; and
- A complete, typewritten description of the type of pharmacy practice, i.e. retail, hospital, compounding, central fill, central processing, etc. including a description of the prescription drugs and services provided to patients in Iowa.

(State Exhibit 3)

The initial application filed by Oldsmar Pharmacy identified the pharmacist-in-charge as George Chrysakis but did not list any staff pharmacists, registered technicians, pharmacist-interns, or supportive personnel. Oldsmar Pharmacy included a copy of its Florida pharmacy license and a copy of its Drug Enforcement Administration (DEA) certificate with the application. The DEA certificate authorizes Oldsmar Pharmacy to dispense controlled substances. The application included the most recent inspection report for Oldsmar Pharmacy by the state of Florida, which was dated July 22, 2013. This was prior to Larry Smith's purchase of the pharmacy in September 2013. (Testimony of Andrew Funk; Larry Smith; State Exhibit 3)

The initial application also included two letters signed by owner Larry Smith. The letters provided answers to questions C, D, and E found in section 10 of the application and state that Oldsmar Pharmacy:

- is a community pharmacy licensed in the state of Florida that dispenses and mails non-sterile compounds to prescribed patients and does not dispense Scheduled Drugs;

- has had no issues of noncompliance in its most recent inspection report;
- does not dispense controlled substances; and
- has the following business hours: M-F 8:30-5:00 and Sat. 9:00-12:30. The pharmacy's toll-free number is printed on each label affixed to each prescription drug container. A copy of the label was attached to the letter.

(State Exhibit 3)

The Oldsmar Pharmacy nonresident license application was reviewed by one of the Board's Compliance Officers, Registered Pharmacist Andrew Funk. Mr. Funk felt that it was unusual for an applicant to submit a DEA certificate while claiming on the application that it does not dispense any controlled substances. On February 10, 2014, Mr. Funk used his personal cell phone to call the toll-free number provided by Oldsmar Pharmacy. Mr. Funk left a message for Oldsmar Pharmacy stating that he had a prescription for topical testosterone cream that he wanted to have filled. Topical testosterone cream is a schedule III controlled substance. (Funk testimony; State Exhibits 4, 5)

On February 11, 2014, Mr. Funk received a voice mail message response from a woman who identified herself as Tayla (phonetic) Smith from Oldsmar Pharmacy. Mr. Funk prepared the following transcription¹ of this message:

Hi my name is Tayla Smith, I'm calling from Oldsmar Pharmacy returning your phone call from yesterday afternoon. I'm calling, umm, to let you know that we actually have contracts with specific doctors and they forward prescriptions to us directly. So if you have a prescription that you would like filled if your doctor has a contract with us then we will gladly take care of it. If it's just a prescription that your doctor has given you to be filled then we do not handle, umm, walk-ins. So, if you have any question or concerns you can give us a call back. Our toll-free number is 855-781 8124 and have a great day, thanks.

(Funk testimony; State Exhibit 5)

¹ Andrew Funk was able to locate and play the voice mail message from his personal cell phone during the appeal hearing. The audio of the voice mail was consistent with the written transcription in Exhibit 5. (Funk testimony)

Andrew Funk submitted a Nonresident Pharmacy Application Review Summary Report for Oldsmar Pharmacy to the Board. Mr. Funk was concerned that while the application stated that Oldsmar Pharmacy did not dispense controlled substances, a pharmacy technician had responded to his request to fill a prescription for topical testosterone and stated that the pharmacy would be happy to fulfill the order if it was submitted by one of their "contracted physicians." (Funk testimony; State Exhibit 4)

On March 12, 2014, the Board issued its Preliminary Notice of Intent to Deny License to Z-Stat Medical, LLC d/b/a Oldsmar Pharmacy. The denial was based on the concerns raised in Mr. Funk's Application Review Summary, including the concerns about misrepresentation, fraud, and the use of contracted physicians. (State Exhibits 2, 4)

Appeal and Submission of an Updated Application

On April 9, 2014, the Board received an email from Dorothy E. Vinson, R.Ph., who identified herself as the pharmacist-in-charge for Z-Stat Medical, LLC d/b/a Oldsmar Pharmacy. Ms. Vinson indicated that Oldsmar Pharmacy was appealing the denial of its application and would be submitting an updated application. Ms. Vinson further indicated that the business was growing and had added additional personnel. (State Exhibit 6)

On April 14, 2014, the Board received an updated Application for Nonresident Iowa Pharmacy License from Oldsmar Pharmacy. In addition to Pharmacist-in-Charge Dorothy Vinson, the updated application listed five pharmacy employees, including one pharmacy technician with a pending registration, two technicians in training, and a billing technician in training. In a letter attached to the application, owner Larry Smith states that Oldsmar Pharmacy does not dispense Scheduled drugs (with the exception of Tramadol C-IV in certain areas). Oldsmar Pharmacy also provided a copy of its policy for Electronic Recordkeeping of Schedule III-IV Prescription Information. (State Exhibits 6, 7, 8)

In a letter to the Board responding to the Preliminary Notice of Intent to Deny License, Ms. Vinson wrote, in relevant part:

...

