

April 14, 2023

**Attention: Dr. Donna Roche:**

**Re: Statutory review of the *Personal Health Information Act***

We would like to thank the Personal Health Information Act Review Committee for the opportunity to provide comments in connection with the second statutory review of the *Personal Health Information Act* (“PHIA”).

### **eDOCSNL: Background and Context**

eDOCSNL is the provincial electronic medical record (“EMR”) program for physicians and other health care providers. The eDOCSNL program is jointly governed by a Memorandum of Understanding between the Department of Health and Community Services, the Newfoundland and Labrador Medical Association and the Newfoundland and Labrador Centre for Health Information (“NLCHI”), and supported by the Information Management Framework policy (attached). .

That joint governance manifests in the eDOCSNL EMR Management Committee, on whose behalf this submission is made. Our committee is responsible for providing ongoing advice, guidance and direction related to the management of the eDOCSNL program. Our goal is to ensure that eDOCSNL is a sustainable provincial program that helps health care providers manage their practice and care for their patients, while facilitating responsible secondary use of data for purposes for policy and planning and other uses as approved by the Management Committee and authorized by PHIA, such as, management, quality control, public health monitoring, program evaluation, research and education.

Over 5000 personnel including over 780 health care providers, other health professionals, and staff from regional health authorities and private practices, participate in the eDOCSNL program and contribute to patient records in over 150 EMR instances. The eDOCSNL EMR includes integration with various components of the provincial electronic health record, HEALTHeNL (such as those relating to medical and drug history, laboratory results and diagnostic imaging) and the Newfoundland and Labrador Medical Care Plan for physician billing.

Health care providers who participate in the eDOCSNL program, rather than independently contracting with an EMR vendor, contract with the Program to receive support and educational resources from eDOCSNL that are aimed at fostering a privacy-respectful culture and compliance with PHIA.

NLCHI has transitioned into the Provincial Health Authority (“NL Health Services”) as of April 1, 2023, and has ceased to exist as an independent corporate entity. All provincial eHealth programs and functionality, as well as all approved provincial eHealth data, will be part of this transition.

## Opportunities & Challenges

In relation to PHIA reform, we often encounter issues with respect to custodianship of records in shared EMR instances – such as responsibility for abandoned records, custodian succession, and the respective obligations of custodians and information managers – not all of which have clear answers under PHIA. We would like to take this opportunity to recommend amendments to certain sections of PHIA in an effort to address these issues.

### 1. Revise definition of “record” to account for audit trails

Section 2(s) of PHIA provides the following definition of record:

“**record**” means a record of personal health information in any form, and includes personal health information that is written, photographed, recorded or stored in any manner, but does not include a computer program or a mechanism that produces records on a storage medium

We have encountered confusion among stakeholders, including EMR vendors and custodians who participate in the eDOCSNL program, about what constitutes a “record” when personal health information exists in electronic format. The answer to this question is of crucial importance to the eDOCSNL program, since it impacts the scope of a custodian’s record storage, retention and disposal obligations under PHIA.

The eDOCSNL EMR contains metadata about health records that is stored in audit trails. In basic terms, an audit trail is a record that shows who has accessed a computer system, when it was accessed and what operations were performed<sup>1</sup> – including what records were accessed and how they were processed. The existence of metadata arising out of audit trails is specific to storing personal health information in electronic format. In our view, it is not clearly reflected in the current definition of “record” (or elsewhere in PHIA).

We take the view that audit trails should be considered part of a “record” for the purposes of Part II (Practices to Protect Personal Health Information) of PHIA, such that storage, retention and disposal obligations apply to audit trails. Similarly, given the value of audit trails for ensuring compliance with PHIA (for example, audit trails are essential for determining if personal health information has been accessed or disclosed without authorization), audit trails should be considered part of a “record” for the purposes of Part VI (Review by Commissioner) of PHIA.

We ask that the Review Committee consider an amendment to the definition of “record” to effect the changes noted above, or otherwise consider how audit trails can be expressly brought under the scope of PHIA. This would improve the protection and integrity of personal health information that is stored in electronic format.

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<sup>1</sup> Brodnik, Melanie, et al. *Fundamentals of Law for Health Informatics and Information Management*. Chicago, IL: AHIMA, 2009, 215.

