Ontario Hospital Association

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July 22, 2020

Evan Mills
Director, Digital Health Program Branch
Ministry of Health
1075 Bay Street West, 12th Floor
Toronto ON M5S 2B1

Re: Feedback on Proposed Regulations Governing Digital Health Interoperability

Dear Mr. Mills:

The Ontario Hospital Association (OHA) welcomes the opportunity to provide feedback on behalf of its member hospitals on the proposed regulation under the *Personal Health Information Protection Act, 2004* (PHIPA) in respect of digital health interoperability. The introduction of the proposed changes to Ontario Regulation 329/04, announced on May 22, 2020, represents an exciting opportunity to ensure that patient information will be able to follow patients in an integrated way across Ontario's health system.

As part of its consultation efforts, the OHA has solicited written comments and feedback from a wide array of senior privacy leaders and legal counsel across Ontario hospitals. The OHA also hosted a virtual consultation on June 25, 2020, to review and discuss the proposed regulatory amendments. More than 100 individuals across our diverse membership participated in this consultation. This submission represents a summary of that feedback and the concerns identified by Ontario hospitals.

While the OHA is encouraged by the push towards implementing standards for information exchange in local, regional and provincial digital health tools, our member hospitals have identified several areas where proposed changes may have unintended consequences, and where additional clarity is required. In many instances, Ontario hospitals are already working collectively to advance digital health interoperability initiatives and develop innovative regional interoperability solutions. The proposed regulatory changes should reflect these advancements and leverage this progress achieved to date.

The OHA would be pleased to facilitate further discussions on any of the topics raised in this submission and connect the Ministry of Health with privacy leaders and legal counsel, as required, in the future.

Proposed Amendments to O. Reg. 329/04 under PHIPA

The OHA supports the government's objective of connecting various points of care and ensuring that different organizations have appropriate access to a patient's personal health information (PHI) in an integrated health system.

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To accomplish this objective, we have outlined a number of considerations that would ensure that inadvertent consequences are avoided, burdensome reporting requirements are not created, and innovation is not stifled among researchers and health system vendors.

I. The Need for "Digital Health Asset" and "Interoperability Specification" Definition Clarity

a. Digital Health Asset

The definition of a "digital health asset" (DHA), as currently drafted, raises several issues for further discussion and clarity. The current proposed definition is as follows:

> "*a product or service that uses electronic means to collect, use, modify, disclose, retain or dispose of personal health information and that is selected, developed or used by a health information custodian ("actif de soins de santé numérique").*"

A common concern raised by hospitals with respect to DHAs is the wide scope of the proposed DHA definition. While the government may intend to broadly capture all products or services that use electronic means to collect, use, modify, disclose, retain or dispose of PHI, the definition may inadvertently capture several of the following products or systems and regulate their use moving forward:

- Systems within hospitals that hold PHI and continue to be kept for a variety of reasons (e.g. archived databases that are no longer supported);
- Systems that are used primarily for research activities (e.g. bio / databanks used exclusively for research) or applications developed by third-party researchers and intended solely for use in same;
- Standalone systems that are not intended to share PHI (e.g. certain diagnostic imaging systems, pharmacy and lab systems);
- Certain medical devices (e.g. Smart Beds, IV pumps);
- Solutions that use PHI data for secondary purposes; and
- Collaborative products or platforms used in virtual and cloud environments (e.g. MS Teams, SharePoint, Google Docs) or third-party applications that support same.

As drafted, a vast majority of member hospitals have expressed concern that the definition is too broad, and that it will require upgrades or restrictions on the use of products or systems we believe go beyond the original policy intention.

The key concern raised by hospitals is that there is no clear distinction between "main" products or systems in hospitals (e.g. EMRs which presumably contain key sources of PHI needed to care for patients) and "adjunct" products or systems that house PHI which can remain internal or unique to the organization. This broad definition may also disproportionally impact certain hospitals over others, including research-intensive HICs or smaller / regional

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HICs that serve specific populations and require electronic solutions to perform specific services.

The OHA recommends refining the definition to address the above-noted issues and providing additional clarity on the underlying policy intention to Ontario hospitals. In refining the DHA definition, government should consider excluding DHAs strictly for research purposes and/or adopt a more refined / itemized list of DHAs that are intended to be included in the definition.

