

service providers. Physicians also need to understand their obligations when participating in or asked to upload portions of their office EMR to an EHR operated by hospitals, regional health authorities, provinces/territories, etc. Among other things, physicians should be aware of the "core data set" for the particular EHR to which they are contributing.

Addressing patient consent issues is particularly important in the implementation of any EMR/EHR system. It is generally recognized that physicians should consider discussing with patients the inclusion of their personal health information in an EMR/EHR. Express consent may be necessary when patient information is shared with others for purposes other than providing health care (*i.e.*, outside the circle of care).

The *Electronic Records Handbook* identifies security requirements of an EMR/EHR as a priority. This includes ensuring applicable security and back-up requirements are available, and encrypting personal health information stored in electronic form. Further, EMRs/EHRs should have an audit trail that can appropriately track access to and editing of the record. EMRs/EHRs should allow the physician to control access to patient information, including through the "lock box" or "masking" requests by patients. Physicians may also need to consider appropriate secu-

urity measures and procedures when communicating personal health information via email or other electronic means.

The use of "patient health records" or "PHRs" raises unique issues for physicians and some of these issues are addressed in the *Electronic Records Handbook*. Physicians who use or access personal medical record services or other similar websites on the Internet will want to discuss with the patient the privacy risks of doing so.

The *Electronic Records Handbook* has been published in both English and French, and is available in print from the CMPA on request or can be readily downloaded from our website <www.cmpa-acpm.ca>. In addition to being a resource publication, it may be used in the continuing dialogue among stakeholders regarding how we can achieve effective EMR/EHR systems across Canada.

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¹ See P. Ceresia, M. Murphy, and S. Cross, "Electronic Records in Medical Practice: Minimizing Risk Through a Data Sharing Agreement", *Telehealth Law*, October 2008, Volume 9, Number 1.

• TELEHEALTH: A RIGHT OR A PRIVILEGE IN ALBERTA? •

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Introduction

The rapid development and growth of new information technologies has greatly expanded the ability of physicians to provide medical care over great distances, or through mediums not previously contemplated. However, the ability to transmit data, provide diagnosis and treatment and provide other clinical services via electronic media has also given rise to a host of regulatory issues. The recent regional reform in Alberta has added a new layer onto those issues.

Much of the legal discourse regarding telehealth in Canada has focused on licensure and provincial/territorial regulation of health care professionals. The recent changes in the administrative structure of

health care delivery in Alberta give rise to a new issue for consideration, namely the granting of privileges for the practice of telehealth. The impact of the changes on the granting of medical staff privileges in Alberta, and the approach taken in the context of provincial Medical Staff Bylaws will be explored in this article.

Background

Telehealth¹ is defined by the College of Physicians and Surgeons of Alberta ("CPSA") as

the provision of medical diagnosis and patient care by means of electronic communication where the patient and the provider are separated by distance, and may include, but is not limited to, the provi-

sion of pathology, medical imaging and patient consultative services.²

Telehealth has the potential to improve timeliness and access to services, but also facilitates the delivery of health care to rural and remote areas in Canada. For these reasons it has been described as “one of the most promising aspects of the Canadian health care system”.³

Licensure of Physicians Practising Telehealth

Despite its growth over the past five decades, a consistent approach to licensing physicians who practise telehealth has yet to be developed in Canada. The intent of an appropriate licensure regime is to ensure that

... physicians are properly qualified and comply with standards of practice imposed by their self-governing colleges so as to be properly accountable to their patients and the public and in order to maintain public trust.⁴

Provincial/territorial regulatory authorities responsible for regulating the medical profession in their own jurisdiction have taken different approaches to the telehealth licensure. The lack of consistency in licensure requires a physician to check with the provincial/regulatory authority (e.g. College) in his/her own jurisdiction, as well as the regulatory authority in the jurisdiction where the patient is located to determine licensure requirements.⁵ Further uncertainty exists regarding which jurisdiction’s laws apply to the telehealth encounter.

