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| MR Legal Counsel | | | **Memorandum** | |
| To: | Alberta Medical Association | Date: | February 9, 2016 |
| From: | Jon Rossall | File: | 131319 |
| Subject: | **PCN Information Management/Sharing Agreements** | | |
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**I Introduction**

We have been asked by the AMA’s PCN Program Management Office to assist in reviewing the current PCN arrangements regarding patient and physician information management, as well as the sharing of health information in the context of existing legislative and regulatory requirements, in order to provide advice regarding the updating of contractual arrangements between custodians of that health information. What follows is our analysis of the variety of arrangements currently in place in Alberta; an overview of legislative and regulatory requirements; a discussion of the impact of those requirements on the various PCN models operating in Alberta; and some recommendations regarding information sharing and management.

**II. Background/Facts**

Primary Care Networks were developed within Alberta as a result of the creation and funding of the Primary Care Initiative as a component of the 2003 Master Agreement Regarding the Tri-Lateral Relationship and Budget Management Process for Strategic Physician Agreements (“the Tri-Lateral Agreement”). As of that point in time, the *Health Information Act* (“*HIA*”) was still in a stage of relative infancy, having been proclaimed into force on April 21, 2001. Even so, the *HIA* established the privacy framework for the gathering, use and disclosure of health information[[1]](#footnote-1) by custodians[[2]](#footnote-2) and their affiliates[[3]](#footnote-3), and the basic requirements for the sharing and management of health information.

While the security and management of patient information was one of the focuses as PCNs evolved in the mid-2000s, the knowledge of how to deal with information sharing and management was not as sophisticated and detailed as is the case in 2015, hence the agreements put in place were inconsistent and in many cases, inadequate. In addition, PCNs took on many different attributes, creating a variety of models of service provision. In order to properly address the current need for information sharing and management agreements, it is necessary to analyze the existing PCN models and address each need in that context.

The following facts and assumptions are relevant to this analysis.

1. Each PCN will fit into one of the following models
2. A centralized model (i.e. no member clinics) overseen by a Board composed of representatives from the Not-for-Profit Corporation (“NPC”).
3. A centralized model (i.e. no member clinics) overseen by a Board composed of NPC representatives as well as AHS representatives.
4. A de-centralized model, with multiple clinics, overseen by a Board composed of representatives from the NPC.
5. A de-centralized model, with multiple clinics, overseen by a Board composed of NPT representatives as well as AHS representatives.
6. A mixture of centralized office and de-centralized clinics, overseen by a Board composed of representatives from the NPC.
7. A mixture of centralized office and de-centralized clinics, overseen by a Board composed of NPT representatives as well as AHS representatives.
8. The majority of these PCNs utilize staff employed by the PCN.
9. The majority of the PCNs utilize Electronic Medical Records (“EMR”s) and contract with system providers (“Vendors”) to provide information management services.
10. There are many PCNs where PCN clinical staff are documenting directly in the clinic/physicians’ EMRs.
11. There are various and diverse arrangements with Vendors relating to utilization of EMRs.
12. There are some scenarios where Information Management Agreements are in place between the PCNs and their Vendors.
13. In addition, there are Information Management Agreements in place between the member clinics and their Vendors.
14. The patient health records in an EMR are records generated as the result of the provision of diagnostic, treatment or care services, or are “registration information[[4]](#footnote-4)” and therefore qualify as health information as that term is defined in the *HIA*.
15. In all PCN models, data is shared with or disclosed to non-custodian third parties (i.e. executive directors, panel facilitators and evaluators) for the purpose of business management, assessment and quality control with the knowledge and consent of physicians working in the PCN.
16. Patients have not given their express consent to that use or disclosure of their information described in #9 supra.
17. Data shared or disclosed is either patient level identifiable or anonymized.
18. In most PCN scenarios, the PCN staff collects, codes, and manipulates patient level data from clinics in the PCN.
19. It is common for PCN-employed clinical staff, such as dieticians, rehabilitation specialists or other health professionals to visit member clinics on a rotational basis. When this occurs, these health professionals will be acting as affiliates of the custodian/physicians working in those clinics and are therefore entitled to access the health records and chart on the clinic EMR.
20. Currently AHS is not receiving or accessing patient identifiable information from the PCNs in the absence of information sharing or management agreements.
21. Staff permission to access and the way staff accesses the data is addressed, to a greater or lesser extent, in employment agreements.
22. Disclosure of information to the non-custodians referenced in items #6 and 7 is not for clinical treatment purposes, but rather for things like internal management purposes, quality improvement, resource allocation, etc..
23. It is arguable that employees of PCNs who collect, code and/or manipulate data for the purpose of use or disclosure by non-custodian third parties are also information managers.
24. Therefore, the sharing and management agreements must deal with secondary use of information.
25. Historically, many custodians of health information have dealt with the issues of appropriate disclosure of information to third parties through the means of Disclosure Agreements.

