

# Ontario Medical Association Submission

## **Amendment to PHIPA Regulation O. Reg. 329/04 to Enable the Health Data Platform for COVID-19**

July 3, 2020



The Ontario Medical Association (OMA) welcomes the opportunity to comment on the proposed regulation changes under the *Personal Health Information Protection Act* (PHIPA) to enable the Health Data Platform (PANTHR). The COVID-19 pandemic has presented individuals, the health system, province, and world at large with new and unprecedented challenges. When faced with a novel virus on a global scale, the availability of timely and reliable data and research is paramount to inform everything from understanding the nature of the virus, to making evidence-based recommendations for public health measures, to developing an effective vaccine.

The OMA supports the need for data and research to tackle COVID-19 and inform timely and targeted policies and interventions. We are pleased to see efforts are being made on multiple fronts to prioritize a data-driven and evidence-based approach to responding to and alleviating the pandemic. However, any approach to data collection, use and disclosure must be nimble and encompass adequate privacy protections.

The Health Data Platform is a significant step in the fight against COVID-19, and the success of the platform or resulting research should not be mired by privacy concerns. As such, the OMA submits the following recommendations for consideration.

### **Parameters and Protections on the Data**

While the purposes for which the Institute for Clinical Evaluative Sciences (ICES) and Ontario Health (OH) can disclose PHI to the ministry are defined, the proposed regulation does not stipulate any limitations on the scope of uses and subsequent disclosures of personal health information (PHI) by the ministry. There is currently no limitation to what the ministry can use the data for once received nor any restrictions to prevent further disclosure of the data by the ministry to others. This lack of protections on the PHI raises serious privacy concerns, primarily the government's unfettered control over a large pool of data from ICES and OH.

Further, there is a lack of privacy oversight built into the regulation as proposed. As written, the regulation only requires ICES and OH to "comply with any requirements specified by the Minister" when making a disclosure. However, these requirements are not specified in the regulation and further, there are no corresponding requirements or oversight by the Information and Privacy Commissioner (IPC) for the disclosure of data by ICES and OH or ministry's use of the data.

The OMA recommends that additional legal parameters and protections on the data be stipulated in the regulation. In particular:

- the data disclosed by ICES and OH can only be *used* by the ministry when necessary for the purposes of researching, analyzing, investigating, preventing, responding to or alleviating COVID-19 or its effects
- the ministry is prohibited from making any subsequent disclosures of the PHI it receives from ICES and OH
- the requirements that ICES and OH must comply with as specified by the ministry

- the IPC has oversight over the parameters and requirements for disclosure of data by ICES and OH, as well as the uses of data by the ministry

### **Time Limitation to Temporary Regulation**

From conversations we have had with ministry staff, it is our understanding that the regulation is intended to be temporary (~24 months) for purposes related to the COVID-19 pandemic. However, the draft regulation does not currently stipulate a time limitation for either disclosure of PHI to the ministry by ICES and OH, or use and retention of PHI by the ministry. As such, as currently written, the government can continue to receive, use and keep PHI in perpetuity.

The OMA recommends that the regulation clearly stipulate time limitations for the disclosure, use and retention of PHI for purposes related to COVID-19, and make provisions for either the destruction of data or transfer to a data trust within 24 months (or as otherwise specified). If the pandemic persists and the information is required beyond the stated time limitation, the regulation can be further amended to extend the time period.

### **Define the Role of Ontario Health**

Ontario Health has assumed several different roles/capacities in the system, including acting as a Prescribed Entity (PE), a Prescribed Registry (PR), and - as proposed to be named in the regulatory amendments to proclaim Part V.1 of PHIPA – the Prescribed Organization (PO).

The proposed regulation does not specify the role/capacity in which OH is acting for the purposes of disclosing PHI to the ministry for COVID-19 matters, but rather, merely names OH as an entity. As currently written, this means OH could act in its (forthcoming) capacity as the PO and disclose PHI from the electronic health record (EHR) to the ministry for COVID-19 related purposes. It is our understanding the information from the EHR is not part of the disclosure, and OH is not acting in its capacity as the PO when disclosing to the ministry. Rather, we understand that OH – along with ICES - will be acting in its capacity as a PE when making the disclosure.