The common law suggests that the *situs* of the service is the place where the patient receives the services. Therefore, in accordance with the common law, it is argued that the provision of care through telehealth should be governed by the laws and practices of the patients’ province or territory. Of course, not all jurisdictions in Canada are governed by the common law. In Quebec, the *Act to Amend the Act Respecting Health Services and Social Services and Other Legislative Provisions* holds that the locus of service is the practitioner’s location.⁶

The CPSA is one of four regulatory authorities in Canada that has existing telemedicine specific by-laws.⁷ On January 1, 2010, the medical profession came under the *Health Professions Act*, RSA 2000,

c. H-7, and the *Standards of Practice* is implemented by the CPSA. Similar to the existing CPSA by-laws, the *Standards of Practice* provide that a physician must not practise telemedicine in the province from a location outside of Alberta unless they are registered with the Alberta College. In addition, a physician in Alberta who provides telemedicine to a patient located outside of the province must comply with any licensing or registration requirements of the jurisdiction where the patient is located. There is an exception to registration with the College where the consultation is for emergency assessment or treatment or where the physician provides less than six telemedicine services in Alberta per year.⁸

The Changes to Alberta’s Regulatory Environment

On April 1, 2009, eight of Alberta’s nine Regional Health Authorities were eliminated and the province became, essentially, one large Regional Health Authority now referred to as Alberta Health Services (“AHS”).⁹ Under Alberta’s *Hospitals Act*, a hospital (and, following the advent of regionalization in 1994, each Regional Health Authority) required:

... the preparation and adoption of bylaws by its medical staff governing the organization and conduct of the medical staff practicing in the hospital [now region] and the procedures whereby the medical staff must make recommendations to the board concerning the appointment, re-appointment, termination or suspension of appointment of, and the delineation of hospital privileges of, members of the medical staff.¹⁰

Previously, each of the nine regions had prepared and adopted its own approved Medical Staff Bylaws. Telehealth, as a means of providing clinical services, was typically not addressed in the context of privileging, being more of an issue for Rules adopted by the Medical Staff, or regional or hospital policy. The Bylaws in place were largely patterned on earlier, hospital-based models.

However, the movement from nine regions to one in Alberta created the need for the creation and adoption of one set of over-arching provincial Medical Staff Bylaws to deal with all interactions between the Region and its now-unified medical staff.

A joint AHS/Alberta Medical Association Working Group (“the Working Group”) was established in

early 2009 with the mandate of drafting such a document. One of the myriad of issues discussed by that Working Group was how to deal with the desired use of AHS resources or facilities by Alberta physicians, or physicians practicing in other jurisdictions, through electronic media (*i.e.*, telehealth).¹¹

Discussion of Telehealth in the Context of Privileges

Privileges grant a physician the ability to provide certain clinical services within certain facilities, using certain specified resources. The Working Group currently defines “Clinical Privileges” as follows:

Clinical Privileges: The delineation of the Procedures that may be performed by the Practitioner; the Sites of Clinical Activity in which the Practitioner may perform Procedures or provide care to Patients; and the AHS Services and Programs that are available to the Practitioner in order to provide care to Patients.

For the purpose of Medical Staff organization, Alberta is notionally divided into five Zones: North, Central, South, Edmonton and Calgary. While the appointment of a physician to the Medical Staff is to be done on a provincial basis, the delineation and granting of privileges will be assessed on a zonal basis, having regard to both geographic and physician workforce issues, as well as the availability of resources.

As mentioned at the outset of this article, the Alberta College defines telehealth. In the current draft Bylaws, the drafters have chosen to define “Telemedicine” as follows:

The provision of services for Patients, including the performance of Procedures via telecommunication technologies, when the Patient and the Practitioner are geographically separated. This will include Practitioners in Alberta, as well as those outside Alberta who are on the Telemedicine Register of the College of Physicians and Surgeons of Alberta.