**III. Role of the Custodian**

All of this is in the context of the custodial responsibilities of the physicians practicing in PCNs. Alberta’s *HIA* places a number of duties on the shoulders of custodians[[5]](#footnote-5). Those duties include:

* The duty to collect, use or disclose health information with the highest degree of anonymity possible;
* The duty to collect, use or disclose health information in the most limited manner necessary to achieve the desired purpose;
* The duty to protect health in formation in that physician’s custody or control;
* The duty to ensure the accuracy of health information;
* The duty to identify responsible affiliates of the custodian;
* The duty to establish or adopt necessary policies and procedures to facilitate the implementation of responsibilities under the *HIA*;
* The duty to prepare appropriate Privacy Impact Assessments; and
* The duty to provide notification to patients regarding reasons for the collection of health information

Meeting these duties and obligations becomes more complex and demanding when custodians share identifiable health information amongst themselves. Custodians who share identifiable health information with other custodians for secondary purposes (i.e. not treatment-related) should have agreements in place governing that sharing. This is in accordance with article 15(b) of the College of Physicians and Surgeons of Alberta (“CPSA”)’s Standards of Practice.

**IV. Relevant Legislation/Standards**

Information Management services are defined in the *HIA* as including the processing, storage, retrieval or disposition of health information; the stripping, encoding or otherwise transforming of individually identifying health information in order to create non-identifying health information; or the provision of information management or information technology services.[[6]](#footnote-6) The definition is very broad.

It is important to note that by definition, Information Managers are affiliates of the custodians who appoint them.

As mentioned in the assumptions above, an EMR vendor qualifies as an information manager. However, it is likely the case that employees of PCNs who collect, code and/or manipulate data for the purpose of use or disclosure by non-custodian third parties are also information managers.

As per section 66(2), a custodian must enter into a written agreement with an information manager for the provision of any or all of the services described in subsection 66(1). Section 66(3) dictates that custodians may only disclose health information to information managers once an information management agreement is in place.

Section 31 of the *HIA* states that “no custodian shall disclose health information except in accordance with this Act.” As noted above, a custodian has the authority to disclose health information to an information manager when an information management agreement is in place between the two parties (information manager and the custodian(s)). If there is no agreement in place, a custodian may be found to have contravened section 31 of the *HIA*.

Section 66(7) of the *HIA* reads “a custodian that is an information manager for another custodian does not become a custodian of the health information provided to it in its capacity as an information manager, but nothing in this section prevents the custodian from otherwise collecting, using or disclosing that same health information in accordance with this Act.” Therefore, the Vendors, or staff who are acting as information managers do not by virtue of the receipt of health information become custodians of that information. They remain affiliates of the custodians who have disclosed or shared the information.

**Regulating Information Management Agreements**

The *Health Information Regulation*, AR 70/2001 (“*HIR”*) sets out what must be contained in an Information Management Agreement, as per section 66(2) of *HIA*:

**7.2** For the purposes of section 66(2) of the Act, an agreement between a custodian and an information manager must

(a) identify the objectives of the agreement and the principles to guide the agreement,

(b) indicate whether or not the information manager is permitted to collect health information from any other custodian or from a person and, if so, describe that health information and the purpose for which it may be collected,

(c) indicate whether or not the information manager may use health information provided to it by the custodian and, if so, describe that health information and the purpose for which it may be used,

(d) indicate whether or not the information manager may disclose health information provided to it by the custodian and, if so, describe that health information and the purpose for which it may be disclosed,

(e) describe the process for the information manager to respond to access requests under Part 2 of the Act or, if the information manager is not to respond to access requests, describe the process for referring access requests for health information to the custodian itself,

(f) describe the process for the information manager to respond to requests to amend or correct health information under Part 2 of the Act or, if the information manager is not to respond to requests to amend or correct health information, describe the process for referring access requests to amend or correct health information to the custodian itself,

(g) describe how health information provided to the information manager is to be protected, managed, returned or destroyed in accordance with the Act,

(h) describe how the information manager is to address an expressed wish of an individual relating to the disclosure of that individual’s health information or, if the information manager is not to address an expressed wish of an individual relating to the disclosure of that individual’s health information, describe the process for referring these requests to the custodian itself, and

(i) set out how an agreement can be terminated. [emphasis added]

In addition, the recent College of Physicians & Surgeons of Alberta (“CPSA”) Standard of Practice regarding Patient Record Retention[[7]](#footnote-7) states as follows:

(2) A regulated member acting as a custodian **must** have policies and procedures in place in accordance with the HIA that:

(a) includes an information manager agreement, if an information manager has been identified;

(b) establishes processes for the retention, protection, access, disclosure and secure destruction of patient health information; and

(c) clarifies roles, expectations and accountabilities of all parties.