The OMA recommends the regulation clearly stipulate that Ontario Health and ICES will be disclosing information to the ministry in their capacity as Prescribed Entities.

### **Fundamental Need for Data Governance**

The proposal to enable a Health Data Platform once again highlights the fundamental need for data governance in Ontario's health care system. As the OMA has previously submitted, with increased access and availability of data comes the need for additional responsibilities to be placed on system stakeholders to ensure data is shared and used appropriately and ethically. Effective data governance can facilitate the sharing and use of information between providers and health system stakeholders, and within the system at large, while further preserving patient

trust in the providers and the healthcare system. The OMA continues to support the use of data analytics to improve population health and research, and believes that digital health has the ability to transform patient care and enhance the quality of health information, statistics and research *if properly implemented*. We must be prudent and act as responsible system stewards when considering PHI being accessible to the government as per the proposed regulatory amendments. We have a duty to preserve Ontarians' privacy and we fear that if not done properly, there will be unintended consequences, particularly for patient care if information is withheld. Further, we also have a duty to ensure Ontarians are aware of the potential uses of their data to preserve confidence in the system. Public trust in the system is especially important in times like the current pandemic, where sensitivities about privacy and suspicions about government overreach are already raised.

The OMA once again recommends that to facilitate data governance, a legislated multi-stakeholder Data Governance and Stewardship Committee should be convened. While we recognize that an "advisory committee" is currently contemplated under section 55.11 of PHIPA, it has not yet been implemented and the scope of the committee is limited to the purposes of Part V.1. There is a broader need in the system for governance of data beyond the EHR, such as the PANTHR database, and thus, the need for a broader Data Governance and Stewardship Committee.

Data governance should be patient-centred and driven by physicians and providers with clearly articulated roles and responsibilities. As the legal custodians and stewards of patients' personal health information, physicians and providers are best positioned to advise on how information should flow. As such, physicians, patients, and other providers should be partners in decision-making processes surrounding digital health governance.

Under the OMA's leadership, a Data Governance and Stewardship Committee in Ontario was previously under consideration in 2013-2014 by health system stakeholders. Much of the draft framework is increasingly important and relevant today and would be an effective way to rapidly implement such a committee, for the purposes of both Part V.1 and this regulatory proposal. The draft proposal is attached as Appendix A ("2014 DGSC Proposal").<sup>1</sup>

The need to have a Data Governance and Stewardship Committee in place is particularly important in situations like the pandemic where there is a sudden and timely need to develop a platform for data. The OMA recognizes that elements of the 2014 DGSC Proposal have been implemented in legislative provisions for the EHR that are proposed to come into force under Part V.1 of PHIPA. As these provisions will require implementation and operationalization to utilize the full benefits of the EHR, the OMA would be pleased to engage in further discussions with the Ministry to co-lead the development of data governance in the system. This extends beyond the EHR to include the interoperability standards and protocols for data exchange between EMRs and other digital health assets, and the governance needs for data trusts for research and system planning, such as that provided by the PANTHR database.

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<sup>1</sup> This draft framework is based on the 2014 model and will be updated as the work progresses.

Once again, the OMA appreciates the opportunity to provide comments on the proposed regulatory amendments being considered.

Draft

# **eHealth System Governance Proposal**

July 2014

## EXECUTIVE SUMMARY

Health system partners have a critical role to play in guiding the development and delivery of an eHealth system governance strategy. The collaboration and involvement of health system partners ensures that such a strategy will support and meet the health care needs of Ontarians. With the movement to an eHealth system, greater personal health information (PHI) is collected in electronic format, which simplifies the data sharing process. The roles of all parties must be clearly defined with respect to eHealth data collection and use. As such, health system stakeholders recommend that a committee reporting directly to the Minister of Health and Long Term Care be legislated comprised of (but not limited to) the following stakeholders:

- The OMA on behalf of physicians
- *[List of appropriate health system stakeholders to be inserted,]*

The following paper provides context for the need for eHealth system governance, involving equal participation and decision making authority of health system stakeholders. To support this need, a legislated committee is recommended and outlined, with various subgroups to support the intent of developing and overseeing eHealth system governance.

