May 1, 2015

BY EMAIL AND REGULAR MAIL

Marshall Moleschi
CEO and Registrar
Ontario College of Pharmacists
483 Huron Street
Toronto, ON M5R 2R4

Dear Marshall,

RE: Regulations under Drug and Pharmacies Regulation Act – Remote Dispensing Locations

MedAvail Technologies Inc. ("MedAvail") is an Ontario-based healthcare technology provider that has developed a patient facing remote dispensing automated pharmacy solution, the MedAvail MedCenter®. The MedCenter supports the dispensing of both prescription and over the counter medications while the patient is engaged in a live, two-way audio and video conference with a pharmacist.

The MedCenter is an innovative approach to the issues of pharmacy access that currently exist within Ontario and other Canadian jurisdictions. A MedCenter can be deployed by any pharmacy to reach patients in remote sites such as employer locations, clinics, hospitals and retail locations.

MedAvail's remote dispensing solution is a global leader, encompassing key features such as: (i) live two-way audio-visual link to a pharmacist; (ii) 24/7 availability and security monitoring; and (iii) complete dispense control by the remote pharmacist.

MedAvail's predecessor entity, Pharmatrust, working with Touchpoint Pharmacy, successfully deployed earlier versions of the MedAvail MedCenter® in various sites across Ontario. MedAvail and its pharmacy partner NuVision Health are currently negotiating deployment of the MedAvail MedCenter in several sites in Ontario. In addition, the MedAvail MedCenter has been deployed in the Unites States on a pilot basis and is being deployed in foreign jurisdictions as well.

The purpose of this submission is to contribute to the regulation making process initiated by the Ontario College of Pharmacists ("College") in March of 2015 and the draft regulations (proposed changes to Ontario Regulation 58/11) that were circulated for public comment at that time ("Draft Regulations").

The comments set out below contribute MedAvial's perspective of the Draft Regulations. In MedAvial's view, one aspect of the Draft Regulations, as explained below, unduly impedes technological innovations, such as the MedCenter, from serving the public interest.

Background

Bill 21: Safeguarding Health Care Integrity Act 2014, made amendments to the Drug and Pharmacies Regulation Act ("DPRA") to extend the College's authority to include the licensure and inspection of pharmacies within public and private hospitals as well as institutional locations. Previously, the College's authority with respect to the licensure and inspection of pharmacies was limited to community practice. As a result of the amendments to the DPRA that were part of Bill 21, the current regulatory framework related to licensure and inspection of pharmacies requires updating and revision.

The current regulations to the DPRA, in relevant part, prohibit the dispensation of narcotics and controlled substances from automated pharmacy systems (APSs) located in remote dispensing locations under the control of community pharmacies. As proposed by the College, in relevant part, the Draft Regulations simply extend the current requirements and limitations that were previously relevant for remote dispensing locations deployed by pharmacies in community practice to those that may be installed in public and private hospitals as well as health care institutional locations. This includes the prohibition with respect to the dispensation of narcotics and controlled substances from any APS located in remote dispensing locations under the control of community pharmacies or located in a hospital or health care institution. Section 26 of the Draft Regulations provides "No controlled drugs, narcotic drugs, verbal prescription narcotics or targeted substances shall be located at or available from a remote dispensing location." With respect, there is no valid public policy reason to prevent the dispensation of narcotics and controlled substances from APSs located in remote dispensing locations within hospitals or health care institutions.

MedAvail's APS, the MedCenter, is a highly secure method of dispensing *all forms* of medication to patients (including narcotic and controlled medication). In addition, MedAvail believes that improved access to pharmacy services helps to improve adherence and compliance rates, thus improving health outcomes for patients. Access is facilitated by establishing remote dispensing locations. This fact explains why, in 2011, the Ontario Ministry of Health and Long-term Care promulgated regulations to allow a pharmacy to deploy an automated pharmacy system installed in a remote dispensing location.

In certain sites, such as a hospital emergency department ('ED"), the dispensation of narcotic and controlled medications is an important benefit that APSs can provide patients, hospitals and the Ontario healthcare system.