And so it is quite possible, if not likely, that on any given day a physician in the Southern Zone will be transmitting diagnostic results and a request for consultation to a physician in the Edmonton Zone. A physician in Calgary could be providing on-line patient care to a patient residing in the Northern Zone. Or physicians in various Zones across the province could

be accessing or receiving diagnostic results from radiology or laboratory facilities located and operating in one specific Zone. All of these clinical activities involve the accessing of AHS resources or facilities, and all are being performed via telehealth media (or, as referred to in the draft Medical Staff Bylaws, “telemedicine”). The question is, how are privileges relating to the provision of telehealth/telemedicine services within Alberta to be granted?

The approach currently being considered by the Working Group is an interesting one. Rather than identifying the clinical services, or even the specific media involved, the thought is to deem telehealth as essentially another “site” where clinical activity occurs.

It was common ground that AHS would grant clinical privileges to physicians which would specify (a) the services and programs to be accessed by the physician; (b) the procedures which may be performed by the physician; and (c) the sites of clinical activity where the procedures may be performed. Telehealth encompasses more than just services and resources to be accessed, or procedures to be performed. The definition requires consideration as well as where the procedures would be performed (much as historically been the case with licensure issues). It seemed to make sense to approach the question of granting privileges to provide telehealth services as if it was the site of clinical activity, albeit a virtual one.

Therefore, the current working model of the Alberta Bylaws specifically provides for the establishment of a list of procedures, from which the specific procedures to be performed by a specific practitioner are to be drawn; and, in addition, defining the various sites of clinical activity at which those procedures may be performed. Those sites will reflect geographic restrictions as well as access to specific facilities. The sites would generally fall into these categories:

- a) Inpatient hospital services (normally including admission and treatment of hospitalized patients and the use of diagnostic and treatment resources);
- b) Specialty and outpatient clinics and services in hospital facilities (normally including the treat-

- ment of ambulatory patients, with access to diagnostic and other treatment resource);
- c) Continuing care facilities; and
- d) Telemedicine.

In the result, the current privileges model being contemplated in Alberta would require an Alberta physician to identify, in his/her application for privileges, whether it is the intention to provide services in Alberta via telehealth and concurrently demonstrate competence and capability to provide such services. The grant of Clinical Privileges would identify telemedicine as one of the Sites of Clinical Activity at which that practitioner was privileged to provide clinical services.

In addition, a physician outside of the province of Alberta would have to seek an appointment to the AHS Medical Staff, either on a Temporary or Active basis, and obtain a grant of Clinical Privileges allowing him/her to either provide clinical services for patients within the province, or alternatively to receive and respond to a request for clinical services from within the province. In order to receive the appointment to the AHS Medical Staff, the extra-provincial physician would need to be on the Telemedicine Register of the Alberta College of Physicians & Surgeons. It is recognized that this may, in some instances, provide a dis-incentive for physicians in other jurisdictions to practise telehealth, but the Working Group felt that the benefits of assuring proper credentialing for services provided in Alberta out-weighed that risk.

While this approach has some appeal and seems to make sense in the context of privileges, there are still questions that need to be addressed. These include:

- What are the rights and responsibilities of physicians who are not members of the Medical Staff in the context of telehealth? More simply, is telehealth in the basket of basic clinical services that all physicians may provide?
- What is the rationale for the CPSA's exception for six or less telehealth encounters in Alberta? With the new appointment and privileges processes in Alberta, will this exception continue to be required?

- How will the region track telehealth use in the context of resource allocation and workforce planning?
- How will resources be allocated as between Zones (or, in other jurisdictions with a similar approach, between regions)?

Much like the process itself, the answer to these questions will continue to evolve in Alberta, and in other jurisdictions, as the process and technology itself evolves. The key is to work with the funding agencies and the regions to facilitate the proper and regulated use of this important technology.

A final word of caution: the Bylaws giving rise to this model are still in draft stage, and have yet to be either ratified by the physicians in the Province of Alberta, nor have they received the approval of the AHS Board or the Minister (as currently required under existing legislation). Nevertheless, the approach advocated represents an innovative answer to the dilemma posed by the increasing use of telehealth/telemedicine by physicians.