The draft outlines the collective proposal for Ontario's physicians; specifically, various physician groups have collaborated to develop this document. It is recognized that with further engagement of other health care providers/health information custodians, that this proposal may be expanded. As such, an iterative process in the development of an eHealth system governance strategy is recommended.

## Ontario's eHealth System Governance Proposal

Ontario's health system partners have the opportunity and system obligation to build on existing roles in collaborating with the Ministry of Health and Long Term Care (MOHLTC) to improve patient care and the quality and efficiency of the health care system. Such collaboration includes the development of an eHealth system governance strategy and framework to provide policy direction on the flow of health information in electronic format. All must be informed and aware of the requirements relating to the collection, storage, transmission, use, analysis and reporting in the electronic health care system including both electronic medical records (EMRs) as well as the system level electronic health record (EHR). Such requirements must be transparent and agreed upon by health system partners.

### **New considerations in an e-Environment**

With the evolution to an eHealth system environment, there are greater system demands from various stakeholders for the use of personal health information (PHI) in electronic format. The availability of PHI in electronic format is advantageous both at the patient and at the system level. Physicians' (and other providers') ease of access to an individual patient's information can help support more effective and efficient provision of care (provided the technologies are properly used). In addition, the compilation of electronic information at the broader system level helps enable health system use of information, allowing for the potential to improve the delivery of care at the population level and lead to more effective and efficient use of resources.

All uses of personal health information must have a legally and professionally acceptable basis. The roles and permitted uses of PHI are outlined in legislation and regulation. Existing legislation and regulations permit much data to flow across the system for patient care, as well as for other purposes such as health system use and planning. The *Personal Health Information Protection Act, 2004 (PHIPA)* governs the manner in which personal health information may be collected, used and disclosed within the health care system. It also regulates individuals and organizations that receive personal health information from health care professionals and identifies organizations authorized to collect PHI for purposes other than the delivery of healthcare.<sup>2</sup> PHIPA provides the basis by which PHI can be shared. All uses of identifiable data must have a legally acceptable basis; even when there is legal basis to process data, data must be used and processed appropriately, and identifiable data should only be used when aggregated or de-identified data will not suffice in addressing the issue. The government has signalled the need for overarching eHealth legislation to support the electronic exchange of PHI, though such legislation has not yet come to fruition. As such, health system providers, stakeholders and partners see an opportunity to support the development and implementation of Ontario's eHealth system governance.

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<sup>2</sup> <http://www.ipc.on.ca/images/Resources/hfaq-e.pdf>



The absence of governance (including common standards and specifications) and complementary technology to enable such flows has put up obstacles in the past, thus challenging many organizations from pursuing their legislative rights in requesting and accessing information. However, now with increased technology and connectivity such flows and information sharing have become much less cumbersome and will (and in many cases have already) become the expected norm. It is critical that a system level eHealth governance strategy be advanced in Ontario to support and oversee the flow and use of electronic health information. While there is variation among users both in terms of legislative rights to access information and also in terms of type of data requested, the ultimate goal should be the same: Ontario's eHealth system should enable users to have the information they needed to ensure health care is provided in the most effective and efficient way possible, while complying with existing legislation and medical records policies, and preserving respect for patient privacy, confidentiality and choice. This includes the use of information for purposes beyond the delivery of care to the individual patient, to allow for health system planning and management, research, and improvements in population health.

This paper will provide high level context for the need for eHealth governance and will propose a structure to oversee the eHealth system, to ensure transparent and consistent application of policies. It should be noted that this paper represents physicians' participation in eHealth system development. It is recognized that other data domains and/or sectors will be considered for inclusion as well.