**Regulating Information Sharing Agreements**

The same Standard of Practice regarding Patient Record Retention also addresses the sharing of patient health information amongst physicians.

(3) A regulated member acting as a custodian who shares patient information with other custodian(s) **must** have an information sharing agreement that clarifies access, transfer and return of patient records.

While at first blush this requirement would appear to be broad enough to capture all situations where one custodian discloses information to another (including when providing continuity of care) as will be seen below, it is likely not that stringent.

The identification of this Standard of Practice should not be seen to ignore the physicians’ professional obligations to the patients who are, after all, the owners of the information which is being shared.

Physicians are bound by the provisions of both the *HIA* and the Standards of Practice of the CPSA. As a result, those physicians who are custodians of identifying health information stored in an EMR are required to be a party to both an information management agreement and an information sharing agreement.

**V. Issues**

1. Who are the information managers in the various PCN models?
2. Are there information management agreements currently in place between information managers and the custodians of the health information?
3. If not, or if they are inadequate, what agreements should be put in place?
4. Are there currently information sharing agreements in place between custodians within the various PCN models?
5. If not, or if they are inadequate, what agreements should be put in place?

**VI. Discussion**

As outlined above, the definition of “information manager” in the *HIA* is very broad and arguably could capture PCN staff or the PCN itself in addition to the clinic Vendors. Clearly the wording of section 66(1) of the *HIA* suggests that the services being provided by an information manager must be technical in nature – processing, storing, retrieving or disposing of information, stripping, encoding or otherwise transforming, or providing information management or technology services.

Affiliate or Information Manager?

Drawing a distinction between affiliates who are providing services to custodians in the course of their employment, and affiliates who are actually information managers is not always easy. Put simply, while all information managers are affiliates, not all affiliates are information managers. Each scenario should be examined on its own merits and circumstances and analyzed to determine if, in fact, information management services are being provided and if so, should an information management agreement be put in place.

It may be that the employment agreements between PCN staff and PCNs address information management issues. However, it is important to distinguish between PCN-employed staff who are providing clinical services at member clinics, and PCN staff who are gathering, using and disclosing information for secondary purposes. The former group would be seen as affiliates[[8]](#footnote-8) of the physicians at the member clinics, and therefore no specific agreement is required. The latter group would not necessarily be affiliates (although they could be in certain circumstances), and some reference to the *HIA* would be necessary to determine if use or disclosure of this information by these individuals is acceptable.

For greater clarity, we have attached a Matrix as Schedule “A” to this Memorandum that lays out the various and varying roles that PCN staff/affiliates may play, and making suggestions regarding scenarios where Information Management Agreements may be required. Where there is doubt, it would be wise to err on the side of caution and implement such an agreement.

Clinic Managers may have specific provisions in their employment agreements with the clinics dealing with the confidentiality of information, the need to protect the information and detailing how, and to whom, information may be disclosed. That agreement, or that wording, may be sufficient to constitute an Information Management Agreement. However, a PCN-employed health care professional who attends at a member clinic to provide clinical services would be seen as an affiliate of the custodial physician(s) at the clinic and would not require an Information Management Agreement. As well, information management agreements should exist between either the PCNs or member clinics and the Vendors currently providing information management services. These agreements were standardized in the time frame where the Physician Office Support Program was in place, but may need to be updated.

The other point is that it is not enough to simply give direction to an affiliate, or to put an information management agreement in place – the custodial responsibilities extend to a continuing obligation to monitor and ensure that the directions, or the terms of the agreement are being honored and that the affiliate or information manager are not going beyond the direction, or the terms and conditions of the agreement.

If information management services are being provided, then agreements must be put in place between those persons/entities providing the services and the custodians of the health information which is the subject matter of the services. Those agreements must address the following[[9]](#footnote-9):

* + - the objectives of the agreement and the principles to guide the agreement;
    - whether or not the information manager is permitted to collect health information from any other custodian(s);
    - whether or not the information manager may use health information provided to it;
    - whether or not the information manager may disclose health information provided to it by the custodian;
    - the process for the information manager to respond to access requests under Part 2 of the Act;
    - the process for the information manager to respond to requests to amend or correct health information under Part 2 of the Act;
    - how health information provided to the information manager is to be protected, managed, returned or destroyed;
    - how the information manager is to address an expressed wish of an individual relating to the disclosure of that individual’s health; and
    - how an agreement can be terminated and what happens to stored information upon termination.

