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February 23, 2016



VIA E-MAIL AND FEDERAL EXPRESS

Nevada State Board of Pharmacy Attn: S. Paul Edwards General Counsel 431 W. Plumb Lane Reno, NV 89509 pedwards@pharmacy.nv.gov

Re:

Alexso, Inc. - Petition for Reconsideration of Application for NV

Wholesaler's License

Dear Mr. Edwards:

Please see my client Alexso, Inc.'s Petition for Reconsideration of their Application for a Nevada Wholesaler's License with the Nevada State Board of Pharmacy. This Petition is filed as provided for under NRS 639.139.

We thank the Board for their consideration of this Petition.

Very truly yours,

Jennifer J. Gaynor

JJG:G

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

Petition of Alexso, Inc., for Reconsideration of The Nevada Board of Pharmacy's Denial of Its Application for an Out-of-State Wholesaler's License

<u>PETITION</u>

Alexso, Inc. ("Alexso" or "Petitioner"), by and through its legal counsel, Jennifer Gaynor, Esq. of Dickinson Wright PLLC, respectfully submits this Petition to the Nevada State Board of Pharmacy ("Board") requesting reconsideration of the Board's denial of Alexso's application for a Nevada Out-of-State Wholesaler License ("Petition").

I. INTRODUCTION

The Board has voted to deny the application of Alexso for a Nevada Out-of-State Wholesaler License. The basis for this denial is the Board's concerns that Hootan Melamed, who is the 68% owner of Alexso, demonstrated insufficient knowledge or interest in disciplinary matters that occurred during the period he was the 44% owner and President of Concierge Compounding Pharmaceutical ("Concierge"). This raised a concern that Mr. Melamed, as an owner and officer of Alexso, would not ensure the company will abide by federal and state laws and regulations relating to the purchase and sale of dangerous drugs and controlled substances.

For that reason, the Board found that Alexso does not meet the high standards of practice required of a Nevada-licensed wholesaler and denied Alexso's application (see

¹ Concierge is a current Nevada-licensed pharmacy in good standing (since 2012), with no record of discipline in Nevada.

Nevada State Board of Pharmacy, Office of the General Counsel letter entitled "Alexso, Inc. – Notice of Denial of Application for NV Wholesaler's License", dated January 25, 2016, attached as *Exhibit A*).

Mr. Melamed and Alexso hereby request the Board to reconsider this decision because, as discussed below, Mr. Melamed and Alexso do take their licensure in Nevada seriously and are prepared to take certain actions to ensure that, if licensed in Nevada, Alexso will abide by all federal and state laws and regulations.

II. BACKGROUND

At the October 2015 hearing of the Board, Mr. Melamed appeared on behalf of Alexso as co-owner and President, and attempted to answer the Board's questions regarding certain licensing and disciplinary issues that his former company, Concierge, had encountered during the period where he was a co-owner and President of Concierge.

During this hearing, the Board was not satisfied with Mr. Melamed's knowledge of the details of the licensing and disciplinary issues that Concierge had encountered. Mr. Melamed admitted that he had been pre-occupied during a portion of his ownership in Concierge by his pending divorce action, and had relied upon his legal team and his partners to help him resolve issues encountered by the company. For this reason, he did not, for example, recall some of the specific details regarding a settlement his company had entered into with the U.S. government. He, in fact, dissolved his partnership in Concierge in August of 2015 due to his own acknowledged lack of time to focus as much as he and his partners would like on the business.

Mr. Melamed, however, had no intention of misleading or hiding any of these facts from the Board. To this end, we are providing, as *Exhibit B*, a full listing of the licensing and disciplinary actions for Mr. Melamed, Concierge (during Mr. Melamed's

period of ownership) and Alexso, and offer to provide any additional information that the Board may request about any of these.

