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September 6, 2019

Via Electronic Mail and Overnight Delivery

Mr. David Wuest
 Executive Secretary
 Nevada Board of Pharmacy
 985 Damonte Ranch Pkwy, Ste 206
 Reno, NV, 89521

Re: MedAvail Technologies, Inc. and CareMore Health
 Joint Petition for Rulemaking

Dear Mr. Wuest:

I am following up on recent discussions between you and Seema Siddiqui of MedAvail Technologies, Inc. ("MedAvail"), and my follow up discussions with you and Paul Edwards, regarding the potential deployment of automated dispensing systems to bring pharmacy services to patients at the point of care in clinics and other locations where health care services are provided. Based on those discussions, we recognize that existing regulations that address automated dispensing systems are somewhat limited, and restrict deployment to within a licensed pharmacy (NV ADC 639.718), or a hospital emergency department (NV ADC 639.720). For that reason, we are submitting this Petition for Rulemaking, to create a new regulation that would extend the reach of this technology to clinic settings. We are requesting that this Petition be placed on the agenda at the Board's next meeting October 9 and 10.

Joining MedAvail as co-petitioner is CareMore Health ("CareMore"). CareMore operates medical clinics in 9 states spanning both coasts, as well as the District of Columbia, and serves over 150,000 patients. It has two clinics in Nevada, one located at 2601 North Tenaya Way, and the second at 3041 East Flamingo Road, both in Las Vegas. CareMore's approach to care is somewhat unique in the industry, in that its clinical programs and services utilize clinicians and non-clinicians who are aligned and coordinated as a team, as opposed to the traditional

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healthcare model that is often fragmented and inefficient. The focus of CareMore's approach to patient care is to provide its patients with one-stop Care Centers that are designed to give additional attention to chronic conditions, general health, and prevention. Case Management teams coordinate care across all parties including providers, hospitals, long-term care, and specialists, taking ownership at the point of admission, ensuring that patients receive a high standard of care and that conditions are properly managed.

CareMore recognizes the key role of pharmacy in the provision of comprehensive patient care, and in order to achieve its goal of providing all-inclusive patient care services at a single location, CareMore has partnered with MedAvail to leverage MedAvail's automated pharmacy system technology to provide pharmacy services at the point of care. Presently, CareMore clinics utilize automated dispensing and pharmacist counseling services at clinics located in Arizona, and have plans to partner in other states, including California, where patient accessible automated pharmacy services have been approved by state pharmacy regulators and legislators.

MedAvail is a technology provider that also operates licensed pharmacies and employs pharmacists and technicians to provide pharmacy care at locations where a full brick and mortar pharmacy, or even a telepharmacy staffed by technicians, would not be feasible or economically viable. MedAvail has leveraged its automated dispensing technology in partnerships with clinics and practitioners across the country to bring pharmacy services at the point of care.¹ Other independent and chain pharmacies have also partnered with MedAvail and other technology companies that have similar technology to increase access to pharmacy services. These partnerships offer the benefit of allowing patients to access pharmacy services at the point of care.

Rulemaking Proposal

The Board of Pharmacy has broad authority to adopt regulations pertaining to the practice of pharmacy in the state. Specifically, the Board may adopt regulations addressing dispensing of prescription drugs, including the use of computerized mechanical equipment for the filling of prescriptions, and to authorize the Executive Secretary of the Board to issue certificates, licenses and permits required to engage in the practice of pharmacy. NV ST § 639.070. By statute, the Board also has broad authority to address remote pharmacy practice, including the authority to authorize registered pharmacists to engage in the practice of pharmacy electronically, including,

¹ A description of the MedAvail MedCenter automated pharmacy technology is enclosed as Exhibit A to this Petition. In addition, a video showing the robust, patient safety focused technology in action is available for review at <https://www.bing.com/videos/search?q=youtube+medavail&view=detail&mid=484CF82D6F42F714DF1E484CF82D6F42F714DF1E&FORM=VIRE>. We look forward to presenting this video to the full board, and responding to questions about the technology, at the October meeting.

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without limitation, through telehealth, from within or outside this State. NV ST § 639.0727. Finally, by statute, any act which is required to be performed by a pharmacist may be performed with the use of computerized mechanical equipment in accordance with the regulations adopted by the Board. NV ST § 639.2655.