Safe and Secure Dispensing

The MedAvail MedCenter has robust security and control/tracking features that, in certain respects, are superior to traditional pharmacy practice. Each system is monitored 24 hours per day/ 7 days a week with a dedicated security protocol followed if an intrusion is attempted.

Each MedAvail MedCenter is made with reinforced steel and weighs approximately 700 kg. Each MedCenter is also bolted directly to the floor and has monitored and alarmed power and data points. In fact, every MedCenter is equipped with an uninterruptable power supply (UPS) that provides back up power to maintain certain functions in the case of a power outage. Access to any component of the system requires the use of a unique security card and PIN assigned to each user (dual authentication). In this way, all access and duration of access is recorded and attributed to a specific individual. All points of access are also monitored and alarmed in the case of an individual attempting to pry their way into an RDL. This robust security is redundant to the site security, security personnel and cameras already in place in all hospital sites (particularly in ED areas).

Further, each written prescription that is submitted to a MedCenter is validated by a licensed pharmacist via College approved scanning technology. The use of the scanner allows the verification of each prescription document and allows the pharmacist to ensure that no modifications have been made to the prescription. The scanner also allows the pharmacist to assess how each prescription was written looking for other cues that may indicate a non-legitimate prescription (this can occur in cases where a prescription pad is stolen). These cues include how the illegitimate prescription is written and how the refills are addressed. Further, each interaction with a patient requires a 2-way audio and video consultation which allows the pharmacist to assess not only the health of the patient but also look for non-verbal cues that could potentially reveal an attempt at diverting medication. This assessment is key in cases where there are no modifications to the prescription document, as in the example discussed above, where the prescription is written on a stolen prescription pad.

It is important to note that each dispensation of narcotic or controlled medication from a MedCenter would conform to MOHLTC requirements for reporting to the Narcotic Monitoring System. Each APS installed at a remote dispensing location is required to adjudicate claims through the use of a pharmacy management system that has undergone the appropriate Ontario Drug Benefit conformance testing.

How APSs fit into Ontario's Narcotic Strategy

Issues concerning the abuse and dispensation of prescription narcotics have been of concern to health regulators and policymakers in Ontario. As a result, Ontario's Narcotic Strategy is designed to make the prescribing and dispensing of narcotics and other controlled substances in Ontario safer and more secure in Ontario. These initiatives have included the education of healthcare practitioners and the public, monitoring prescribing and dispensing via the provincial narcotics monitoring system, and providing treatment options and support for those addicted to prescription narcotics and controlled substances.

Remote dispensing technologies such as the MedAvail MedCenter not only offer expanded access to pharmacy services, as discussed above, they also support the goals of the MOHLTC by supporting the key elements of Ontario's Narcotics Strategy.

The installation of an APS in a site where the prescribing of narcotic and controlled medications occurs allows for the independent control of medications by an accountable pharmacy entity. In some emergency situations, hospitals elect to dispense a holdover supply to patients. This may occur in some situations where local pharmacy services (such as the Hospital's outpatient pharmacy) may not be available such as in case where no 24 hour pharmacy services exist nearby or where the patient's regular pharmacy is closed. By directing patients to an onsite APS, the site potentially reduces the opportunity for internal staff diversion while simultaneously saving on medication dispensing costs that the hospital would otherwise have to absorb. The separation of the prescribing and dispensing function provides for better control of the narcotic supply and also tracking through the Ontario Narcotics Monitoring System ("ONMS") where medications currently dispensed in the hospital are not tracked through this system. It is important to note that an APS such as a MedAvail MedCenter would allow the controlling pharmacy of the remote dispensing location to verify all of the required information to dispense controlled medications in Ontario (such as patient ID) as well as submit the required data to the ONMS, if the dispensation of controlled medications through an APS is permitted.