In addition, as Mr. Melamed discussed in the October Hearing, while at Concierge, he worked with his legal team when issues arose to correct any flaws in the company's processes to ensure that errors were not repeated. For example, when Concierge encountered an issue with improper distribution of prescriptions in Oregon when the company was not licensed in Oregon, Mr. Melamed worked with his team to set up a "triple-check" system," which ensured prescriptions were only filled and shipped to states where Concierge held the proper license. Mr. Melamed is prepared to enlist similar programs for Alexso to prevent such issues.

Mr. Melamed has also sold all of his other business interests (as of August 2015) and now devotes all of his time and energy to the operation of Alexso.

Mr. Melamed and Alexso, however, understand the Board's concerns that history indicates that Mr. Melamed may not take enough of a leadership role to ensure Alexso's safe and legal operations in Nevada. Therefore, Alexso wishes to alleviate those concerns by appointing his partner, H. Troy Farahmand, to act as President, and by providing a roadmap for how Alexso, if granted licensure in Nevada, will proactively educate its officers and employees on all federal and state law and regulations for a wholesale distributor and ensure their compliance with those laws and regulations.

III. DISCUSSION

If granted a license to operate as a Nevada wholesaler, Alexso is prepared to work closely with the Board to ensure that the company operates in full compliance with all federal and state law and regulation. This includes appointing an individual to act as its Nevada compliance officer and enacting comprehensive education and training programs and compliance oversight, as explained in more detail below.

a. Alexso

Established in 2010, Alexso is headquartered in Los Angles, California, and is currently licensed as a pharmaceutical wholesaler in 19 states². Alexso's focus is workers compensation and personal injury, and the company markets and sells its medications exclusively to pharmacies or wholesalers/re-packagers that specialize in providing services to this market. Alexso does not distribute its products to end users, which eliminates the potential for issues regarding the collection of patient copayments.

Alexso has successfully operated as a pharmaceutical wholesaler in California and across the U.S. since 2010, and looks forward to safe and successful operations in Nevada as well.³

b. The Alexso Team

Alexso understands that safe and successful operation in the pharmaceutical wholesale business relies in large part upon its leadership. To that end, Alexso has appointed H. Troy Farahmand, a California-licensed attorney, to act as its President.⁴ Mr. Farahmand brings more than a decade of business management and leadership to Alexso. Having spent the last several years immersed in the pharmaceutical industry, he has helped Alexso grow exponentially and continues to provide the guidance Alexso needs to flourish in the future to provide high quality pharmaceutical medications to not only Alexso's local communities, but nationally as well.

Alexso is currently licensed in: Arizona, California, Connecticut, Delaware, Georgia (as of 2/19/16), Kansas, Kentucky, Minnesota, New Hampshire, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Virginia, Washington, and West Virginia.

³ Note that Alexso recently completed a DEA audit, which found no issues. If the Board would like, Alexso will provide a copy of this report.

⁴ Hootan Melamed remains a shareholder, but will not be acting as an officer of Alexso.

c. Employee Training and Education

Alexso's proactive measures to ensure compliance with all federal and state laws and regulations will include comprehensive and regular training and education of its officers and employees on those laws and regulations. Each employee and officer will be issued a training manual that includes an overview of the relevant federal and state law and regulations.

Alexso will also provide legal training for its staff in all state and Federal laws and regulations relating to the operation of a pharmaceutical wholesaler business, with the legal obligations of licensed Nevada wholesalers, including those requirements detailed in NRS 639.500- 639.595 and NAC 639.585 – NAC 639.607, emphasized. This training will consist of both the training of initial hires, and periodic refresher training for its employees that meets or exceeds the requirements of the Nevada laws and regulations.

d. Compliance Oversight

Alexso will follow all applicable Nevada Revised Statutes sections, Nevada Administrative Code and federal law as it regards the operation of a pharmaceutical wholesale business. To ensure this, Alexso will appoint one of its employees (Shoshana Robello) to be its Nevada compliance officer. Ms. Robello will take a position of leadership to ensure that all employees receive the proper education and training, and that there are procedures put into place as needed to ensure compliance with all laws and regulations. This may include, but will not be limited to, procedures similar to the "triple-check" process discussed above to ensure that the company has the proper licensing before fulfilling any orders in a certain jurisdiction.

e. Additional Training, Compliance and Oversight

Alexso is also open to any recommendations by the Board as to additional training, compliance or oversight measures the Board would like to see to provide comfort that Alexso will operate in compliance with all applicable laws and regulations.

