

Comments of the Information and Privacy Commissioner of Ontario on Proposed Interoperability Regulations under *PHIPA*

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Information and Privacy
Commissioner of Ontario

Commissaire à l'information et à la
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The May 23, 2020 edition of the Ontario Gazette contains a notice by the Minister of Health (the Minister) of proposed regulations under the Personal Health Information Protection Act, 2004 (the Proposed Regulations). The Proposed Regulations require Ontario Health to establish, subject to the direction and approval of the Minister, interoperability specifications relating to digital health assets (e.g. hospital information systems, electronic medical records, etc.). The Proposed Regulations also set out a framework for compliance, certification, monitoring and enforcement with respect to the interoperability specifications. As a backdrop to the Proposed Regulations, the Ontario Government also posted to its Regulatory Registry the “Digital Health Information Exchange Policy” (the Policy).¹

The Information and Privacy Commissioner of Ontario (IPC) has reviewed both the Proposed Regulations and the Policy. While the IPC generally supports the government’s laudable goal of increasing interoperability across Ontario’s digital health information assets, the IPC makes the following recommendations to amend the Proposed Regulations and help guide future development and implementation of the Policy. In brief, these recommendations are intended to strengthen the protection of Ontarians’ personal health information through:

- Broader and earlier consultation with the IPC;
- Expanded opportunities for compliance monitoring by Ontario Health; and,
- Enhanced coherence of Ontario’s health privacy oversight regime.

1. BROADER AND EARLIER CONSULTATION WITH THE IPC

Subsection 27 (5) of the Proposed Regulations requires the Minister to consult with the IPC before approving interoperability specifications that relate specifically “to the content of data or a common data set for electronic data or privacy or security”. The IPC supports the principle behind this obligation to consult but recommends that it be expanded in two ways.

First, rather than limit the categories of specifications in respect of which the Minister must consult the IPC, we recommend that such obligation be triggered any time a proposed interoperability specification relates to the confidentiality of personal health information, the privacy of individuals or the rights of individuals to access or correct their personal health information records. This will ensure that the IPC is consulted about any specifications that may have direct or incidental impact on the privacy and access rights of individuals and the duties of health information custodians under *PHIPA*. Such an approach would be more in keeping with the nature and scope of

¹ The Policy, along with the Proposed Regulations, was posted in Proposal Number: 20-HLTC021.

the IPC's mandate and the type of expertise we have to offer. Also, approaching the obligation to consult by relevance, rather than fixed category, will ensure that other proposed specifications which may be interrelated across several categories and/or have incidental or inadvertent impacts on privacy, security and access, will likewise benefit from IPC review and advice. As an example, interoperability specifications on "the format or structure of messages exchanged between digital health assets" may be based on flawed assumptions of what constitutes non-identifiable information, which in turn may be informed by erroneous use of "terminology, including vocabulary, code sets or classification systems."

Second, the IPC recommends that the Minister be required to consult with the IPC earlier in the process. Subsection 27 (1) of the Proposed Regulations requires the Agency (Ontario Health) to establish, maintain and amend interoperability specifications, subject to the review and approval of the Minister. Subsection 27 (2) also permits the Minister to direct the Agency to establish or amend interoperability specifications. This means that a given interoperability specification might either be established or amended at the Agency's initiative under subsection 27 (1) or, alternatively, at the Minister's direction as per subsection 27 (2).

Subsection 27 (5) of the Proposed Regulations requires the Minister to consult with the IPC before approving interoperability specifications that have been established, maintained or amended by the Agency under subsection 27 (1). While the IPC supports this requirement, we recommend that, where an interoperability specification is established or amended at the Minister's direction under subsection 27(2), the IPC should likewise be consulted *before* the Minister issues its direction to the Agency. This will allow the IPC to identify possible concerns at an earlier point in the process as the Minister is setting certain policy directions in motion.

To give effect to these two submissions, the IPC recommends that subsections 27 (5) and (6) of the Proposed Regulations be amended to read as follows:

(5) Before approving interoperability specifications under subsection (1), or directing the Agency to establish or amend interoperability specifications under subsection (2), that relate to the confidentiality of personal health information, the privacy of individuals with respect to that information, or individuals' right of access to, or correction of, records of personal health information, the Minister shall,

(a) submit a draft of the specifications or the direction to the Commissioner for the purpose of the Commissioner reviewing and making recommendations on the draft specifications or direction; and

(b) consider the recommendations, if any, made by the Commissioner and amend the specifications or direction if the Minister considers it appropriate to do so.

(6) The Minister shall allow the Commissioner a period of at least 30 days for the purpose of reviewing the draft specifications or direction and providing recommendations under subsection (5), unless the Minister believes that the urgency of the situation requires it, in which case the Minister may abridge the review period for the Commissioner to a period of not less than five business days.