Members of the public are permitted to petition the Board to adopt regulations. NV ADC § 639.140. MedAvail and CareMore believe that a regulation that will allow Nevada pharmacies to provide remote pharmacy services, including the dispensing of prescription drugs, through the use of sophisticated telecommunications technology, will improve patient care. The Board has already recognized that mechanical dispensing systems can be used to safely dispense prescription drugs to patient in pharmacies, and in hospital emergency departments. *See*, NV ADC §§ 439.718, 439.720. Petitioners seek the adoption of a new regulation that will allow the use of those devices in clinics and other settings to dispense both new and refill prescriptions.

There are numerous studies and anecdotal reports that confirm the significant public health and safety benefits associated with increasing access to pharmacy services.² These studies and reports show that even in urban settings, where retail pharmacy services are presumably readily available, providing pharmacy services at the point of care can increase first fill rates. There is also no doubt that involving pharmacists in patient care from time that drug therapy is first initiated, to collaborate with prescribers and provide counseling at the point of care, can improve adherence and compliance. Leveraging technology to improve access fits squarely within the Board's mandate to promote, preserve and protect public health, safety and welfare will be substantially furthered by the granting of the Petition and adopting regulations is request.

As required by NV ADC § 639.140, a copy the proposed regulation is enclosed with this Petition. The proposed new regulation, NV ADC § 639.721, identifies the new locations where

² *See, e.g.*, Saunders, Patient Compliance in Filling Prescriptions After Discharge from the Emergency Department, *Am. J. of Emergency Medicine*, Vol. 5, No. 4 (July 1987) (Twenty percent of ED patients at Vanderbilt University Hospital ED did not fill prescriptions, with no distinction between Medicaid versus self-insured); Ginde, et al., The Effect of ED Prescription Dispensing on Patient Compliance, *Am. J. of Emergency Medicine*, Vol. 21, No. 4 (July 2003) (Study conducted at Barnes Jewish Hospital in St. Louis, finding that dispensing azithromycin in the ED significantly increases likelihood that patient will obtain the medication, with just 74% of patients given a prescription actually filling the prescriptions); Kripalani, et al., Medication Use Among Inner-City Patients After Hospital Discharge: Patient-Reported Barriers and Solutions, *Mayo Clin Proc.* 2008;83(5):529-535 (Transportation, cost, and wait times at the pharmacy cited as main barriers); Kajioka EHN et al., *Annals of Emergency Medicine*, October, 2003, p. S2; presented at the American College of Emergency Medicine Research Forum, October 12-13, 2003; Boston, Massachusetts (following discharge from the ED, 63% of patients failed to have their prescriptions filled at all, and of those who did have the prescription filled, 17% failed to have the prescription filled that day); Hohl, et al, Adherence To Emergency Department Discharge Prescriptions, *J of Canadian Assoc. Emer. Physicians*, March 2009; 11 (2) (higher risk of a revisit to an ED or clinic in non-adherent patients); Fischer, et al, Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions, *J Gen Intern Med* 25(4):284-90 (2010) (72% fill rate for new prescriptions).

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mechanical devices can be used to furnish prescriptions drugs directly to patients. *See*, Exhibit B
In addition, NV ADC § 639.715 presently provides that "[n]o drug, controlled substance, medicine, chemical or poison . . . may be sold or offered for sale or dispensed by means of any mechanical device except as otherwise provided in NAC 639.718 and 639.720." Petitioners request that the Board amend this regulation to add the new section 639.721 as allowing the furnishing of prescription drugs via mechanical devices in other patient care settings. *See*, Exhibit C.

Representatives from MedAvail and CareMore will be present at the next Board meeting to present this Petition, and to answer any questions concerning any aspect of this request. On behalf of Petitioners, I thank you for your attention to this matter, and look forward to seeing you next month.

Respectfully submitted,



Edward D. Rickert
On Behalf of MedAvail Technologies, Inc. and
CareMore Health

Enclosures

cc: Paul Edwards
Seema Siddiqui, MedAvail Technologies, Inc.
Syed Sumair Akhtar, MD, MHCDS, CareMore Health

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EXHIBIT A

Description of MedAvail MedCenter

Although the proposed regulation will allow for the deployment of any type of mechanical system that complies with the patient safety and security requirements of the regulation, Petitioners believe that it will be helpful for the Board to understand how MedAvail's MedCenter operates. MedAvail has successfully deployed the MedCenter in numerous locations in several states, and sets standards for safety and security that the Board should be mindful of as it proceeds with rulemaking in Nevada.