IV. CONCLUSION

For the foregoing reasons, Alexso, Inc., requests that the Board reconsider its denial of Alexso's application for licensure as an Out-of-State Wholesaler and provide Alexso the opportunity to demonstrate that it can operate safely and legally in the state of Nevada.

Respectfully submitted this 200 day of February, 2016.

Dickinson Wright PLLC

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Jennife J. Gaynor Nevada Bar No. 9544 8363 West Sunset Road

Suite 200

Las Vegas, NV 89113

Attorney for Alexso, Inc.

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Exhibit A



NEVADA STATE BOARD OF PHARMACY

OFFICE OF THE GENERAL COUNSEL

WRITER'S DIRECT DIAL: (775) 850-1440 • E-MAIL: PEDWARDS@PHARMACY.NV.GOV • FAX: (775) 850-1444

January 25, 2016

VIA U.S. CERTIFIED MAIL AND ELECTRONIC MAIL

Alexso, Inc.

Attn: Troy Farahmand 2317 Cotner Ave., 2nd Fl Los Angeles, CA 90064

Re: Alexso, Inc. - Notice of Denial of Application for NV Wholesaler's License

Dear Mr. Faralımand:

As you are aware, in October 2015, the Nevada State Board of Pharmacy (Board) considered and denied Alexso, Inc.'s application for an Out-of-State Wholesaler License. That denial was based on information, events and prior legal issues relating to Hootan Melamed, the company's president and majority shareholder, and his former company, Concierge Compounding Pharmaceutical (Concierge), which were disclosed and discussed during the hearing on your application. Based on that information and hearing, the Board found grounds under NRS 639.210 to deny the application.

In particular, the Board Members had many questions and expressed concerns regarding Mr. Melamed's prior conduct, including individually and as an owner of Concierge. The Board Members also expressed concern during the hearing that Mr. Melamed, as an owner of Concierge, and as a pharmacist who should have been an integral part of resolving issues at Concierge, demonstrated little interest, claimed to lack knowledge and/or otherwise failed to adequately answer Board Member questions regarding his prior activities and those of his former company.

Based on Mr. Melamed's history and Concierge's history under his ownership and control, the Board Members expressed concerns about Mr. Melamed's character and willingness to, as an owner/officer of Alexso, Inc., abide by federal and state laws and regulations relating the purchase and sale of dangerous drugs and controlled substances. Those factors led to the Board's determination that Alexso, Inc. does not meet the high standards of practice required of all Nevada-licensed wholesalers. A copy of the audio recording of the hearing is available to you upon request.

Alexso, Inc. has the right under NRS 639.139 to petition the Board for reconsideration of its application. The statute provides in relevant part:

NRS 639.139 Denial of application: Procedure for reconsideration.

1. At any time within 30 days after receipt of the notice of denial of an application, the applicant may petition the Board for reconsideration of the application. The petition must set forth a denial, in whole or in part, of the violations alleged and a statement that the applicant is prepared to submit evidence in support of the denial of the allegations.

. . . .

(Emphasis added.)

SelEdwards)

If Alexso, Inc., opts to exercise its right to petition the Board for reconsideration, please submit that petition and all supporting evidence you wish to present to the Board's offices at 431 W. Plumb Lane, Reno, Nevada 89509, within thirty (30) days of receipt of this notice.

Additionally, please feel free to contact me if you have questions.