It is also important to review and understand the nature of current disclosure or sharing with non-custodial third-parties such as PCN clinic managers, executive directors, or panel facilitators, and under what circumstances or pursuant to what agreements such use or disclosure is occurring. Custodians who share identifiable health information with other custodians in an EMR should also have agreements in place governing that sharing. This is in accordance with article 15(b) of the CPSA Standards of Practice.

Use vs. Disclosure

In reviewing the use or disclosure of health information by custodians, PCNs, and PCN staff, it is important to note that the secondary uses and disclosures of individually identifying health information are clearly outlined in the *HIA.* It is obviously critical to distinguish between the PCNs or the custodians’ use and disclosure of information in this regard because the rules are different. For example, in the confines of a member clinic, health information gathered in the course of clinical visits may be viewed, relied upon and “used” by custodians for many purposes. The concept of “using” information includes viewing, and even copying. The key is that the custody and control of the information is not lost.

However, the ability to “disclose” that information to third parties outside the clinic is more constrained. “Disclosure” goes one step further and embodies the notion of releasing custody or control of the information.

Section 27(1) of the *HIA* spells out how a custodian may use individually identifying health information in its custody or control. Those are as follows:

(a) providing health services;

(b) determining the eligibility of an individual to receive health services;

(c) conducting investigations, disciplinary proceedings or practice reviews;

(d) conducting research on certain terms and conditions;

(e) providing for health services provider education;

(f) carrying out a purpose provided for by Canada’s or Alberta’s laws; and

(g) for internal management purposes, including planning, resource allocation, policy development, quality improvement, monitoring, audit, evaluation, reporting, obtaining or processing payment for health services and human resource management.

Given that custodians are entitled to utilize the services of affiliates in order to fulfill custodial duties and obligations, it would seem that the use of health information by the PCN staff for the purpose of analyzing efficiencies, uses, and quality improvement within the PCN is authorized under the *HIA*.

Sections 35 – 39 of the *HIA* deal with authorized disclosures of individually identifying health information by custodians with custody and control of that information. Significantly, the anticipated disclosures do not include the ability to disclose information to non-custodians such as executive directors, clinic managers, or panel facilitators for the purposes of analyzing the operations of the PCN or carrying out quality improvement or monitoring (unless the panel is designated as a Quality Assurance Committee pursuant to section 9 of the *Alberta Evidence Act*). (Note: if those executive directors, clinic managers or panel facilitators are actually affiliates of the custodians, then disclosure is authorized under the HIA).

It is noteworthy that a custodian may disclose individually identifying health information to another custodian for the same purposes as identified above, under the discussion regarding uses. Those uses include “…internal management purposes, including planning, resource allocation, policy development, quality improvement, monitoring, audit, evaluation, reporting, obtaining or processing payment for health services and human resource management”.[[10]](#footnote-10) However, the key is that the disclosure must be to another custodian.

The notion of “disclosure” is in many ways synonymous with the “sharing” of information. So, a disclosure of information to another custodian would be seen as a sharing of such information and therefore would bring into question the need for an Information Sharing Agreement. This would be onerous indeed if every custodian involved in the continuity of care for a given patient was required to enter into an Information Sharing Agreement before disclosing information. The answer is, under the HIA a custodian may disclose individually identifying health information to another custodian outside of his/her clinic for the purpose of providing a health service, and that does not trigger the need for an ISA because it is for the purpose of patient treatment.

That said, if the individuals to whom the information is being disclosed are affiliates of the custodians, then the information could be seen to be “used” by those affiliates for appropriate purposes. However, the relationship that creates the custodian/affiliate relationship should be properly documented with either a Service Agreement or other documentation, and should establish the parameters of use.

It may be useful, at this point, to briefly discuss the use of Disclosure Agreements. Historically these documents have been created and relied upon ostensibly to satisfy the requirements of the *HIA* by identifying the purpose of disclosures and any restrictions. The reality is that Disclosure Agreements are not required under the *HIA*. Disclosures are permitted under the *HIA* in certain identifiable situations without the need for a written agreement. In fact, in many situations it is impractical if not impossible to put an agreement in place regarding disclosure. In other situations, such as use of health information for research purposes, the disclosure is captured in a Research Agreement mandated by the Ethics Committee. It is our view that the continued use of Disclosure Agreements is unnecessary and confusing and the focus instead should be on Information Management and Information Sharing Agreements.

