



Digital Health Information Exchange Policy

DRAFT FOR DISCUSSION



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Purpose

The purpose of this policy is to provide the technical foundation for information exchange that is needed for an integrated health system. The policy will enable Ontario to more easily and rapidly adopt and implement standards for information exchange in local, regional and provincial digital health tools. As a result, information will be able to follow patients in an integrated way across the health system, digital health tools will be better able to interoperate with each other and patients will benefit from improved access to their own personal health information.

Introduction

The government's vision for simpler, faster and better end-to-end service across a people-centred government, when viewed through the health system lens, means starting with the patient. This means connecting various points of care so that patients and their health care providers (HCP) from different organizations have access to the patient's personal health information (PHI). Access and exchange of health information across sectors is central to the government's objectives for ending hallway medicine and Ontario Health Teams (OHT).

In order to meet these objectives, foundational system redesign is needed to support more efficient use of limited resources while improving patients' experiences in receiving care and better health outcomes for Ontarians as a whole. To this end, recent efforts to modernize Ontario's health system have been enabled, in part, by the increasing ability of patients and their HCPs to access patient health data that is stored in different types of digital health assets (e.g. patient portals that connect to clinical systems such as hospital information systems, the Ontario Laboratory Information System, the Digital Health Immunization Repository).

While progress has been made in sharing information across the health system, a large amount of clinically useful patient health information is stored in closed systems that are only accessible by sector and program-specific digital health tools – this presents significant gaps in seamless access to integrated patient records and has led to fragmentation, redundancies and an inconsistent user experience. Filling these gaps would enhance the quality of patient care through improved patient handover for example and streamline provider workflows; it would also enable value-added uses of data such as advanced detection and tracking of disease and other risks to population health. As we transition to an integrated model of healthcare, the future state of digital health in the province will focus on the ability for OHTs and other HCPs to leverage current and future digital health technologies to access and exchange PHI to provide a seamless and consistent experience for patients and their providers.



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To enable timely access to the PHI across sectors and systems, the Personal Health Information Protection Act, 2004 (PHIPA) is being modernized to enhance privacy-protected, improved information sharing across the health system while increasing sanctions for misuse of that information. Among the aims of PHIPA modernization is the encouragement of adoption of digital health principles and practice in patient care. Additionally, the Digital First for Health Strategy streamlines Ontario's approach to digital health delivery by promoting modern technical standards and guiding ministry investments in projects that increase the interoperability, technical capacity, and value of existing digital health assets. The strategy will also act as the primary lens for the ministry to consider options for improving health system efficiency and increasing integration to better meet the needs of both patients and providers.

In alignment with this strategic direction, the province's digital health infrastructure is also being improved to increase interoperability so that Ontarians, HCPs, and innovators may access and exchange trusted patient health information in a frictionless, reliable and consistent manner. Furthermore, in contemplating the ways in which to make health data interoperable and accessible to a wider audience, patient safety, privacy and security of PHI is of paramount concern (see Appendix B: *Protecting privacy*). This is why the ministry is exploring a number of initiatives, including increasing cybersecurity capacity across the health sector and options for establishing a patient digital identity – to provide health information custodians (HIC) with the assurance that the PHI held in their digital health assets is being accessed by authorized users.

Through increased interoperability of clinical systems and provincial digital health assets, including those within and outside of OHTs, the anticipated impact of this policy and the underlying (proposed) regulation is more flexibility in ways Ontarians and their HCPs access patient health information, improved information sharing between providers, and greater value for money and increased utility of government investments.

To enable access and exchange of PHI, this policy:

- Directs specified HICs to adopt the interoperability specifications that have been established by Ontario Health (OH) for the digital health assets that the custodian selects, develops or uses, as required by the regulation.
- Encourages HICs to make use of any OH resources and supports, including certification programs, to guide digital health asset modernization efforts and vendor management.
- States the mandatory requirements HICs must fulfill to be compliant with the regulation.
- Promotes the adoption of interoperability specifications that are recognized by the health sector as secure and reliable.

This policy supports the Digital First for Health Strategy and creates an overarching framework that is enabled, by regulation under PHIPA.

Additionally, the Connecting Care Act, 2019 prescribes OH to oversee health care delivery, improve clinical guidance and provide support for providers to ensure better quality care for patients. This includes streamlining the technical infrastructure that runs the province's health system and providing a centralized point of governance, accountability and oversight for this policy's implementation.

Effective Date and timelines

The effective date for this policy is October 1, 2020.

- By the effective date, OH will have designed and implemented a program to establish interoperability specifications. This program would include implementation requirements for HICs and digital health product vendors to ensure compliance with the regulation and policy is attained.