## 2. Provide guidance on custodianship in the context of a shared EMR

The concept of custodianship is central to PHIA and to the operation of the eDOCSNL program. When custodians use a shared EMR, they no longer have sole custody or control of the personal health information in that shared system. Shared accountabilities pose unique legislative compliance challenges if custodians (or their agents and information managers) are uncertain about which obligations apply to them or how they should structure their arrangements regarding their shared EMR.

The EMR Management Committee has sought to clearly delineate accountability among all parties involved in the eDOCSNL program through the MOU, contracts with licensed users and the Information Management Framework. These governing documents set out the roles of the respective parties and expectations for how they will handle personal health information within a shared EMR instance, in accordance with PHIA.

Nonetheless, not all custodians who participate in the eDOCSNL program interpret PHIA in the same manner, particularly as it relates to custodianship in the context of a shared EMR. Although PHIA does not expressly contemplate a model of “joint” custodianship, but that there is some ambiguity as to how custodianship would apply in a shared EMR – and differing interpretations among certain custodians have led to some program challenges that we believe could be easily avoided. Thus, we request that the Review Committee consider how the concept of custodianship should apply in the context of a shared EMR.

We recommend that PHIA be amended to mandate that custodians who “use a shared electronic medical record to disclose personal health information to one another” must enter into a written agreement or have written policies that addresses certain prescribed requirements (prescribed in PHIA or by subsequent regulations).

This approach would, in effect, legislate existing guidance from health regulatory bodies that emphasizes the need to establish clear lines of accountability in order to protect patient records.<sup>2</sup> The recommended amendment would ensure that all custodians who participate in a shared EMR have turned their minds to certain key issues *before* problems arise.

Those key issues, to be reflected in the prescribed requirements for the written agreement or policies among the custodians using the shared EMR, could include: ensuring access to records among participating custodians; expectations around security, access controls, monitoring and auditing; responsibilities in the event of a privacy breach; and what happens to patient records in the event of the relocation, retirement or death of a custodian.

This approach would achieve the benefits of clarifying that shared EMRs are permitted and under what circumstances they are permitted, while being flexible enough to account for changes to data sharing in the future. It would continue to allow custodians to structure their arrangements,

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<sup>2</sup> See, for example, the Canadian Medical Protective Association’s [Electronic Records Handbook](#), which sets out data sharing principles for EMR/EHR agreements.

amongst themselves and/or their EMR vendors, in a manner that is best suited to the needs of their practice.

### **3. Clarify who is a custodian in the context of a group practice**

Section 4(1) of PHIA sets out the definition of “custodian”, which includes “a health care professional, when providing health care to an individual or performing a function necessarily related to the provision of health care to an individual” and a “health care provider.”

With increasing frequency, instances of the eDOCSNL EMR are deployed by group practices that are owned and operated by a corporate entity that contracts with individual health care professionals or health care providers to provide care to patients. Issues of custodianship, such as who is accountable and who has the right to retain records, arise when the group practice dissolves or when an individual health care professional or provider leaves the group practice.

We ask that the Review Committee consider whether a person who operates a group practice (whether they be an individual or entity) is intended to be a custodian under PHIA. In our view, given the current realities of the eDOCSNL program, PHIA should be amended to expressly include the operator of a group practice in the definition of “custodian.” This would acknowledge the increasing role that operators of group practices play in the delivery of health care and would impose statutory privacy obligations on them that are commensurate with that role.

### **4. Clarify that a custodian may be an information manager to another custodian**

Section 4(2) of PHIA clarifies that an “information manager” shall not be considered a custodian in respect of personal health information he or she may collect, use, disclose or dispose of while performing the powers or duties described of an information manager.

NLCHI is designated as a custodian under section 4(1)(i) of PHIA. NLCHI is the custodian of personal health information that is disclosed to NLCHI by participating custodians via the integration between an EMR instance and HEALTHe NL. NLCHI is also the custodian of personal health information that is disclosed to NLCHI by participating custodians for specific secondary uses.

For the purposes of the eDOCSNL EMR program, NLCHI does not operate in its capacity as a custodian. NLCHI provides information management services to participating custodians; custodianship of personal health information within the eDOCSNL EMR rests with one or more of those participating custodians, pursuant to section 22 of PHIA.