Hospitals have also identified that the inclusion of the term "used" in the DHA definition suggests that the interoperability specifications will apply retroactively to DHAs used by a HIC prior to the interoperability specification coming into effect.

If the interoperability specifications apply retroactively, hospitals have questioned whether there will be funding provided to support DHA transition, what these transition timelines will look like, and if legacy systems will be grandfathered into the proposed regulatory requirements. If adopted, grandfathering will need to be considered both from Day 1 implementation following the effective date, and on an ongoing basis thereafter. We would ask the government to consider the extent to which hospitals will have project costing in place, appropriate resources to support the transition, and sufficient timing to meet the new regulatory requirements.

b. Interoperability Specification

The definition of "interoperability specification", as currently drafted, also raises several issues that require discussion and clarity. The current proposed definition is as follows:

> *"a business or technical requirement established by the Agency that applies to a digital health asset or to a digital health asset's interaction with other digital health assets, and that may include, without being limited to, a requirement related to,*
>
> *(a) the content of data or a common data set for electronic data,*
> *(b) the format or structure of messages exchanged between digital health assets,*
> *(c) the migration, translation or mapping of data from one digital health asset to another,*
> *(d) terminology, including vocabulary, code sets or classification systems, and*
> *(e) privacy or security."*

The OHA supports interoperability specifications which allow for a patient's information to follow them between different points of care across Ontario's health system. The proposed

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definition is broad enough to support this flow of information, but also raises cautionary considerations.

"Content of Data" and "Common Data Sets"

For example, hospitals have indicated that some types of frontline clinical documentation (e.g. narrative data used by mental health clinicians) should not be adversely affected by interoperability specifications which require specific "content of data" or "common data sets" [see subparagraph 26(a)]. Similarly, interoperability specifications should not adversely limit the content of data or common data sets as this can adversely impact innovation in artificial intelligence or machine learning for better applied research or community health studies.

"Format or Structure of Messages Exchanged"

Other requirements related to the "format or structure of messages exchanged" between DHAs [see subparagraph 26(b)] should be cautiously approached to ensure that interoperability specifications do not adversely impact underrepresented populations. For example, an interoperability specification which mandates a "format or structure of messages" or "code sets or classification systems" that requires a fixed address entry has consequences for transient or homeless patients and those hospitals that support these populations.

"Privacy or Security"

Some OHA members have also expressed concern about the scope of the "privacy or security" requirement under the proposed interoperability specification. While the policy intention may be to adopt a "business or technical requirement" that relates to privacy or security, the operational reality in hospital is that privacy and security often relies more on technology implementation, rather than the underlying technology itself (e.g. how often an audit is run; whether staff are trained to respond to patient requests; or how PHI access is provisioned).

More clarity is required to determine if these type of security standards are being contemplated under the proposed changes. Furthermore, it is unclear if any proposed "privacy or security" requirements would incorporate a regular assessment of new features and functionality as technology evolves. Hospitals have stated that technological change has a direct impact on privacy and security compliance, so regular assessments must be integrated into any proposed interoperability specifications which relate to "privacy or security" [see subparagraph 26(e)].

The OHA recommends reviewing these issues related to the definition of "interoperability specification" and providing additional clarity to Ontario hospitals with respect to same. The OHA would be pleased to discuss these issues with you further or connect you with senior privacy leaders and legal counsel, should you require it.

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II. The Need for More Transparency and Engagement in the Interoperability Specification Selection Process

The OHA understands that under the proposed regulatory changes, Ontario Health will have the authority to establish, maintain and amend interoperability specifications, subject to review and approval by the Ministry of Health [see sections 27-29]. This process includes, without limitation, the requirement for review and recommendation with the Office of the Information and Privacy Commissioner of Ontario (IPC).

As a general principle, the OHA strongly recommends that all relevant stakeholders, including hospital representatives, be consulted early on and throughout the process of developing interoperability specifications. DHA users are often best positioned to advise government on the opportunities and challenges posed by digital health interoperability and the OHA welcomes the opportunity to facilitate further discussions with hospital stakeholders on this issue.