Application and scope

This policy applies to all Health Information Custodians.

Over time, the OH program that establishes interoperability specifications would also name the HIC or class of HIC that would be required to comply with the specification, and the date on which the specification becomes effective.

Principles

Health data is valuable.

- Health data being generated at a rapid rate, and increasing interoperability optimizes and sustains its value to all actors in the health system.
- Access to clinical data informs evidence-based high-quality care, and new ways to support clinical decision-making are important for being able to do more with increasingly scarce resources.
- Implementing interoperability specifications will help improve some of this and will contribute to streamlining and learning how to be more effective as patients, providers, and a health system.

Health data should be interoperable.

- Health data should adhere to common structure and terminology specifications that are adaptable and evolve over time, so that it may be accessed securely and used easily for a number of purposes.



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- These purposes could include improved safety, quality, coordination and continuity of care, monitoring and controlling the spread of disease for population health protection, and improved data quality.

Health care providers should not face undue burden.

- Limited data sharing often requires HCPs to create redundant documentation and retest their patients to get current information. These inefficiencies increase risk to patient care through longer wait time for treatment and potential data entry errors.
- Enabling data exchange across sectors will change the way HCPs and their patients communicate with one another – for the better. Data exchange across sectors will result in modernizations in system design and clinical workflow that would evolve over time to meet providers’ access and use needs and including data capture in point-of-service systems across sectors.
- So that HCPs are able to deliver high-quality patient care and protect the health of Ontarians through the use of digital tools, vendors should facilitate access to the PHI held in their clinical systems in a manner that is aligned to the spirit of this policy.

National and international standards should be adopted where possible.

- Reflecting standards-based approaches to digital health in other jurisdictions, the same approach to increasing the interoperability of Ontario’s digital health assets is at the core of this policy.
- Accounting for the need to be responsive to Ontario’s reality, the interoperability specifications prescribed under this policy should align with national and international standards where possible, to also prevent undue burden on digital health product vendors.

Foster innovation and economic development in Ontario’s health care system.

- Increased connectedness of digital health assets should result in more opportunities and potential for innovation, growth and faster adoption of digital health tools and services. This includes the province taking a strong leadership role in promoting and evolving widely adoptable health informatics specifications to support information sharing now and in the future.

Mandatory Requirements

This policy establishes the expectation that all HICs must:

1. Comply with the interoperability specifications established by OH so that patients and HCPs may access and exchange recognized and clinically useful data.
2. Modernize relevant digital health assets that are selected, developed or used by the HIC according to interoperability specifications and implementation timelines established by OH.



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3. Make use of any OH resources including the list of OH-certified digital health assets to guide digital health asset modernization efforts and vendor management, and provide a report to OH that sets out the HIC's compliance with the requirement to select, develop or use digital health assets that comply with the applicable interoperability specifications.

Approach for implementation

To modernize health care in Ontario and deliver it more efficiently, the connectedness of digital health assets across sectors must increase. This means that each digital health delivery partner must do its part to enable authorized connections to digital health assets it oversees, operates, creates or provides.

To this end, OH is responsible for establishing, maintaining and amending interoperability specifications and establishing a process for certifying digital health assets that are compliant with those specifications. See Appendix A: *Enabling transitions in care*, for an example of a use case that could inform OH's work in this regard.

Understanding that interoperability specifications would evolve over time, an operational working group with relevant sub-committees would be formed and co-Chaired by OH and the ministry to oversee the process for establishing and evolving the interoperability specifications under the regulation and as described by this policy. The inclusion of HICs, HCPs, digital health product vendors and innovators, and other health system partners including patient groups, could guide the defining of requirements and determining the appropriate specifications and stages for implementation.

Roles and responsibilities

This policy introduces new expectations for traditional and non-traditional actors in Ontario's health system – one that requires active coordination and cooperation to support the policy's implementation across the health system.

Understanding that the application of the regulation and this policy may differ from sector-to-sector, the table below highlights the major in-scope health system actors and provides a description of their roles and responsibilities.

Ministry of Health
The ministry sets the overall goals for the health system, sets policy direction, establishes relevant levers for compliance and change supports, and determines the priority for different data access and data exchange use cases for the policy. Furthermore, the ministry would:

- Set clear direction to Ontario’s health sector by publishing the Digital Health Information Exchange policy and updating it for relevance.
- Establish and maintain the needed legislative and regulatory instruments to create a legal requirement of compliance with interoperability specifications and clarify OH’s role.
- Explore options for supports required to mitigate risks and assist with implementation of the regulatory requirements and policy.
- Retain the right of final approval for any data access and data exchange use cases, and interoperability specifications and implementation timetables recommended by OH.