## **Priorities/Principles**

At a minimum, the following principles should be used to drive the development of a patient-oriented eHealth system strategy, ensuring ease of usability and functionality for providers:

- Patient-provider trust must be preserved.
- Physicians/providers should, as a first priority, use information for the delivery of patient care.
- Physicians/providers should share information to support the delivery of patient care and improve overall patient health.
- Physicians/providers should share information to improve overall population health.
- Physicians/providers should collaborate with key stakeholders to share information for system delivery.
- Health system stakeholders should partner in developing an eHealth strategy.

## **Vision for eHealth**

The health care system's partners' vision for eHealth involves a system where all records are secure in electronic form. The system must be integrated, allowing for the seamless exchange of information to provide patient care, while ensuring respect for privacy. This will enable all providers within a patient's circle of care to have the information needed to provide the best quality of direct patient care.

In addition, the vision for eHealth supports the use of information for secondary use purposes, to improve patient care, population health, and system planning and delivery. Only the minimal necessary amount of identifiable data should be used thus protecting the confidentiality while contributing to system evaluation and/or improvements.

## Partners' Roles

### a) Ontario's Physicians (Represented by the OMA)

Physicians in Ontario have the unique role of delivering care to patients and advocating on their behalf. Physicians are trusted stewards, representatives and supports to Ontario's patients. In addition, community physicians have the role of adopting and implementing EMRs, creating the data, and serving as health information custodians. The OMA, as the representative of Ontario's physicians, is in a unique position to participate in and influence the development of a sustainable eHealth system. The OMA, on behalf of Ontario's physicians and as a steward of Ontario's healthcare system, has a critical role in eHealth system development and implementation.<sup>3</sup>

The OMA can support physicians' enhanced use of EMRs by providing the resources necessary to contribute to Ontario's EHR and participate in the secure exchange of secondary use information. The OMA recognizes tremendous value in the exchange of high quality de-identified data for population-based analyses and health system planning. To this end, the OMA supports the profession in becoming better informed and participating in information exchange for secondary use purposes.

***[Roles of other health system partners to be inserted by the respective stakeholders.]***

## Setting the Stage for the Need for eHealth System Governance

Ontario has seen great progress in the general eHealth environment with the implementation of technologies by providers. However, while many users have implemented technology and technology has evolved, an identified gap in system level policy exists. Specifically, in many instances, the implementation of individual projects has driven both system and practice level policy. It is critical that system stakeholders engage in a transparent eHealth priority setting process so that system participants are well informed and prepared. In particular, the absence of a system level governance structure for eHealth management challenges providers faced with requests for data. At the current time, the system is lacking a streamlined process for the exchange of data at the individual practice level, an integrated strategy, as well as a comprehensive understanding of the agreed upon uses of data.

While the sharing of data for patient care falls within the circle of care and the rationale is clearly articulated in *PHIPA*, policies related to the exchange of PHI for other purposes, including the provision of data into the slowly evolving system level EHR are less clear. The OMA's Guidance for Data Sharing in Community Practice document provides physicians with data sharing support and guidance both for contributions into the electronic health record for

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<sup>3</sup> [http://www.cpsa.ab.ca/Libraries/Information\\_for\\_physicians/Section\\_5\\_Framework\\_-\\_1\\_1\\_FINAL.pdf](http://www.cpsa.ab.ca/Libraries/Information_for_physicians/Section_5_Framework_-_1_1_FINAL.pdf)

the direct provision of care (primary use) as well as for research, planning and system management (secondary use purposes).

Among many other issues, the OMA's Guidance for Data Sharing in Community Practice document seeks to provide physicians with guidance on:

- Evaluating requests for data;
- Provision of data into the EHR;
- Who can request data.

Ontario's providers, patients and the system will benefit from the development and consistent application of eHealth policies. It is recommended that a multi-stakeholder oversight body be established as part of a comprehensive eHealth system governance framework.