We never did any controlled substance dispensing. Currently we are using Tramadol in one of our pain creams which is controlled in certain states. Appropriate PMP reporting is in place for those states.

I do not know who answered the questions about the topical testosterone. The central fill pharmacy, APS, does compound that drug. At the beginning of business, technicians from APS did their order entry in our office next door. Perhaps it was such an individual who answered the question.

There are no 'contracted physicians' associated with Oldsmar Pharmacy.

We are currently open 40 hours per week. Your 6 days a week requirement will be immediately addressed as to remote access to the ultimate user's record when we are licensed in Iowa.

(State Exhibit 8)

Additional Information Obtained During Appeal Hearing

At hearing, owner Larry Smith explained that Oldsmar Pharmacy has been growing rapidly since the initial application was submitted to the Board in October 2013. As of the date of the appeal hearing, Oldsmar Pharmacy had a total of ten employees, and Mr. Smith believed that he would be hiring three additional employees within two weeks. On January 27, 2014, Dorothy Vinson, R.Ph. was hired as the pharmacist-in-charge for Oldsmar Pharmacy, and she took over this position from George Chrysakis on February 3, 2014. Ms. Vinson is currently the only pharmacist employed by Oldsmar Pharmacy, and she is at the pharmacy from 9-5, Monday through Friday. Ms. Vinson testified that she personally responds to all messages left for Oldsmar Pharmacy after hours. (Testimony of Larry Smith; Dorothy Vinson)

Oldsmar Pharmacy is currently licensed in 28 states and its business model is to become licensed in all 50 states. Larry Smith described Oldsmar Pharmacy as a "niche business" that provides transdermal pain, wound, and dermatology creams, as well as some vitamin capsules. Some of Oldsmar Pharmacy's transdermal creams contain Tramadol, which is a scheduled drug in some states but not in Iowa. Mr. Smith does not believe that the nonresident pharmacy applications filed with the Board were

misleading or inaccurate because Oldsmar Pharmacy does not plan to dispense scheduled drugs in Iowa. (Testimony of Larry Smith)

Larry Smith denied that Oldsmar Pharmacy has "contracted physicians," and he testified that Oldsmar Pharmacy would accept prescriptions from any licensed prescriber so long as it was for a product that they make and dispense. Larry Smith testified that due to the limited nature of their business, they know most of the doctors who submit prescriptions for their transdermal creams. Oldsmar Pharmacy markets its products by sending representatives to meet with physicians and by providing the physicians with prescription pads that have the custom formulas for 7 or 8 products. The prescription pads do not have the Oldsmar Pharmacy name or contact information on them, but that information is provided to the physician separately. (Testimony of Larry Smith)

When Oldsmar Pharmacy receives a prescription, Dorothy Vinson checks the prescription for a proper prescriber signature and then takes the prescription next door to APS, which compounds all of the products sold by Oldsmar Pharmacy. When APS delivers the finished product back to Oldsmar Pharmacy, the product is checked by Ms. Vinson before Oldsmar Pharmacy ships it out to the customer. Oldsmar Pharmacy is currently filling an average of 90 prescriptions a day, 5 days a week. (Testimony of Larry Smith)

Larry Smith denied that Oldsmar Pharmacy would accept or fill a prescription for testosterone cream, which is a controlled substance. Mr. Smith testified that Oldsmar Pharmacy would refer any patients with testosterone cream prescriptions to APS, who could accept and fill the prescription for the customer. (Testimony of Larry Smith)

Dorothy Vinson was the pharmacist-in-charge when Andrew Funk called and left the message about the testosterone cream. In their initial testimony, neither Larry Smith nor Dorothy Vinson could identify who would have left the message for Mr. Funk that referred to the pharmacy's willingness to fill his testosterone cream prescription if it came from one of the pharmacy's "contracted physicians." Mr. Smith acknowledged that his wife's name was Tadwa Smith but he described her role in the company as limited to conducting research on obtaining pharmacy licenses. He denied that his wife would ever return a phone message from a customer. Mr. Smith speculated that the call might have been returned by former employee "Danielle Smith," who was terminated for having poor phone etiquette. In addition, Ms. Vinson speculated that an APS

employee might have responded to Mr. Funk not knowing the business model of Oldsmar Pharmacy. (Testimony of Dorothy Vinson; Larry Smith)

