OMA Ontario Medical Association

Ontario Medical Association Submission

Amendment to PHIPA Regulation O. Reg. 329/04 to Enable Digital Health Interoperability

July 22, 2020

The Ontario Medical Association (OMA) welcomes the opportunity to comment on the proposed regulation changes under the *Personal Health Information Protection Act* (PHIPA) and accompanying Digital Health Information Exchange (DHIEX) policy to enable digital health interoperability.

The OMA has long supported and advocated for the ability of providers to seamlessly access integrated patient information. An integrated information sharing system is paramount to developing an integrated health care system. Interoperability of different digital health systems is an important and laudable system goal to achieving this, and the OMA supports these efforts in principle. However, in order for interoperability to be realized, appropriate policy and successful implementation are key.

As proposed, the draft regulation and policy require physicians to comply with standards on interoperability for the digital health systems they use – i.e. to make sure the EMR they are using complies with specifications to be set by Ontario Health. Given the new work required for vendors to update their systems, it is possible that financial costs may be downloaded onto physicians by vendors, potentially in the form of increased fees. If so, we note that the Binding Arbitration Framework between the government of Ontario and the OMA includes *"Electronic Medical Records (where required by legislation, government, government agency or program, or non-fee for service agreement) fall within the scope of arbitration".* This means that the costs associated with fulfilling regulatory requirements for EMRs are arbitrable – i.e. if a physician incurs costs as a result of having to switch or upgrade to a new compliant EMR.

Further, the additional obligations placed on physicians and potential for requiring new technology, disruption to workflow and administrative burden will potentially lead to higher burnout rates.

As such, the OMA submits the following recommendations for consideration:

- **The government has two options to fulfill the goal of achieving interoperability in the system:**
    - **1) Instead of the punitive approach of using PHIPA as a lever that places undue burden on physicians, the obligations to achieve interoperability should be placed on vendors, or**
    - **2) If the proposal to achieve interoperability via regulating physicians through PHIPA is pursued, we submit:**
        - **The costs associated with fulfilling regulatory requirements for EMRs are arbitrable, and**
        - **To ease implementation, the existing OntarioMD vendor management and certification program should be relied upon to fulfill physician accountability and reporting requirements.**

- **As part of the mandate to establish interoperability between digital health systems, the appropriate policy and technological requirements to ensure alignment between individual practice EMRs and the provincial EHR should be pursued, in order to ensure coherent, effective, and seamless implementation of consent directives across the health system, that meets the needs of patients and providers.**
- **Additional clarity and education need to be provided to health care providers on the circle of care, consent management, and information sharing.**
- **To facilitate data governance in the system, a legislated multi-stakeholder Data Governance and Stewardship Committee should be convened.**

These recommendations have been informed by feedback that was elicited from Sections of the OMA via a consultation process. A consolidated summary of the feedback received has been provided to the ministry team. We look forward to and appreciate the willingness of the ministry to engage in continued conversations with the OMA and hear directly from physicians as the recommendations are being reviewed and contemplated.

Two Options to Achieve Interoperability

1) The Problem with Using PHIPA as a Lever to Achieve Interoperability

The proposed regulation attempts to achieve interoperability by using PHIPA as a lever and imposing mandatory compliance with specifications on health information custodians (HICs), rather than targeting vendors to fulfill these requirements directly. Further, although the proposed DHIEX policy sets out roles and responsibilities for digital health vendors, the policy only applies to "all Health Information Custodians" and does not mandate vendors. Based on additional information provided by the ministry team, we have been informed that the proposed approach of mandating compliance on HICs via PHIPA is being pursued in the absence of a legislative regime for imposing requirements on digital health product vendors. HICs should not be held responsible for what vendors may or may not be willing to provide in the absence of regulation.

However, this proposed approach is problematic for the following reasons:

- **Targets the end user (physicians), instead of developers (vendors)**
    - The interoperability specifications that will be developed are technical standards, not clinical standards. This proposal puts obligations on physicians that they are not equipped to fulfill in their role as health care providers.
    - Physicians, as HICs, do not have direct control over the specifications that will be established by Ontario Health (OH). The government's reliance on HICs to drive 'market forces' is both ineffective and unreasonable as a mechanism to drive system interoperability policy, as it creates a demand upon physicians

for which there is no guaranteed supply from vendors now or in the future. At the same time, to the extent that vendors do change their digital health assets to conform with the specifications based purely on demand by physicians as consumers, this would be no less a consequence of government regulation through an indirect and complicated approach.

- It places the onus on physicians, with far less leverage than the government, to regulate vendors indirectly while placing them at risk of consequences arising from non-compliance.
- It is challenging to impose compliance with specifications on HICs without first establishing a set of vendors in compliance from which custodians may select. Physicians cannot be compelled by law to comply with something that does not exist (i.e. if the 'market forces' do not convince vendors to change their technology, and in turn, there is no technology that complies with the specifications available for physicians).