Best regards,

S. Paul Edwards General Counsel

Nevada State Board of Pharmacy

Cc: Larry Pinson, Executive Secretary of the Nevada Board of Pharmacy

Exhibit B

Explanations of Licensing and Disciplinary Actions for Hootan Melamed, Concierge Compounding and Alexso

Hootan Melamed:

• <u>United States of America v. Hootan Melamed</u>. On or about January 19, 2001, Hootan Melamed was convicted of Conspiracy to Commit Securities Fraud, a Class D Felony. He was sentenced to the custody of the Bureau of Prisons for a term of 10 months, five months of which was to be completed in a home detention program with electronic monitoring, and five months of which was to be completed in a community correctional facility. He was ordered to pay restitution and interest. <u>United States of America v. Hootan Melamed</u>, U.S. Dist. Ct. No. CR00-7-GAF.

Concierge Compounding:

- U.S. v. Concierge Compounding Pharmaceuticals, Inc. On January 10, 2014, the U.S. Attorney's Office for the District of Nevada and Concierge agreed to settle claims on behalf of the Drug Enforcement Administration and the Defense alleging that Concierge had shipped compounded Health Agency, pharmaceuticals, many of them controlled substances, outside Nevada without being licensed as a pharmacy in the states where the drugs were received. Concierge agreed to pay the United States \$273,500. The investigation supported audit findings that Concierge had waived patient cost-shares and shipped prescriptions out of state to states for which Concierge had not complied with the state's pharmacy requirements. The claims resolved by the settlement are allegations only, and there has been no determination of liability.
- Texas Board of Pharmacy. When Concierge applied for its Pharmacy License in Texas, the Texas Board of Pharmacy took note of the disclosure that its corporate officer, Hootan Melamed (President) had been convicted in 2001 of the felony offense of Conspiracy to Commit Securities Fraud. Concierge agreed to a Board Order, which was entered by the Board on 08-06-13, under which Concierge's pharmacy license was granted and placed on 1-year probation with conditions.
- South Carolina State Board of Pharmacy. On August 15, 2013, the South Carolina State Board of Pharmacy denied Concierge's application for a nonresident pharmacy permit. The denial was based upon Mr. Melamed's prior felony (which was disclosed on the application) and concerns by the Board regarding the accuracy and completeness of the compounding formulas provided in the application for Concierge.
- Oregon Board of Pharmacy. The Oregon Board of Pharmacy issued a \$13,000 fine to Concierge for issues of non-compliance. Specifically, as Mr. Melamed explained at the October hearing, the issue was that a Concierge pharmacist

shipped a few prescriptions to Oregon even though Concierge was not licensed in Oregon at that time. This was due to a misunderstanding about in which states Concierge held a license. Mr. Melamed worked with Concierge's legal team to set up a "triple-check" system to ensure that there were not any further misunderstandings by employees about in which states Concierge was licensed.

Ohio State Board of Pharmacy. The Ohio State Board of Pharmacy denied Concierge's application for registration as a "Terminal Distributor of Dangerous Drugs" in December 2014. This denial was based upon applicant failing to disclose in their application the felony conviction of Hootan Melamed, as well as two disciplinary actions by the Nevada Board of Pharmacy for Concierge employee-pharmacist Michelle Badten, R.Ph. See https://pharmacy.ohio.gov/Documents/Pubs/Minutes/2014/201412%20-%20Minutes%20(Dec%202014).pdf.

Alexso:

- Alexso has not faced any disciplinary actions, but has or is currently appealing denials of licensure by a few state Boards of Pharmacy where the Boards had concerns stemming from the issues listed above:
 - Ohio. Alexso is currently scheduled to appear before the Ohio Board of Pharmacy in April of 2016 to appeal its licensing denial there.
 - **Alabama**. Alexso has withdrawn an application for licensure that had been filed with the Alabama Board of Pharmacy.
 - **Nevada**. (this appeal)
 - **Georgia**. The Georgia Board of Pharmacy's initial denial of Alexso's license application was recently overturned and Alexso has been granted licensing in the state of Georgia.

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