Recommendations and Needed Clarity

The OHA understands that an "operational working group with relevant sub-committees would be formed and co-Chaired by [Ontario Health] and the ministry to oversee the process for establishing and evolving the interoperability specifications under the regulation and as described by this [Digital Health Information Exchange Policy]." While this background policy information is helpful, more transparency on the decision-making process and accountability is required within the proposed regulatory changes. Hospitals have specifically identified the following issues and recommendations:

- The selection process does not mandate or include a consultation requirement in regulation for HICs, including hospitals, to review and provide input on interoperability specifications. The OHA recommends that this be integrated into the selection process. Similarly, further information is required for hospitals to determine how the proposed sub-committees will be constituted and how hospital members will be nominated and/or selected.

- The proposed regulatory changes and supporting documentation do not indicate how long certification will last once a DHA is certified. The timeline to certify a DHA must align with the timeline to implement the DHA within an organization. It is unclear if a HIC will be able to implement the DHA before it is certified under the proposed rules. Establishing a certification period and providing more transparency on the certification process itself is recommended.

- The proposed regulatory changes do not include an appeal process for HICs or vendors to challenge decisions on interoperability specifications. This should be

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considered given the potentially large impact on hospital information technology (IT) budgets required to move all DHAs to comply with interoperability specifications.

- Ontario Health may have specific business interests that could conflict with its role in overseeing the process for "establishing and evolving" interoperability specifications. Specifically, if Ontario Health is a vendor for certain products or services that meet the definition of a DHA, how are potential conflicts of interest accounted for under the existing Operational Working Group Terms of Reference? The OHA is not aware whether these Terms of Reference have been established or shared for consultation to-date but would recommend a review to ensure transparency and clarity as to how these conflicts will be managed.

- The proposed regulation and the Digital Health Information Exchange Policy do not provide adequate details on if or how the DHA vendor community will be responsible for ensuring compliance with interoperability specifications. This issue is discussed in more detail in Part IV below. As structured, all compliance responsibilities currently reside with HICs. Consideration should be given to the role of vendors, including, without limitation, including references in guidelines or directives under applicable procurement legislation to ensure that HICs do not inadvertently procure non-compliant DHAs.

- Further clarity should be provided on the overlapping role and authority of Ontario Health and the IPC in the interoperability specification selection process and subsequent enforcement. This issue is discussed in more detail in Part III below. As drafted, the IPC has an ability to review and provide recommendations on interoperability specifications [subsections 27(5)-(6)], but these decisions ultimately rest with Ontario Health (subject to Ministry of Health review and approval).

    - The technical rationale for the IPC reviewing certain interoperability specifications is unclear, given that the proposed changes also provide the IPC with legal authority to then adjudicate HIC compliance with the interoperability specifications [see section 34]. Hospitals have suggested improved language to clarify and delineate between ownership of the interoperability specification selection process and the monitoring / enforcement obligations in sections 32 to 34 of O. Reg. 329/04.

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Alternative Options for Selecting Interoperability Specifications

Some hospitals have also indicated that alternative options can exist for selecting interoperability specifications. These include, without limitation, the Ministry of Health or Ontario Health setting out digital health interoperability "objectives" it wishes to achieve and then working with HICs, including hospitals, to develop a list of technical options and cost estimates that meet these objectives. This may provide government with a more realistic expectation of what DHAs are currently available to meet a proposed interoperability standard and establish a realistic cost expectation for government as it moves forward.

The OHA recommends that the government to review the proposed interoperability specification selection process to ensure that the above-noted concerns are considered and addressed. Our member feedback provided indicates that there are existing gaps in the decision-making process and accountability structure, and that these gaps could have significant impacts on the initiative as it moves forward.

III. Concerns with Respect to Reporting, Monitoring and Enforcement

The OHA acknowledges the importance of accountability measures to ensure that organizations adhere to standards in sharing PHI and delivering high-quality patient care. The OHA has long supported a range of accountability measures in existing legislation that applies to hospitals, including, without limitation, the *Public Hospitals Act,* the *Connecting Care Act, 2019*, the *Excellent Care for All Act*, the *Broader Public Sector Accountability Act*, and PHIPA.