Ontario Health

OH would be accountable for internalizing the policy into its operations and would lead its implementation. This would include defining interoperability requirements, establishing specifications, subject to approval by the ministry, and actively working with vendors and HICs through a certification program to monitor and verify compliance. Furthermore, OH would:

- Provide technical leadership by establishing and leading the process for determining interoperability specifications. This would include expanded engagement for specifications development, compliance assurance services, sustainment of the program and related processes of change and vendor management.
- Leverage partners (e.g. OntarioMD and its electronic medical record (EMR) certification program) and its existing resources and expertise (e.g. standards groups within the Digital Service business unit) to determine and publish the interoperability specifications, as required by the regulation.
- Be responsible for establishing a process for monitoring HICs’ compliance with the regulation.
 - This could include OH’s use of levers and supports within its controls (e.g. service accountability agreements, technical resources, access to provincial digital assets); and,
 - Advising the ministry on options for and use of additional levers (e.g. contracts with non-OH funded HCPs; additional legislation / regulation).

Health Information Custodians

HICs represent the market demand for digital health products, services and systems, and would contribute to OH’s work on determining the recommended interoperability specifications. Furthermore, HICs would:

- Inform OH's recommendations for interoperability specifications, ensuring that the direction taken to enable data access and exchange for one use case does not hinder progress when it comes time to focus on other use cases.
- Be supported and eventually compelled to adopt compliant digital health products and services. The mix of levers and supports available to HICs will vary by sector but would be defined by OH in partnership with the ministry.
- Report to OH that their digital health assets are compliant with the prescribed interoperability specifications.
- Report new digital health investments to OH.

Digital health vendors

Digital health product vendors represent the market supply for digital health products, services and systems and would contribute to OH's work on determining the recommended interoperability specifications that they would adopt into their products and services to remain competitive in the Ontario market. Furthermore, digital health vendors would:

- Inform OH's recommendations for interoperability specifications, ensuring that the direction taken to enable data access and exchange for one use case does not hinder progress when it comes time to focus on other use cases.
- Develop and implement relevant technologies (e.g. APIs) per the interoperability specifications published by OH, that would enable connections to the vendor's digital health products, services and systems in use by their customers – the HICs, HCPs and individuals who would access and exchange PHI.
- Ensure that compliance with the policy does not hinder or prevent HICs from making available the PHI in their digital health assets.

Table 1 - Roles and responsibilities



Definitions

The definitions provided in this section have been drawn from various sources and are for the purposes of providing non-technical, simplified descriptions of some of the terms used in the regulation and in this policy.

Digital Health

Digital health describes the many uses of information technology that supports the delivery of patient care in the health system. This can include the coordinated use of web, mobile and cloud technologies to integrate points of care.

Digital Health Asset

A digital health asset is an electronic product, service or system that uses electronic means to collect, use, modify, disclose retain or dispose of PHI, and that is selected, developed or used by a HIC.

Digital Health Delivery Partner

A digital health delivery partner is any agency, organization or HCP in Ontario's health system that oversees, operates, creates or provides digital health technology to address the healthcare needs of patients and providers. Examples of digital health delivery partners may include ministry agencies (e.g. OH), integrated care delivery system, HCPs (e.g. hospitals, primary care providers, home and community care organizations), and digital health product and service vendors (e.g. health apps, patient portals).

Electronic Medical Record

An electronic medical record ("EMR") is a digital version of the traditional paper-based record for a patient kept by HCPs such as a family doctor.

Health Information Custodian

A health information custodian ("HIC") is a person or organization described under Ontario's Personal Health Information Protection Act, 2004 who has custody or control of PHI. This may include a health care practitioner, a long-term care home, a pharmacy, an ambulance service, and others under the legislation that collect, use or disclose PHI for the purpose of providing healthcare to patients.

Hospital Information System

A hospital information system (“HIS”) is a comprehensive and integrated software-based information system that manages all of the information flows in a hospital, including clinical and administrative information, among others. This policy pertains to the clinical set of information in the HIS (i.e. it does not include non-clinical information in a hospital , for example finance and payroll).

Interoperability

Interoperability means the ability to capture, manage, communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings, and exchange data so that the clinical or operational purpose and meaning of the data remains unchanged.

Interoperability is based on three components:

1. **Semantic interoperability.** This relates to the data content within the exchange of information; defining the structure and organization of a digital message or document content. This includes the definition of common data sets for specific message types.
2. **Technical interoperability.** This would include the ability to represent concepts in an unambiguous manner between a sender and receiver of information, and which may include structured vocabularies, terminologies, code sets and classification systems to represent health concepts.
3. **Functional interoperability.** This refers to the shared (legal and organizational) rules of information exchange, including business rules and information governance.