- **Downloads significant obligations, burden, and costs on physicians**
  - The regulation and policy as proposed place additional obligations on and oversight over community-based physicians (who in many cases are HICs), including:
    - Ensuring that the digital health assets they select, develop or use comply with interoperability specifications.
    - Reporting their compliance to OH, upon request.
    - OH would establish a process for monitoring HIC compliance, and the HIC would be required to cooperate and assist OH in monitoring its own compliance, including providing information or records upon request.
    - Enforcement of the regulation would occur through the ability of OH to lodge complaints with the Information and Privacy Commissioner (IPC) about physician non-compliance.
  - Given the new work required for vendors to update their systems, it is possible that financial costs may be downloaded onto physicians by vendors, potentially in the form of increased fees.
    - If so, we note that the Binding Arbitration Framework between the government of Ontario and the OMA includes *"Electronic Medical Records (where required by legislation, government, government agency or program, or non-fee for service agreement) fall within the scope of arbitration".* This means that the costs associated with fulfilling regulatory requirements for EMRs are arbitrable – i.e. if a physician incurs costs as a result of having to switch or upgrade to a new compliant EMR.
  - Physicians may have to switch to a compliant system because their existing vendor does not upgrade or does not upgrade in time. This will require the physician to invest additional time in learning a new system, cause disruption to their workflow, and mean less time available for patient care.

- Physicians who have to switch to a new compliant product may also have to cancel contracts with non-compliant vendors, export/import data to new systems, and experience all associated change management impacts and costs.
- Any form of additional reporting will increase administrative burden for physicians.
- The additional obligations placed on physicians and potential for financial costs, requiring new technology, disruption to workflow and administrative burden all further contribute to physician burnout. Technology and administrative burden are common and oft-cited contributors to physician burnout.
- Disrupting existing electronic medical record systems, workflows, and burdening physicians in the midst of a pandemic risks disrupting patient care, information flows, and provider well-being. Interoperability policy should be designed to support and achieve the Quadruple Aim, not hinder it.
- The proposal does not provide clear detail on implementation supports that will be provided to physicians, including change management and financial supports. There is thus a significant imbalance of levers being enforced without corresponding supports. This imposes an extraordinary potential burden on practicing physicians.

- **Lack of physician choice and risk of physician disenfranchisement**
  - Based on additional information provided by the ministry team, we understand that the ministry believes this policy does not call for health care providers to immediately 'rip and replace' systems that are already in place. The ministry team has suggested a HIC has a 'number of choices' if they are using a digital health asset that is non-compliant with a published specification, including delaying the upgrade, choosing a new (compliant) product, or upgrading to a non-compliant product and then work with OH and the vendor on a remediation plan.
  - However, all of these options (acknowledging the possibility of exceptions as stated in the regulation) lead to the same outcome – the physician having to either switch or upgrade to a compliant product. Thus, the HIC in fact has no choice and becomes entangled in a quagmire of regulatory privacy requirements with vendors, OH, and the ministry.
  - The ministry team has also indicated in additional information they have provided that if a physician decides to never replace or upgrade their system, the ministry and OH could at a future time elect to establish interoperability specifications that would require HICs to update their EMRs, whether an upgrade or procurement was planned.
  - This raises concerns of the government making EMRs mandatory, which further usurps physician choice in the medical record-keeping system they use. Until EMRs are established as the standard of care by the regulatory college, physician use of EMRs and other digital health tools should remain in their discretion and choice.
  - A poor and punitive approach to this policy initiative to achieve interoperability could lead to a risk of major disenfranchisement of physicians (particularly

community-based physicians) with significant resistance. This would in turn mark the failure of this policy initiative, given that if physicians do not choose digital health assets that comply with the specifications, interoperability will not be achieved. It will also potentially lead to higher rates of burnout.

As such, given these negative impacts of using PHIPA to achieve interoperability, **the OMA recommends that instead of the punitive approach of using PHIPA as a lever that places undue burden on physicians, the obligations to achieve interoperability should be placed on vendors.**

2. Pursuing the Option to Use PHIPA to Achieve Interoperability

If the proposal to achieve interoperability via regulating physicians through PHIPA is pursued, the OMA submits:

- **The costs associated with fulfilling regulatory requirements for EMRs are arbitrable, and**
- **To ease implementation, the existing OntarioMD vendor management and certification program should be relied upon to fulfill physician accountability and reporting requirements.**

Invoking the BAF

- As proposed, the draft regulation and policy require physicians to comply with standards on interoperability for the digital health systems they use – i.e. to make sure the EMR they are using complies with specifications to be set by Ontario Health.
- Given the new work required for vendors to update their systems, it is possible that financial costs may be downloaded onto physicians by vendors, potentially in the form of increased fees.
- If so, we note that the Binding Arbitration Framework between the government of Ontario and the OMA includes *"Electronic Medical Records (where required by legislation, government, government agency or program, or non-fee for service agreement) fall within the scope of arbitration".* This means that the costs associated with fulfilling regulatory requirements for EMRs are arbitrable – i.e. if a physician incurs costs as a result of having to switch or upgrade to a new compliant EMR.