It should also be noted that there is a proviso that a custodian may disclose health information to the Minister of Health (or delegate) if the disclosure is necessary or desirable (in the opinion of the custodian) to enable the Minister to carry out his or her duties. And, section 46(1) allows the Minister to request disclosure for health system management purposes.

Finally, section 47(1) of the *HIA* allows AHS to request disclosure of health information from a custodian where the information relates to a health service that is fully or partially paid for by AHS, or that has been provided using AHS’ financial, physical, or human resources.

While it may be possible (and sometimes required) to disclose identifying patient information to AHS or the Minister, or to another custodian, for internal management purposes, the disclosure of this information to non-custodial third-parties for the purpose of analyzing PCN activities or quality control is not specifically authorized under the *HIA*.

**VII. Guiding Examples**

To assist custodians in determining when they will require certain agreements, the following list is instructive, but not exhaustive, of potential circumstances custodians may find themselves in:

* **Information Management Agreement**
  + PCNs or member clinics are using a billing agent or external transcription service;
  + PCNs or member clinics are using a storage firm for electronic or paper records;
  + Improvement facilitators or other external consultants are being given access to the EMR data
  + PCN staff are sharing EMR data with AHS and receiving altered data in return;
  + PCNs or member clinics are using an application service provider or remote data storage;
  + Data is processed, stored, retrieved, or disposed of by a party other than the custodian, including non-clinical PCN staff;
  + Data is stripped, encoded, or transformed by a party other than the custodian, including non-clinical PCN staff; or
  + A party other than the custodian provides information technology services.
* **Information Sharing Agreement**
  + Identifiable Health Information is stored in an electronic record and accessed, used or disclosed by more than one custodian;
  + Identifiable Health Information is shared between PCN clinic sites;
  + Identifiable Health Information is shared within the PCN for the purpose of patient care;
  + Identifiable Health Information is shared externally for the purpose of patient care; or
  + Identifiable Health Information is disclosed to external third party custodians, such as Alberta Health Services or the Health Quality Council of Alberta.

**VIII. Recommendations**

1. Existing agreements between PCNs and Vendors, individual custodians and Vendors, and PCN staff and PCNs/clinics should be analyzed to determine if some or all of these requirements are being addressed, and if not, amendments to those agreements should be undertaken.
2. Where custodians are relying on Vendors, or PCN staff to provide information management services, and there are no existing agreements covering those services, then agreements should be put in place that meet the requirements of the *HIA*.
3. Where custodians are obtaining information management services from other sources, Information Management Agreements should be entered into between those custodians and the Information Manager.
4. Where physician custodians are sharing identifiable information amongst themselves in an EMR, Information Sharing Agreements should be put in place to accord with article (3) of the CPSA Standard of Practice regarding Patient Record Retention.
5. Emphasis should be placed on implementing Information Management and Information Sharing Agreements, and in educating custodians regarding the approved uses and disclosure of health information, rather than relying on Disclosure Agreements.
6. The disclosure of individually identifying health information by custodians to non-custodial third parties for the purposes of analyzing PCN business activities or quality control should cease, as it is not authorized under the *HIA*. Alternatively, if those non-custodial third parties are actually affiliates of the custodians using the health information on the specific directions of custodians, then service agreements or other documentation should be developed to clarify the custodian/affiliate relationship and to put necessary parameters on that use.

1. As that term is defined in s. 1(1)(k) of the *HIA* [↑](#footnote-ref-1)
2. In this Memorandum, where appropriate the word “custodian” may be interpreted to include health professionals other than physicians who are identified as custodians either in the HIA or the Health Information Regulations [↑](#footnote-ref-2)
3. As that term is defined in s. 1(1)(a) of the *HIA* [↑](#footnote-ref-3)
4. As that term is defined in s. 1(1)(u) of the *HIA* [↑](#footnote-ref-4)
5. As that term is defined in the HIA, which includes (but is not limited to) physicians. [↑](#footnote-ref-5)
6. *HIA*, s. 66(1) [↑](#footnote-ref-6)
7. Approved by Council December 4, 2015, Effective January 2016 [↑](#footnote-ref-7)
8. As that term is defined in the HIA [↑](#footnote-ref-8)
9. HIA, s. 66(2) [↑](#footnote-ref-9)
10. *HIA,* s. 27(1)(g) [↑](#footnote-ref-10)