Recent History

APS installed at remote dispensing locations have safely dispensed narcotic medications in Ontario for over 2 years. Currently, the regulations to the DPRA prohibit the dispensation of narcotics and controlled substances from an APS located in a remote dispensing location under the control of a community pharmacy. The prohibition does not apply to APSs in hospital settings. Under the current regime, MedAvail notes that narcotic and controlled substances were successfully dispensed from APSs deployed in

Sunnybrook Health Sciences Centre, Holland Arthritic and Orthopedic Centre (a division of Sunnybrook) and Collingwood General and Marine Hospital between 2010 and 2012 without error or incident. The dispensation of narcotic and non-narcotic medications in these locations provided timely access to appropriate medication therapy to patients being discharged from each site.

Another example of the safe and secure dispensing of narcotic and controlled medication to patients can be taken from Mercy Hospital located in Chicago, Illinois. Since July of 2014, patients of the emergency department have experienced safe, secure and controlled access to all types of prescription medication (including narcotic medications) without any issue. The system has performed over 150 dispenses of narcotic and controlled medications to date.

Improved Access / Better Health Outcomes

MedAvail believes that a key component in reducing rates of non-adherence is increasing the access to pharmacy services which will ultimately result in better health outcomes for patients overall.

Investigators have long studied the link between the lack of adherence to prescription medications and lower health outcomes for patients. Studies conducted by the National Association of Chain Drug Stores (NACDS) estimated that between 30-50% of prescriptions are not relayed to a pharmacy with 75% of medications not being taken properly [See, NACDS Paper entitled Pharmacies: Improving Health, Reducing Costs. [Available from: http://www.maine.gov/legis/opla/healthreformpharmacies.pdf] In fact, the NACDS pegged the cost of non-adherence at approximately $290 billion for the US healthcare system. Similarly, the cost of non-adherence is estimated at $4 billion annually in Canada.
[See,http://www.sunlife.ca/static/canada/Sponsor/About%20Group%20Benefits/Group%20benefits%20products%20and%20services/Pharma/files/Pharma%20BrightPaper%202014%20GB00215%20E.pdf

There are significant public health, safety and welfare benefits associated with increasing access to pharmacy services specifically in a hospital environment. A recent study, by Brigham and Women's Hospital in Boston looked at prescription fill rates for 75,000 Massachusetts residents [See, Fischer, et al., Primary Medication Non-Adherence: Analysis of 195, 930 Electronic Prescriptions, J Gen Intern Med. 2010 Apr; 25(4) 284-290.]. That Brigham study showed that 22 percent of the prescriptions were never filled, with the rate even higher at 28 percent when the researchers looked only at first-time prescriptions. Alarmingly, approximately 1/4 to 1/3 of patients given new prescriptions for conditions such as depression, asthma and gastrointestinal illnesses failed to have

their prescriptions filled. This failure to obtain needed medications can result in an increased number of visits to the ED and hospital admissions, and the potential for increased patient morbidity and a greater financial burden for the health care system. Making pharmacy services more accessible and convenient will go a long way towards increasing compliance and potentially reducing patient readmissions that currently cost the Canadian Healthcare system approximately $1.8 billion dollars over an 11-month period [See, All-Cause Readmission to acute care and return to the emergency department – CIHI.]

In Canada, a study conducted by Hohl et al. in British Columbia investigated the rates of prescription-filling and adherence in adult patients discharged from the ED of Vancouver General Hospital, a large tertiary care facility that sees 69,000 patients annually [See, Hohl , et al, Adherence To Emergency Department Discharge Prescriptions, J of Canadian Assoc. Emer. Physicians, March 2009; 11 (2)]. The study showed that approximately 4 of 10 patients discharged from the ED did not adhere to their prescribed medication showing that compliance and adherence issues is relevant to both US and Canadian health care systems.