Vendor Management and Certification by OntarioMD (OMD)

- To ease implementation of the obligations on physicians, OMD's vendor management and certification should be relied upon to fulfill physician accountability and reporting requirements.
- The effort to advance the consistent implementation of technical interoperability standards needs to be rationally focussed on 14+ certified vendors representing 20,000 physicians, instead of asking 20,000 physicians to uniquely direct the business of 14+ vendors.

- The ministry and Ontario Health have continued to underline the importance and dependency on Certification to advance EMR maturity in the province.
- "Integration" and "standards" have been used for 20 years and can be further enforced with EMR vendors through OMD's Certification Program. OMD is recognized for its working relationships with EMR vendors, and other key sector stakeholders to advance EMR maturity, often with common vendors and common objectives. OMD's Certification program has to-date been critical in equipping physicians with technology and integrating EMRs with the EHR.
- OMD, as a critical resource needs to be clearly represented in the ministry's DHIEX policy and implementation response to reassure physicians and vendors both who have come to rely on the program and supports.

Physician input is fundamental to the success of interoperability policy. Successful implementation of integration initiatives will recognize clinical workflow and be designed and delivered to ensure the optimum clinical experience. Integration and interoperability priorities must also include consideration of clinical relevance and impact. The role of OMA and OMD in facilitating input and prioritization will continue to be critical.

The benefits of using OMD's Vendor Management and Certification program to provide a smooth implementation process include:

- This process would be collaborative and supportive, with physicians participating as health system partners alongside the government, digital health vendors, and other stakeholders to achieve the shared goal of interoperability. Physicians will be engaged with prioritization of changes based on clinical relevance and impact.
- The legitimacy of OMD as a physician trusted organization driving implementation and reducing burden on physicians would result in better (faster, more efficient) adoption and implementation by physicians as digital health infrastructure evolves.
- With OMD operating as a third-party entity, the process for certifying vendors would be fair and transparent, allowing physicians to make the upgrades they seek, providing them with a choice in products, and ensuring the products they rely on are protected, all while achieving the system goal of interoperability.
- OMD would be able to provide change management supports to physicians based on their needs, so that physicians can adjust to systems that enable interoperability with the least amount of disruption.
- To the extent additional reporting can help the health care system in a meaningful way, OMD as a trusted intermediary to HICs can assist in the provision of reporting.

It is recognized there are limitations to this implementation approach, namely that its focus is EMRs and digital health assets that focus on interoperability, integration and information exchange and that to-date this has not incorporated other sectors or HICs beyond physicians and nurse practitioners. That said, it represents the combination of program supports that are necessary for successful implementation and serves as a model that should be built upon.

Consent Directives

At the crux of interoperability is patient information. This once again brings to light issues regarding patient consent directives, and the need to balance patient privacy with the duty of physicians to provide patient care. As the OMA recently submitted in its response to the consultation on regulatory amendments to enable proclamation of Part V.1 of PHIPA:

- Privacy must not act as a barrier to the provision of care. While patients should have the right to 'mask' data, it must not be in a manner that undermines delivering health care to them or the functionality of the EHR. Physicians have a duty to care for their patients, and the barriers to access to information imposed by blocking entire patient records may impede a physician's ability to discharge that duty. Although the ability to override a consent directive is available, physicians should not need to turn to this approach to access information in order to care for their patients. Physicians should have access to the information they need to effectively provide care for their patients, including as the EHR is intended to provide, efficient and comprehensive information at their fingertips.
- The parallel systems for consent directives at the local and provincial level requiring patients to request multiple consent directives from differing entities (i.e. the Prescribed Organization and their provider) is likely to prove challenging for patients, who may be under the impression that masking information at the provincial/EHR level means that information is masked at *all* levels, including local provider EMRs (and vice versa). Further, this two-level approach to applying consent directives adds significant complexity for providers in navigating the masking of patient information – even if the information is presented the same way. This divided, two-level approach also conflicts with the current system goal of establishing an integrated and seamless manner for providers to access patient information.

The infrastructure should be designed to support the seamless management of consent directives applied at the local and provincial levels. The burden should not be placed on patients and providers to make and execute multiple requests. Technology must support the implementation of consent directives in a precise manner and current limitations or flaws in technology should not be the basis of the implementation approach.