Conclusion

It is difficult to argue against the value of telehealth in a country like Canada. The sheer distances and logistical difficulties in providing hands-on clinical services combine to demand innovative approaches to the provision of clinical services. The evolution of electronic medical records and associated transmission of data amount to one of those innovative approaches.

However, the regulatory challenges associated with the provision of telehealth cannot be ignored. While clearly there has been much work done in the context of licensing and the regulation of physicians by colleges, the need to address resource allocation on a provincial or regional basis now requires a similar approach in the context of privileging. That, in and of itself, will present further challenges, but it is hoped that the model currently being proposed in Alberta will provide some guidance or, at least, some basis for further discussion.

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- ¹ Note: “Telehealth” and “telemedicine” are used interchangeably in this article.
- ² The College of Physicians & Surgeons of Alberta, “*Health Professions Act: Standards of Practice*” (Approved September 11, 2009) at p. 32 online: <http://www.cpsa.ab.ca/Libraries/Res_Standards_of_Practice/HPA_Standards_of_Practice_Consolidation_Issued_Jan_1_2010.pdf>.
- ³ National Initiative for Telehealth, “*Framework of Guidelines*” (September 2003) at 18.
- ⁴ Dr. John R. Carlisle, “*Regulatory aspects of telehealth*” *Future Practice* at 26 online: <http://www.cma.ca/Multimedia/CMA/Content_Ima

ges/Inside_cma/WhatWePublish/LeadershipSeries/English/regulatory.pdf>.

⁵ *Ibid.*

⁶ Madeleine Donahue, “Quebec Moves the Telehealth Yardstick Forward” (2006) 27:2 *Health L. Can.* 29 at 29. However, it is notable that the *Act* only applies to telehealth services delivered within the province and does not govern telehealth services that are delivered across provincial/territorial borders.

⁷ Madeleine Donahue, “*Licensure and telemedicine: A national review of policies*” *Canadian Healthcare Technology* (February 2009) at 10 online: <<http://www.macleodixon.com/images/DOC001.PDF>>.

⁸ *Supra* note 2.

⁹ Alberta Ministerial Order #93/2008.

¹⁰ *Hospitals Act*, RSA 2000 Chapter H-12, s. 17(1)(a).

¹¹ It is important to understand that the current model being contemplated in Alberta does not require all physicians to be members of the Medical Staff; only those who wish to utilize AHS facilities or services and resources. There will be a basic group of services and resources (including laboratory and diagnostics) which will be available to all physicians without the need for an appointment or privileges.

• IMPLICATIONS OF ISO CERTIFICATION AND LICENSING OF PATIENT MANAGEMENT SOFTWARE •

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Introduction

On August 31, 2009, Health Canada’s Medical Devices Bureau posted an announcement (file number: 09-122095-269; Subject: Classification of Medical Devices Class I or Class II patient management software) that patient management software may be subject to classification as either Class I or Class II medical devices and will require compulsory licensing. Currently, a large number of patient management software providers are not licensed. This is not a new licensing issue; Health Canada has classified patient management software as medical devices for almost five years. However, this is the first time Health Canada has set a deadline for licensing approval and International Organization for Standardization (ISO) certification, and it is the first time Health Canada has publicly announced that patient management software that allows data to be “manipulated” will be classified as Class II medical devices.

There are implications associated with Health Canada’s announcement for physicians and health care administrators, federal and provincial health ministries, and industry: The disruption in the use or sale of patient management software could potentially compromise the ability of these stakeholders to administer effective health care.

Objective

The purpose of this article is to identify the issues surrounding this topic and the potential impact that Health Canada’s classification of patient management software as medical devices will have on health care administrators, physicians, federal and provincial health ministries, and industry.

Findings

The main issue concerning all stakeholders is that there is not enough capacity in Canada to support vendors requiring ISO compliance for patient man-