While the proposed regulatory changes provide some information on reporting, monitoring and enforcement requirements to be established in sections 32 to 34 of O. Reg. 329/04, further details are required for the OHA and its members to be able to properly comment on these requirements and assess their consequences for hospitals.

OHA members have stated that the proposed reporting requirements in subsections 32(1)-(4) will create additional regulatory burdens that require resource allocation (financial and staffing) and pose significant time delays before implementation. The resource allocation concerns also extend to government, as Ontario Health will be required to monitor HIC compliance as set out in subsections 33(1)-(4). These costs could include planning and providing funding to HICs, including hospitals, in support of the proposed changes as well. Members have suggested that a reporting and monitoring budget should be properly defined to accurately assess these costs when weighing the benefit of the proposed interoperability specifications.

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Recommendations and Needed Clarity

With respect to the proposed monitoring and enforcement requirements in sections 33 and 34 of O. Reg. 329/04, hospitals have identified the following preliminary concerns that should be considered as the government moves forward:

- **Overlapping Roles**: As discussed above in Part II, there are several overlapping roles with respect to the interoperability specification selection process [see subsections 27(5)-(6)] and monitoring / enforcement powers provided to Ontario Health and the IPC [see sections 33 to 34].
    - There is additional overlap in the role of Ontario Health as both hospital funder (under the *Connecting Care Act, 2019*) and quasi-regulator for the purposes of the proposed section 33. Members have rightfully questioned how this will be implemented in practice. Specifically, will the compliance monitoring function be independent of the funding function or will funding be contingent on strict compliance with the requirements of O. Reg. 329/04?

    - If the latter, the OHA cautions that a strict compliance requirement without adequate transition funding from government will be extremely problematic for all HICs, including hospitals. The OHA recommends further discussion and clarity on these important points.

- **Compliance Costs**: The proposed section 34 contemplates that Ontario Health may make a complaint to the IPC under Part VI of PHIPA. Members have cautioned that if the reason a HIC is unable to comply with an interoperability specification is due to cost or a vendor's inability / refusal to make a required product or system change, an IPC enforcement order mandating compliance or a fine (if applicable) will not remedy the situation. While this point likely requires further discussion, the OHA recommends that Ontario Health use its consultation and advice powers [subsection 33(4)] in these instances to better understand what HIC barriers may exist to achieving regulatory compliance, as opposed to the strict complaint and enforcement measures contemplated under the proposed section 34.

- **Enforcement Measures:** Members have requested further details on what type of enforcement measures the IPC will utilize upon receiving a complaint from Ontario Health pursuant to the enforcement powers proposed under section 34. Specifically, will this include administrative monetary penalties and at what threshold would a complaint be filed under the proposed section 34?
    - The concern has also been raised that, from a drafting perspective, Ontario Health's consultation and advice powers under the proposed subsection 33(4) can operate at the same time as the complaint referral process provided for under section 34. This would seemingly defeat the purpose of providing a

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window of time for Ontario Health to assist a HIC in achieving compliance with the regulatory requirements. The OHA recommends reviewing the operation of these sections and providing further information considering the above-noted concerns.

IV. The Role of Vendors and the Need for Vendor Engagement

Hospitals are concerned that the interoperability specifications and the certification process may impact DHA costs, availability and choice among vendors. The OHA cautions that this important interoperability initiative should not become a disincentive to innovation among DHA vendors, particularly at a time when the government is seeking increased adoption and use of digital health tools in integrated health care environments such as OHTs. These types of policy risks should be identified, quantified, and a mitigation plan developed, to ensure that adverse impacts to patient care are avoided.

With respect to vendors, several hospitals have expressed concern that restrictive interoperability specifications could limit a hospital's ability to purchase future products or services. Notably, if a hospital needs an application to meet a very specific need, there may already be a limited pool of vendors to choose from *or* an individual hospital may lack market power to require changes to an existing product or service to ensure regulatory compliance.