## **Proposal for Ontario's eHealth Governance Structure**

Ontario's eHealth system requires the consistent application of policies by health care delivery organizations as well as health care providers representing the health needs of Ontario's patients. To represent the needs of the entire health care system, it is advised that a legislated committee (Committee) be developed and comprised of key health system stakeholders, that reports directly to the Minister of Health and Long Term Care. Members of this Committee should have shared decision making authority. This Committee would have the mandate of protecting the public interest and the providers within the system in the development of an eHealth governance strategy.

The proposed Committee should include representatives from the government, providers (i.e. Health Information Custodians), as well as the public.

This executive level Committee should be responsible for providing strategic advice and leadership on eHealth initiatives, and providing guidance and support for the exchange of personal health information in the eHealth environment. Further, this Committee will ensure that data is used to benefit the patient and other transparent agreed upon uses. Membership identified ensures adequate provider and public consultation on the development and implementation of health information exchanges. As the model evolves, the Committee should have the authority to develop working groups as necessary.

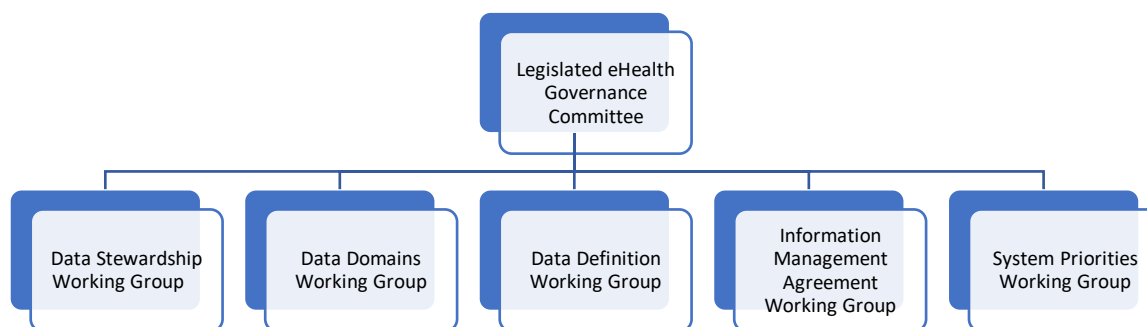
Policy related to the management of health information in electronic form has not kept pace with emerging technologies. Many unanswered questions regarding the roles and responsibilities of data users exist. As such, this proposed Committee offers the opportunity to clarify eHealth system roles and responsibilities to support the development of future technology and information sharing, with the goal of improving patient care and health system delivery.

The proposed Committee should be responsible for setting direction on the management of information collected and maintained by the EHR and any other health information exchanges

including rules related to access, use, disclosure and retention of personal health information through the EHR. This will be beneficial to the system, given the need for consistent policies in the management of PHI. Further, health care providers will benefit from the support this Committee can offer in terms of advising on ethical and professional decisions in respect of electronic data disclosure and use. The Committee should provide direction enabling effective data stewardship in all eHealth initiatives including, but not limited to, maintaining the balance between patient confidentiality and the reasonable use of PHI for purposes beyond the delivery of patient care, such as research and health system planning. Such uses are critical to ensuring public trust in providers and the healthcare system.<sup>4</sup> Further, such uses will ultimately lead to improvements in patient care, and more effective and efficient delivery of healthcare. The Committee will set the policy direction to ensure the seamless exchange of information, as well as quality assurance in eHealth. This would include, but not be limited to setting policy on issues related to breach notification, consent management and the implementation of consent directives, as well as information corrections, notifications and reconciliations. It is recognized that custodians collecting information may also use information collected for their own quality improvement purposes. This is beyond the scope of this paper and not within the scope of the Committee.