As such, the OMA once again submits that **as part of the mandate to establish interoperability between digital health systems, the appropriate policy and technological requirements to ensure alignment between individual practice EMRs and the provincial EHR should be pursued, in order to ensure coherent, effective, and seamless implementation of consent directives across the health system, that meets the needs of patients and providers.**

Further, the feedback received from the Section consultation has uncovered that ongoing confusion regarding the circle of care, consent management, and information sharing remains amongst providers. As such, **the OMA recommends the need for additional clarity and education to be provided to health care providers on the circle of care, consent management, and information sharing.**

Fundamental Need for Data Governance

The proposal to enable digital health interoperability 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, and public awareness of the urgent need to liberate data for epidemiological purposes further heightens concerns about PHI protection.

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, 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, including for the purposes of both Part V.1. The draft proposal is attached as Appendix A ("2014 DGSC Proposal").[1]

[1] This draft framework is based on the 2014 model and will be updated as the work progresses.

The OMA recognizes that elements of the 2014 DGSC Proposal have been implemented in legislative provisions 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 forthcoming PANTHR database.

Once again, the OMA appreciates the opportunity to provide comments on the proposed regulatory amendments being considered. We value engaging in continued conversations with the ministry as the recommendations are being reviewed and contemplated.

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. [2] *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.

[2] 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.[3]

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

[3] 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.

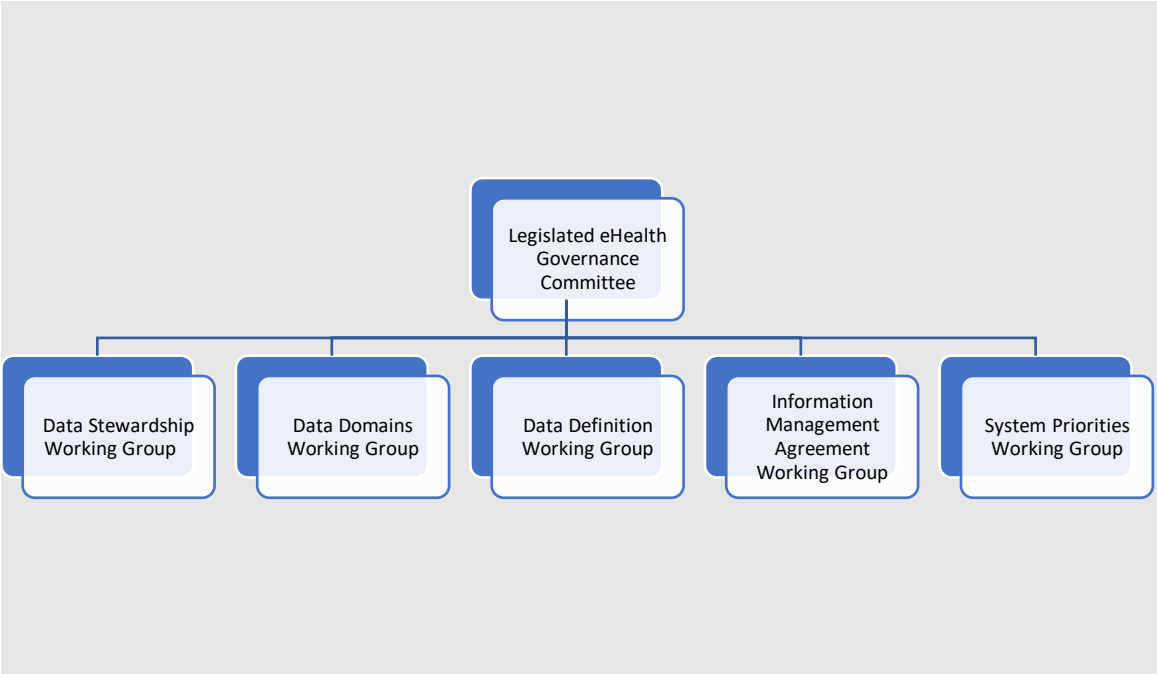
Policy related to the management of health information in electronic form has not kept pace with emerging technologies. Many unanswered questions regarding the roles and responsibilities of data users exist. As such, this proposed Committee offers the opportunity to clarify eHealth system roles and responsibilities 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.[4] 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:

[4] 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[5]. 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

[5] Other domains will be added and included as appropriate.

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.[6] The Information Management Agreement Working Group will be responsible for the development and management of data sharing agreements to 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. [7]

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

[6] http://www.cpsa.ab.ca/Libraries/Information_for_physicians/Vision_for_eHealth.pdf
[7] http://www.albertanetcare.ca/documents/An_Overview_of_Albertas_ERHIS.pdf

forward to the opportunity to participate in and provide ongoing support in the development of Ontario's eHealth system.