Description of MedCenter Technology

The MedAvail MedCenter is a patient-facing, automated solution that allows patients to access pharmacist counseling and support combined with prescription dispensing at the point of prescribing. The system is placed at the point of care such as in a pharmacy, health clinic, or emergency room, to allow the patient to connect with a pharmacist via a live, 2-way audio and video connection. The prescription submitted by the patient (or e-prescribed to the pharmacy), prescription label, and the identity of the prescribed medication is verified, processed and dispensed to the patient under the complete control of the pharmacist located at either the Automated or Remote Pharmacy locations. Records are maintained by the pharmacy that operates the MedCenter, in that pharmacy's pharmacy operating system. No records or data persist outside of the pharmacy's own systems. Those records clearly identify the pharmacies and pharmacists assisting in the dispensing process. Before finalizing the release of the prescribed medication, each medication package is verified by a pharmacist thereby maintaining the pharmacist's judgment and accountability throughout the dispensing process. The system tracks and records all verification and dispensing for auditing purposes.

Medications stocked in the MedCenter are provided in unit-of-use containers, sourced either from an FDA registered repackager, manufacturer, or registered wholesaler, or in some instances, will be pre-packaged by the pharmacy that is responsible for operating the system. In addition, each container of medication placed in the MedCenter is labeled with a separately created bar code, which identifies not just the lot number of the medication, but also the expiration date of the repackaged or prepackaged medication. Medications nearing the expiration date can therefore be proactively identified and removed from the dispenser by pharmacy staff. This added step ensures that no outdated medication will ever be dispensed from the dispenser. The bar coding technology can also identify medications that may be subject to a manufacturer's recall, so that the medications can be removed from the MedCenter and segregated for return or destruction, subject to the terms of the recall.

All medications are stocked in the MedCenter by pharmacists or pharmacy technicians that have tightly controlled and limited access to the MedCenter. When stocking the device, the user has no access to the main drug vault. Rather, the medications are placed in a bay that closes and securely locks before any medication is placed in the drug vault through the use of sophisticated automation. If prescriptions are presented to the MedCenter for filling, the paper copy of prescriptions that has been scanned and processed through the MedCenter is stored in a secure location for later retrieval by the technician.

The MedCenter is designed to permit the pharmacist to cancel the dispensing process at any time, and when an order is cancelled, any medications that are in process for dispensing can be moved to a holding bin if for whatever reason the pharmacist elects not to dispense an in-process prescription (including medicine that has already been labeled). As such, an additional task and responsibility of the technician will be to retrieve any medications from this bin, accounting for and reconciling them with inventory records, and then either restocking the items into the MedCenter (where possible) or returning these items to the repackager, wholesaler, or retail pharmacy.

Description of System Security

In developing the MedCenter technology hardware and software, patient safety and security of drug inventory have been of paramount importance to MedAvail. As was discussed with Board staff at a past meeting with MedAvail representatives, the MedCenter design ensures the greatest degree of patient safety and drug inventory security. For instance, the MedCenter weighs approximately 1,800 pounds fully stocked, is constructed with 10 gauge reinforced steel and secured to the concrete floor of each deployment site. All points of access (be it for consumables replenishment, maintenance and repair, or drug inventory management) are alarmed and monitored. Access to the various areas of the vault and door are controlled with a roles-based access system – each authorized user receives both a PIN number and a magnetic card, both of which are required in order for such user to gain access to the appropriate area of the MedCenter. This system ensures, for instance, that only a pharmacist or technician can ever access the drug inventory or paper prescription vault, while permitting other users (such as the on-site retail staff) to maintain consumables (printer paper, label rolls, etc.) without accessing restricted areas.

In addition, the MedCenter is designed to monitor internal and ambient temperature, and is capable of maintaining the internal temperature at approximately 5 degrees Fahrenheit above ambient temperature. In the event that the internal temperature in the MedCenter rises above a level that is safe for drug storage, the MedCenter will alert the pharmacist so that appropriate responses can be taken.

A key safety component of the MedCenter is the secure bar-coding technology and pharmacist involvement in the dispense process. All prescription document scans are reviewed and entered into the pharmacy management system by a pharmacist or technician. This allows drug utilization review (“DUR”) and interaction checks to be maintained. The MedCenter robotics retrieve each package (by verifying its bar-code) and in turn label the package. High resolution images of each medication package are verified and approved by the pharmacist before authorization of the dispense to the patient. In this way, the pharmacist’s judgment and accountability remain key safeguards during each dispense.

Finally, concerning safety and security of patient data, the MedCenter does not persist or maintain any HIPAA or other patient data following a dispense – all such information is safely housed within the Pharmacy Management System of the operating pharmacy. MedAvail, as the vendor of the technology, has no access to any patient data. All transmission of such information occurs via 128 bit encryption.