To avoid ambiguity, we request that the Review Committee consider an amendment to PHIA to clarify that the role of “custodian” and “information manager” are mutually exclusive with respect to the same record of personal health information. For example, section 66(7) of Alberta’s *Health Information Act* provides:

“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.”

## **5. Improve the process for appointing a successor custodian**

The EMR Management Committee has experienced circumstances where health records within an eDOCSNL EMR instance are abandoned by the responsible custodian(s), generally in cases where a custodian has ceased practicing or has moved their practice outside of the province.

When records are abandoned, the EMR Management Committee makes efforts to arrange for the appointment of a successor custodian, in accordance with the process set out in PHIA and the by-laws of the College of Physicians and Surgeons of Newfoundland and Labrador. This process is time-consuming and challenging, particularly when there is no successor who is willing to step in and assume custody and control of the records. eDOCSNL does not have custody or control over the abandoned records for the purposes of PHIA – and therefore no legal authority to act on its own behalf with respect to such records – but nonetheless assumes responsibility for the secure transition of abandoned records as this is clearly in the interests of applicable patients and the health system generally.

The EMR Management Committee is currently reviewing the approach to custodianship succession planning that is set out in contracts with participating custodians and in the eDOCSNL governance framework. To support these efforts, we ask that the Review Committee consider adding to the possible regulations the authority for the Lieutenant-Governor in Council to designate a person for the purpose of paragraph 4(4).

## **6. Increase accountability of information managers under PHIA**

On behalf of the eDOCSNL program, NLCHI procures an EMR solution from a single vendor for use by all participating custodians. The relationship between NLCHI and the EMR vendor is governed by section 22 of PHIA and is subject to a written agreement that provides for the protection of personal health information that is processed by the EMR vendor. The EMR Management Committee has a vested interest in ensuring that the EMR vendor complies with its obligations under PHIA and provides a solution that enables participating custodians to do the same. In particular, we are concerned with ensuring that participating custodians have appropriate access to records within the eDOCSNL EMR and that accountability for the retention and disposal of health records is clearly delineated. Similar concerns arise for EMR solutions not part of the eDOCSNL program – where health care providers contract directly with various EMR vendors.

We ask that the Review Committee consider the addition of more prescriptive regulatory requirements that would apply to information managers who, pursuant to section 22(7) of PHIA, “construct or create an integrated electronic record of personal health information comprising individual records, the custody or control of each of which may be in one or more custodians.” The eDOCSNL program would benefit from being able to leverage direct regulatory obligations on EMR vendors when requesting technical solutions to meet the needs of participating custodians,

rather than relying primarily on flow-through obligations via contract. In addition, such change would assist individual custodians who contract directly for EMR platforms (beyond the eDOCSNL program).

Imposing direct regulatory obligations on this sub-category of information managers would reflect the fact that they play a more involved and distinct role in respect of health records in a shared EMR, as compared to information managers who provide services to individual custodians in a more traditional sense. Shared EMR vendors are more appropriately placed than individual custodians to identify and manage certain privacy and security risks that are unique to shared EMRs.

It would be reasonable and more effective to make EMR vendors accountable to custodians, under regulation and not just contract, for aspects of compliance that are specific to the EMR as a whole and that are difficult or duplicative for custodians to address individually. For example, EMR vendors should be statutorily required to conduct privacy impact assessments of their solutions, maintain appropriate audit trails and implement policies for the retention and deletion of records that comply with instructions from the custodian(s).

## **7. Ancillary Amendments**

In section 39(4), we suggest replacing the word “person” with “individual.” This would logically mirror the language in section 39(1) and would more accurately reflect the fact that personal health information is necessarily about an individual, rather than a person, as per the definition of “personal health information” in PHIA.

Throughout PHIA, we suggest replacing the personal pronouns “he” and “she” with “they” or “it” when used in respect of custodians. This would reflect the fact that many of the persons who are included in the definition of custodian, such as NLCHI, are persons and not individuals.

## **Conclusion**

We thank the Review Committee for taking the time to consider our comments and welcome all opportunities for further collaboration and consultation. Please do not hesitate to reach out should you require clarification on any items discussed in this submission.

Sincerely,

eDOCSNL Management Committee