After Larry Smith testified that he would have liked to have heard the actual voice mail message in order to help him identify the caller, Andrew Funk searched his personal cell phone and was able to locate and play the voice mail message on the record at the hearing. After hearing the voice mail message, Larry Smith identified the woman leaving the message as his wife, Tadwa Smith. Mr. Smith could not explain why his wife would have responded to Andrew Funk's voice mail. (Testimony of Larry Smith)

CONCLUSIONS OF LAW

A pharmacy located outside of Iowa that delivers, dispenses, or distributes, by any method, prescription drugs or devices to any ultimate user in this state shall obtain a nonresident pharmacy license from the Board.² The Board may deny, suspend, or revoke a nonresident pharmacy license for any violation of Iowa Code section 155A.13A, 155A.15, subsection 2, paragraph "a," "b," "d," "e," "f," "g", "h", or "i", chapter 124, 124A, 124B, 126, or 205, or a rule of the Board.³

Applicants for a nonresident pharmacy license must submit a completed application and application fee as determined by the Board.⁴ In part, applications must include evidence that the nonresident pharmacy maintains records of the controlled substances delivered, dispensed, or distributed to ultimate users in this state.⁵

It is an unethical practice for a licensed pharmacy, licensed pharmacist, registered pharmacy technician, registered pharmacy support person, or registered pharmacist intern to engage in misrepresentative deeds. This includes making any statement intended to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.⁶

² Iowa Code section 155A.13A.1(2013); 657 IAC 19.2.

³ Iowa Code section 155A.13A(3)(2013); 657 IAC 19.10.

⁴ Iowa Code section 155A.13A(1)(a)(2013).

⁵ Iowa Code section 155A.13(1)(d)(2013).

⁶ 657 IAC 8.11(1).

It is also unethical for a pharmacist to accept professional employment or share or receive compensation in any form arising out of, or incidental to, the pharmacist's professional activities from a prescriber of prescription drugs.⁷ It is unethical for a pharmacist or pharmacy to enter into any agreement which negates a patient's freedom of choice of pharmacy services. A pharmacist or pharmacy shall not participate in prohibited agreements with any person in exchange for recommending, promoting, accepting, or promising to accept the pharmaceutical services of any pharmacist or pharmacy.⁸

In addition, the Board is authorized to discipline a licensee when it determines that the licensee, permittee, or registrant is guilty of...Fraud in procuring a license. Fraud in procuring a license includes but is not limited to an intentional perversion of the truth in making an application...to operate a pharmacy doing business in this state...⁹

After reviewing the entire record, the Board continues to have the same serious concerns that led to the issuance of the Notice of Intent to Deny. The representatives for Oldsmar Pharmacy were unable to provide a satisfactory explanation for the voice mail message received by Andrew Funk in direct response to his request to fill a prescription for testosterone cream, which is a controlled substance. The voice mail message clearly came from Oldsmar Pharmacy, and the message content was inconsistent with the pharmacy's claim on their applications that they would not be dispensing or selling any controlled substances in Iowa. The voice mail was also inconsistent with the pharmacy's claim that they do not use "contracted physicians." A pharmacy's use of "contracted physicians" is prohibited by the Board's rules prohibiting unethical conduct.¹⁰

Dorothy Vinson was the pharmacist-in-charge of Oldsmar Pharmacy when Andrew Funk left his message on the pharmacy's toll free line and when Tadwa Smith returned Mr. Funk's call the following day and left her own voice mail. Ms. Vinson and Mr. Smith were unable to explain how or why Tadwa Smith would have intercepted Mr. Funk's message and provided such a specific response, if in fact she was unauthorized to speak to customers on the pharmacy's behalf or was unfamiliar with the pharmacy's

⁷ 657 IAC 8.11(2).

⁸ 657 IAC 8.11(5).

⁹ 657 IAC 36.1(4)(a).

¹⁰ See 657 IAC 8.11(2), 8.11(5).

business model. Based on this record, the Board was unable to conclude that Oldsmar Pharmacy would operate in Iowa in conformance with its application and in conformance with the Board's rules governing nonresident pharmacies.

DECISION AND ORDER

IT IS THEREFORE ORDERED that the application for a nonresident pharmacy license filed by Z-Stat Medical, LLC d/b/a Oldsmar Pharmacy is hereby DENIED.

Dated this *2nd* day of *July*, 2014.



Edward Maier, Chairperson
Iowa Board of Pharmacy

cc: Laura Cathelyn, Assistant Attorney General

Any aggrieved or adversely affected party may seek judicial review of this decision and order of the board, pursuant to Iowa Code section 17A.19.