Specific to the hospital environment, timely access to medication dispensing and education by a pharmacist can result in improved first-fill rates, improved adherence and reduced rates of readmission. Studies show that patients failed to have their prescriptions filled even in urban settings, where retail pharmacy services are readily available in the community. A study conducted by Saunders et al. studied the compliance of patients filling prescriptions after discharge from an emergency department in Tennessee [See, Saunders, Patient Compliance in Filling Prescriptions After Discharge from the Emergency Department, Am. J. of Emergency Medicine, Vol. 5, No. 4 (July 1987)]. The study noted that cost or payment method did not seem to be a factor as rates of non-compliance were similar for patients on U.S. Medicaid and private insurance plans however 14% of patients cited lack of transportation to a pharmacy as a factor in their failure to fill their prescription. The study went on to suggest that an area of further exploration would be the effect of supplying medications directly to patients to start their treatment.

Subsequently, the issue of the effect of supplying medications directly to patients to start their treatment was studied by Ginde et al in a large tertiary care centre with over 75,000 ED visits each year [See Ginde, et al., The Effect of ED Prescription Dispensing on Patient Compliance, Am. J. of Emergency Medicine, Vol. 21, No. 4 (July 2003)]. The Ginde study evaluated whether dispensing medications in the emergency department (vs. in a pharmacy located 8 blocks away) would affect patient compliance and return visits to the ED. The study concluded that providing the entire course of antibiotics before discharge from the ED is a better delivery method than having patients fill prescriptions at an outside pharmacy. These findings are particular relevant to Ontario where some regional

hospitals service populations where no after-hours pharmacy services exist in one large site that sees approximately 98,000 ED patients a year - a patient must travel over 10km south to the nearest 24 hour pharmacy and in another example – with a site that sees 55,000 ED patients annually - no 24 hour pharmacies exist in the entire city, forcing patients to travel a distance of over 40km to the nearest town with a pharmacy open overnight.

MedAvail believes that improved access to medications at the point of prescribing results in better health outcomes for patients. Ultimately, this improved access and improved first fill rates lead to better health outcomes for the patient. By offering expanded access to pharmacy services and education upon discharge, remote dispensing locations have the potential to reduce hospital readmissions and therefore lower the financial burden to the healthcare system. While the current regulatory framework in Ontario permits the installation and operation of APSs in a hospital environment, the proposed limitation on narcotic and controlled medications will limit the benefits of such installation, and as noted above, for no public purpose.

The Importance of Narcotic and Controlled Medication Dispensing

In our discussion with hospitals in Ontario regarding deployment of MedCentres in their facilities, a number have indicated that they would welcome the potential for such deployments to have the ability to dispense narcotic and controlled substances. Recently NuVision Health, an Ontario accredited pharmacy, examined the prescribing patterns at a large regional hospital and discovered that approximately 28% of the prescriptions written for patients were for narcotics or controlled substances. 11% of written prescription for more than one medication had narcotics co-prescribed (written on the same prescription) with a non-narcotic medication.

If the Draft Regulations in their current form were to be implemented, approximately 20% of these prescriptions (11% non-narcotic and 9% narcotic) could not be filled at an APS located in the hospital. The result would be that patients that present with prescriptions with narcotic or controlled medications could not be serviced even if prescribed non-controlled medications were written on the same prescription.

Regulation in Other Jurisdictions

MedAvail has reviewed the regulations technologies similar to APSs throughout Canada and the United States. It found that in no other Canadian or US jurisdiction was there a specific prohibition on the dispensation of a particular class of medication. Each of the other jurisdictions has instead left the choice of stocking the appropriate types of medication up to the designated manager (DM) or PIC (pharmacist in charge). Specifically,

the Remote Automated Pharmacy System rules found in the Illinois Administrative Code section 1330.510 (b)(3) (Telepharmacy) do not place any limitations for narcotic medications dispensed from a remote APS such as the MedAvail MedCenter. Similar rules from British Columbia concerning Telepharmacy deployments reflected in the BC College of Pharmacists professional practice policy – 55 do not place limits on narcotic or controlled medications. While the BC telepharmacy rules do not reference APSs specifically, the BC rules are an example where medications are permitted to be dispensed from a satellite site of a pharmacy staffed by a technician. The MedCenter is considered a telepharmacy technology in many jurisdictions.