Appendix A: Enabling transitions in care

This appendix is meant to serve as an example of a use case for data access and exchange.

Aligning with quality standards¹ established by Ontario Health Quality, improving the timely and efficient exchange of clinical information at patient handover would reduce discontinuities in care that is increasingly recognized as potentially dangerous for patient safety and associated with adverse events².

One example of operationalizing patient handover is the provincial eServices program that is being developed to improve access to specialists, decrease wait times and support smoother transitions in care through digital health tools. Examples of eServices include referrals and consults and could expand to include prescriptions, lab test orders and other types of clinical support services. eServices would replace fax and paper-based processes of sharing information between HCPs, thereby reducing discontinuities in care through improved efficiency, timeliness and accuracy of patient health information shared between providers.

Digital health assets that could be in-scope for bi-directional data exchange under the patient handover use case would be acute and primary care information systems (i.e. HIS and EMR systems), and provincial repositories of PHI operated by OH. Examples of PHI* that could be in-scope for access and exchange may include:

- Assessment and plan of treatment
- Goals
- Clinical notes (including discharge summary)
- Vital signs
- Medications

(*For illustrative purposes only and not meant as a recommendation.)

Appendix B: Protecting privacy

¹ <https://www.hqontario.ca/Evidence-to-Improve-Care/Quality-Standards>

² Niraj K. Mistry, Alene Toulany, John F. Edmonds and Anne Matlow. 2010. Optimizing Physician Handover Through the Creation of a Comprehensive Minimum Data Set. *Healthcare Quarterly* 13: 102-109.



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This policy does not allow or enable unrestricted access to Ontarians' PHI. Care must be taken by all health system actors to responsibly enable and control access to digital health assets, especially those holding PHI.

This policy recognizes the immense value that digital health delivery partners and public and private sector innovators bring to the health care system, and is committed to supporting digital health innovation. The policy also recognizes that providing more opportunity for non-HICs to connect their digital health products and services to provincial digital health assets may increase the risk of exposing PHI to unauthorized audiences. In order to help HICs meet their obligations and accountabilities under PHIPA while also providing assurance that the PHI being accessed is being disclosed to an authorized audience for authorized purposes, the ministry is currently exploring options for a standardized approach to access controls that would provide Ontarians with a way to digitally prove who they are, access their PHI and manage their consent directives. Furthermore, this policy underscores the need for all parties that access PHI held in provincial digital health assets to have appropriate data-sharing agreements in place between digital health delivery partners, relevant HICs, patients, and any other party involved in the access and disclosure of PHI.

The policy recognizes that increasing the interoperability of the province's digital health assets necessitates consideration for safeguarding privacy and security of PHI. Furthermore, interoperability means increased ability for digital health delivery partners to share recognized and meaningful data and use it for analytical use purposes. To address these issues and mitigate risks, work is currently underway on a number of fronts to protect health data and PHI while enabling increased access to it by authorized users, including the establishment of a Health Sector Cyber Security Executive Steering Committee to guide the development and implementation of projects aimed at improving health sector maturity in this area, including:

- Collaborating with partner ministries in sharing intelligence across the health sector to improve provider preparedness and response capacity;
- Supporting access to resources including cybersecurity training and maturity assessment tools to identify areas for improvement; and,
- Exploring managed and shared service models to increase health system capabilities.

Appendix C: Supporting change

For the government to achieve its goals for an integrated health system through OHTs, HCPs must be able to access and exchange meaningful patient health information. To do so, this means they would be required to choose digital health products and services that are compliant with this policy.

Through the ministry's regulation making powers under PHIPA, OH is prescribed as the centralized point of governance, accountability and oversight for this policy's implementation. Accordingly, OH



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would launch a program to lead the process to determine and amend interoperability specifications, including actively working with vendors to manage the change through any certification program and service accountability agreements, and oversee HIC compliance monitoring. Additionally, OH would determine the appropriate mix of supports and incentives needed for HICs to comply with this policy and for digital health vendors to implement the operational changes required to respond to market forces in this regard.

In addition to OH determining the right mix of supports for HICs and digital health vendors, the ministry is considering additional program-level levers to ensure adherence to the policy, including:

- Using existing accountability and funding mechanisms to require transfer payment recipients and other publicly funded entities to comply with this policy.
- Incorporating relevant requirements within existing certification programs for clinical systems (e.g. OntarioMD EMR certification).
- Granting OH additional oversight responsibilities including the power to investigate and issue compliance directives to HCPs funded by the agency.

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