Existing relationships and vendor agreements may also be impacted by the proposed regulatory changes. Depending on the terms and conditions of existing contractual agreements with vendors, hospitals have cautioned that they may be contractually limited in their ability to impose new requirements, particularly if the proposed interoperability specifications apply retroactively to existing DHAs. This can lead to significant financial and reputational consequences for all HICs, including hospitals. In an extreme scenario, a HIC may have to abandon existing DHAs or DHAs that are currently in development under contract if they are unable to comply with the proposed interoperability specifications.

The OHA recommends that these vendor considerations be reviewed as the government moves forward with the proposed regulatory changes. Specifically, the government must engage with the DHA vendor community and ensure that the proposed regulatory requirements do not disincentivize innovation among DHA vendors, nor should they adversely impact DHA cost, availability and choice. The proposed regulatory requirements must also reflect the reality of existing contractual arrangements between DHA vendors and HICs, and not require that HICs breach existing agreements to achieve regulatory compliance.

V. Alignment with Existing National and International Interoperability Standards

OHA members have emphasized that the Ministry of Health and Ontario Health should leverage and adopt existing national and international standards wherever possible when establishing interoperability specifications. The rationale here is threefold:

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- from a patient perspective, this approach offers the greatest portability of patient PHI;
- from a hospital perspective, this will have an impact on the cost and availability of DHAs that meet the interoperability specifications; and
- from a vendor perspective, this will have an impact on DHA innovation and competition.

By way of example, in the U.S. the Office of the National Coordinator for Health Information Technology, a federal resource within the U.S. Department of Health and Human Services, can serve as a potential model for how to approach interoperability specifications and mandating technical concepts like Application Programming Interfaces (APIs).[1]

The U.S. *Health Information Technology for Economic and Clinical Health (HITECH) Act* also sets out rules with respect to "meaningful use" for electronic health records that are interoperable between hospitals and incentivizes the adoption of same. This type of legislation encourages HIS vendors to provide interoperable capabilities "out of the box", which can trigger faster adoption and implementation across many U.S. hospitals, often at a lower cost to individual organizations. These HIS solutions can also be implemented as regional solutions, offering smaller hospitals or regional HICs immediate interoperability benefits if selecting DHAs from shared vendors.

While not a legislative approach, some hospitals have identified the CanHealth Program as a Canadian model for establishing stronger relationships between vendors and HICs, with the ultimate goal of incentivizing interoperable DHAs for quick adoption across the health care system.

Considerations when Reviewing Interoperability Standards

The following list provides a range of non-exhaustive considerations that can be used by government when reviewing national and international interoperability standards and establishing specifications for Ontario:

- Investigate, evaluate and leverage existing national or international capabilities (such as those in the U.S.) as a starting point, and determine any Ontario-specific requirements or extensions;
- Investigate and evaluate the U.S. roadmap for the development and adoption of more modern standards and consider aligning Ontario to this process to increase vendor selection;
- Consider negotiating directly with DHA vendors on behalf of HICs on a common strategy and roadmap to advance capabilities and reduce cost to Ontario;
- Develop specifications for DHAs to meet local requirements only where required; and

[1] For further details, please see the U.S. Office of the National Coordinator for Health Information Technology, *About APIs* (online): link (accessed July 2020).

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- Promote the sharing and reuse of DHAs between HICs (e.g. a library of projects using widely adopted DHAs or other solutions – similar to the Ontario Digital Health Playbook).

This type of approach can offer many potential benefits including, without limitation: lower health system costs due to one-time build requirements by vendors; a roadmap for vendors to establish market predictability and certainty; faster adoption of existing interoperability specifications; and maximum global market access for hospitals (as opposed to strict Ontario-based DHA solutions).

The OHA recommends reviewing these multi-jurisdictional perspectives to ensure that the proposed digital health interoperability initiative successfully leverages existing standards, while also allowing Ontario hospitals to maintain access to important global supply chains and vendors.

Closing Comments

We hope that our feedback is viewed as constructive as the government moves forward and considers the proposed regulatory changes to enable digital health interoperability. We would be pleased to discuss all of these issues and the range of OHA member feedback at your convenience.

Please do not hesitate to contact us should you have any questions or wish to discuss further.

Sincerely,

E. Carlton

Elizabeth Carlton
Vice-President, Policy and Public Affairs