Given the regulation of automated and telepharmacy systems in other jurisdictions it appears that the College's stance on narcotic dispensing from an APS, when fully controlled by a pharmacist, is out of step with current regulatory practice. The decision to place controlled or narcotic medications in these systems should therefore be left to the Designated Manager of a pharmacy who is accountable to the College.

Should the DM decide that there is a need for narcotic medications to effectively serve a specific population, they would be required to ensure that the appropriate policies and technology safeguards are in place. The dispensing of specific classes of required medication should not be restricted without an opportunity to prove to the College that the dispensation of controlled medications is in a safe environment and benefits the patient population it will serve.

Recent Development of Relevance

Last Thursday, April 24, 2015, in the 2015 Ontario Budget, the Government of Ontario endorsed the recommendations of the Ontario Health Innovation Council. It noted that to support the growth and competitiveness of Ontario's health technology sector, the Ontario Health Innovation Council (OHIC) was established in November 2013. In December 2014, the Council issued a final report and provided recommendations to the Government, including options to reduce barriers to innovation and to better support the use of health care technologies in Ontario. In the 2015 Budget the Government stated as follows:

> The Province will adopt all of the Council's recommendations… (The Office of the Chief Health Innovation Strategist, working with stakeholders through-out the innovation ecosystem, will develop, evaluate, and coordinate pathways for the adoption and diffusion of innovative health technologies across the full continuum of the health sector (e.g., including health promotion, community care, hospitals, and home care).

In addition, the Government will continue working on shifting to strategic, value-based procurement and creating incentives for innovation.

MedAvail is an Ontario based health care technology with global potential. It has the potential to make a positive contribution to the delivery of health care in Ontario. It also has the potential to become a major exporter of Ontario originated health technology on a global scale. MedAvail deserves the full support of all parties responsible for the oversight of the delivery of health care to the residents of Ontario, including the College.

Proposed Regulation Change.

To maximize the public benefit of installing APSs in hospital and other institutional health care settings, the proposed Section 26 of the Draft Regulation must be amended. MedAvail proposes the following language:

> No controlled drugs, narcotic drugs, verbal prescription narcotics or targeted substances shall be located at or available from a remote dispensing location, except a remote dispensing location operated within a hospital or healthcare institution, or as otherwise determined by the College.

This proposed amendment will provide the College adequate discretion to authorize narcotic drugs, verbal prescription narcotics or targeted substances to be located at or available from an APS outside of a hospital setting, where appropriate safeguards are in place.

It is MedAvail's view that to prohibit in all circumstances the dispensation of narcotic and controlled medications would not serve the public interest as it would restrict access to these medications to patients in specific settings who are in acute need of treatment. While a prohibition against the dispensing of narcotics or controlled medications from a remote dispensing location outside of a hospital or other controlled setting is perhaps justified, on occasion, by security and other related concerns, there is no such rationale for extending this prohibition to APSs in hospitals, for example, emergency rooms or specialty hospital clinics, where the use of narcotics or controlled medications is an essential requirement of care.

Final Comments

The Accreditation Committee in a Council Briefing Note with respect to the Proposed Regulations dated March 2015 stated as follows:

"The results-based approach to regulation will set the objectives that the College wishes to achieve, without including the specific means to achieve them, which limits the ability of the regulation to remain relevant. Pharmacy practice is changing more rapidly than ever before as new technology becomes available and scopes of practice of practitioners change. Simply adding provisions for hospital pharmacies to the existing regulation framework will not provide the flexibility needed to adapt to practice change in any pharmacy setting."

MedAvail respectfully submits that the Draft Regulations fails to achieve a "results-based approach to regulation" with respect to the provision for the dispensation of narcotic and controlled medications from APSs in hospitals or other controlled settings.

We urge the College to review the issue of the dispensation of narcotics and controlled substances and come to a decision that is more consistent with the public interest.

Sincerely,

Edwin Kilroy
CEO, MedAvail Technologies Inc.