MedAvail and CareMore believe that board staff and task force that will be reviewing this petition would benefit from a video demonstration of the MedCenter, to allow them to see first-hand the robust, patient safety focused technology in action. We will therefore provide the following URL link to a video of the technology for your review:

<https://www.bing.com/videos/search?q=youtube+medavail&view=detail&mid=484CF82D6F42F714DF1E484CF82D6F42F714DF1E&FORM=VIRE>.

EXHIBIT B

Proposed New Regulation NAC 639.721

NAC 639.721. Use by pharmacy to furnish prescription drugs to patients through the use of automated pharmacy system technology. (NRS 639.070, 639.2655)

1. Except as otherwise provided in this section, a pharmacy may use automated pharmacy system technology to furnish a prescription drug to a patient through a device that is licensed by the board as an extension of the pharmacy that operates the system. The technology and device must conform to all of the following provisions:

(a) The device must contain only prescription drugs:

(1) For which counseling is not required pursuant to NAC 639.707, unless the device utilizes real-time audio and video technology that links the patient to a Nevada licensed pharmacist who has access to the patient's profile information for purposes of providing patient counseling; and

(2) For which the prescriptions have been processed, verified and completed in the same manner as prescriptions for drugs that are delivered manually by the pharmacy, including the provision of printed medication guides and any other information required pursuant to NAC 639.707.

(b) The device must not contain any controlled substances unless the system is authorized by the federal Drug Enforcement Administration to dispense such substances.

(c) The device must be designed to ensure that the device:

(1) Utilizes user based access technology that limits access:

(I) For stocking, cleaning, maintenance or any other purpose, only by a pharmacist, a member of the staff of the pharmacy, or when deployed in a clinic or other practitioner location, by a person authorized by the pharmacist-in-charge at the pharmacy that operates the device to access the device, through technology that (i) identifies the person who gains access to the device, and (ii) limits that access to areas of the device that are necessary for performance of the specific function that person is tasked to perform; and

(II) Is secure from unauthorized access to and removal of prescription drugs from the device.

(2) Records the name of each person at the pharmacy who authorizes access to the device.

(3) Cannot be used by a patient unless the patient previously has indicated to the pharmacy that the patient desires that his or her prescription drugs be furnished by the mechanical device.

(4) Provides a method to identify the patient and furnishes a prescription drug only to the patient or to an authorized agent of the patient.

(5) Can furnish one, any combination or all of the prescription drugs available to a patient at the option of the patient at the time that the patient removes the prescription drugs from the device.

(6) Records the date and time that the patient removes the prescription drugs from the device.

(7) Informs a patient:

(I) That a prescription drug is not available to be furnished by the device if the pharmacist is unable to counsel the patient regarding the prescription drug.

(II) If the patient is using the device at the time that the pharmacy is open, that the patient may discuss questions and concerns regarding the prescription drug with a pharmacist at the pharmacy, or through the use of a real-time audio and video link with a Nevada licensed pharmacist who has access to all pertinent patient information necessary to perform counseling.

(III) If the patient is using the device at the time that the pharmacy responsible for operating the device is closed, that the patient may discuss questions and concerns regarding the prescription, and prescriptions may be reviewed and dispensed by, a Nevada licensed pharmacist who has access to all pertinent patient information necessary to perform dispensing and counseling.

2. A pharmacy shall not use an automated pharmacy system or device to furnish a prescription drug to a patient until the Board has issued to the pharmacy a license for the device. The device license shall:

(a) Identify the type of device that will be used;

(b) Identify the location of the device; and

(c) Identify the pharmacy and pharmacist in charge that is responsible for operation of the device. The device shall be considered to be an extension of the pharmacy that has been issued the license, and that pharmacy shall be responsible for all requirements set forth under Nevada law for the dispensing of prescription drugs.

3. The Board may prohibit a pharmacy from using an automated pharmacy system and device to furnish a prescription drug to a patient if the Board determines that the device or the pharmacy's use of the device does not comply with this section.

4. The provisions of this section do not prohibit the use of the automated pharmacy system and device to furnish a drug or device that is approved by the Food and Drug Administration for sale over the counter without a prescription if the pharmacy using the is otherwise authorized to use the device pursuant to this section.

EXHIBIT C**Proposed Amendment to NAC 639.715**

Additions are denoted by double underscoring, and deletions by ~~striketrough~~.

NAC 639.715. Mechanical devices: Restrictions on use. (NRS 639.070, 639.2655)

No drug, controlled substance, medicine, chemical or poison, as those terms are defined in chapters 453, 454 and 639 of NRS, may be sold or offered for sale or dispensed by means of any mechanical device except as otherwise provided in NAC 639.718, ~~and 639.720,~~ and 639.721.