## Proposed Subgroups

There are various subgroups that should be developed as part of this eHealth system framework. These subgroups should report directly to the legislated Committee. The following table represents the proposed structure of Ontario's eHealth System Governance Framework:



<sup>4</sup> [http://www.cpsa.ab.ca/Libraries/Information\\_for\\_physicians/Vision\\_for\\_eHealth.pdf](http://www.cpsa.ab.ca/Libraries/Information_for_physicians/Vision_for_eHealth.pdf)

## 1. Data Stewardship Working Group

The first proposed subgroup should have the mandate of advising the system level oversight Committee on the needs and best practices of physicians (and other providers), in order to ensure that the eHealth policies under development best represent the needs of providers and their patients. Physician groups should be included in this working group.

As other HICs are added to the legislated committee, additional subgroups will be developed to determine best practices and system needs for such professionals.

## 2. Data Domains Working Group

This working group will be comprised of all data domains, specifically, groups which develop datasets that will feed into the EHR. Domains include, but are not limited to: Community Care Access Centres, laboratories, and pharmacies<sup>5</sup>. This group will develop appropriate strategies for the movement of data and integration, and may work in conjunction with the Data Definition Working Group outlined below.

## 3. Data Definition Working Group

The Data Definition Working Group will determine the specific extract (i.e. data elements) to be shared and the terms and conditions for the exchange of PHI within the EHR. This group will include representation from across the continuum of care to define a core data set that will flow from a provider's EMR into the system EHR. It is recommended that the data that becomes standardized for disclosure be useful to providers caring for a patient in an emergency situation, and for those covering for a patient's provider in his/her absence. As such, it is important to explore specific data elements that should automatically flow across the system according to a structured process.

While work is underway in Ontario regarding the definition and scope of clinical document repositories, other provinces have defined health data to be automatically made available in the EHR. For example, Alberta has defined data streams which include: demographics, prescriptions +/- medications and medication history, immunizations, encounters, allergies, medical history, surgical history, and advanced directives (including Do Not Resuscitate Orders). The data and/or indicators that flow must be determined by physicians and other stakeholders through a structured process.

## 4. Information Management Agreement Working Group

To support providers' participation in the EHR, the use of standardized processes and data sharing agreements is recommended.<sup>6</sup> The Information Management Agreement Working Group will be responsible for the development and management of data sharing agreements to

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<sup>5</sup> Other domains will be added and included as appropriate.

<sup>6</sup> [http://www.cpsa.ab.ca/Libraries/Information\\_for\\_physicians/Vision\\_for\\_eHealth.pdf](http://www.cpsa.ab.ca/Libraries/Information_for_physicians/Vision_for_eHealth.pdf)

enable the seamless exchange of information housed in EMRs into the system-wide EHR. This group will create a formal information management relationship between participating physicians represented by the OMA, and the MOHLTC, and will support physicians in sharing an extract, to be determined by Data Definition Working Group, with other participating physicians and providers, as well as with the system-level EHR. Such a model is dependent on technology enabling the seamless exchange and integration of electronic records/extracts. This Working Group should report directly to the oversight Committee, and be comprised of the MOHLTC and the OMA, on behalf of participating physicians.<sup>7</sup>

A similar model may be proposed for other Health Information Custodians.

## 5. System Priorities Working Group

There are currently many system initiatives underway developing and defining indicators and guidelines. No clear coordination exists, and there is much overlap and uncertainty on how priorities should be set. As such, it is recommended that a committee be struck to determine system level priorities, and the best approach for implementation.

Established system priorities will help inform the development of future technology.

Health system stakeholders are committed to collaboration and promotion, and encouraging meaningful provider participation in the eHealth system. Participation, coupled with a transparent governance strategy, supports Ontario's eHealth system in enhancing quality patient care and improving the health care system. Partners referenced in this proposal look forward to the opportunity to participate in and provide ongoing support in the development of Ontario's eHealth system.

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<sup>7</sup> [http://www.albertanetcare.ca/documents/An\\_Overview\\_of\\_Albertas\\_ERHIS.pdf](http://www.albertanetcare.ca/documents/An_Overview_of_Albertas_ERHIS.pdf)