2. EXPANDED OPPORTUNITIES FOR COMPLIANCE MONITORING BY ONTARIO HEALTH

Under the Proposed Regulations, the Agency (Ontario Health) provides the first layer of monitoring to promote health information custodians' compliance with applicable interoperability specifications respecting digital health assets. This is a critically important "first line of defence". The IPC recommends that Ontario Health be given expanded opportunities to encourage compliance at the front end, thereby reducing the need for more extensive complaint investigations and formal enforcement measures by the IPC.

To give effect to this submission, the IPC recommends that Ontario Health be authorized to consult with health information custodians regarding their compliance in a broader range of circumstances than currently provided for in the Proposed Regulations. Section 32 of the Proposed Regulations requires health information custodians that select, develop or use digital health assets to provide reports to the Agency (Ontario Health) about the custodians' compliance. Section 33 requires that the Agency establish a process for monitoring custodians' compliance and authorizes the Agency to consult with custodians to provide advice on achieving compliance. Specifically, subsection 33 (4) provides that "[i]f, *after reviewing a report provided by a health information custodian under section 32*, the Agency has reasonable grounds to believe that the custodian is not in compliance with the requirements under subsection 30 (1), the Agency may consult with the health information custodian...." [Emphasis added].

In the IPC's view, the wording of subsection 33 (4) suggests that a report under section 32 is the only trigger that would permit the Agency to engage in consultation with health information custodians. Limiting consultation in this way could undermine the ability of the Agency to monitor compliance in other ways and provide meaningful advice to custodians. Although reviewing reports made under section 32 might be an important component of the Agency's monitoring process created under subsection 33 (1), it will not necessarily be the only component of this process. In fact, the Policy

contemplates that Ontario Health will “determine the appropriate mix of supports and incentives needed” for health information custodians to comply. It is important, therefore, that Ontario Health not be limited in its ability to detect instances of potential non-compliance and either provide advice with a view to resolving them, or bring any persistent or systemic issues to the IPC’s attention as appropriate.

Therefore, the IPC recommends that subsection 33 (4) of the Proposed Regulations be amended to read:

(4) ~~If, after reviewing a report provided by a health information custodian under section 32,~~ the Agency has reasonable grounds to believe that the custodian is not in compliance with the requirements under subsection 30 (1), the Agency may consult with the health information custodian and provide advice to the custodian on how compliance may be achieved.

The Policy further indicates that the Ministry of Health is considering granting Ontario Health “additional oversight responsibilities including the power to investigate and issue compliance directives to [health care providers] funded by the agency”. To the extent that the Ministry of Health is considering yet another level of investigation and enforcement (as opposed to compliance monitoring at first instance), the IPC would welcome further discussion on how such additional mechanisms of oversight (as least in respect of privacy, security and access and correction matters) can best be designed to ensure complementarity with the IPC’s existing role and mandate under *PHIPA*, as opposed to creating what may be a duplicative layer and unnecessary regulatory burden for health care providers concerned.

3. ENHANCED COHERENCE OF ONTARIO’S HEALTH PRIVACY OVERSIGHT REGIME

The Policy describes the government’s goal of increasing interoperability of digital health assets and facilitating access and exchange of personal health information throughout the health system – with the ultimate aim of enabling patient-centred care and ending hallway medicine. The IPC generally supports these important policy goals, and is hopeful that increased digital interoperability will result in more accurate and secure electronic records of personal health information and less reliance on systems that are known to be more vulnerable to breach and error-prone (e.g. fax²). However, these policy goals may also give rise to a new generation of privacy and security concerns by virtue of the commercialization incentives they engender and the types of actors they attract in Ontario’s health sector.

2 See 2018 IPC Annual Report, p. 31, <https://www.ipc.on.ca/wp-content/uploads/2019/06/ar-2018-e.pdf>.

Specifically, the Policy states:

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.

...

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.

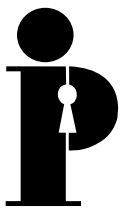
While commercialization may be an integral part of a health innovation agenda, when it comes to potentially monetizing Ontarians' personal health information — even in de-identified form — this is a highly sensitive topic which sparks significant public concern, particularly in a publicly-funded health care system. Accordingly, any commercialization potential would, in our view, require more fulsome, transparent and thoughtful policy debate in order to earn the social license needed to support any movement in that direction.³

Moreover, to the extent that the creation of interoperability specifications enables new entities to more easily access digital health information of Ontarians — potentially for commercial gain — this raises certain regulatory gaps in Ontario's health privacy regime that warrant timely attention. Although the participation of private sector entities may help drive and accelerate innovation, robust oversight mechanisms must be put in place to govern these public-private partnerships in a more coherent and seamless way.

Private sector entities that are not health information custodians governed by *PHIPA*, must otherwise be brought into the same regulatory fold. In the IPC's view, all actors participating in Ontario's digital health information exchange must be held to commensurate privacy standards and subject to similar enforcement rules under Ontario's health privacy law. This will help ensure that individuals' personal health information is seamlessly protected by a single, coherent regulatory framework, and does not risk straddling inefficiently between different jurisdictional regimes, or worse yet, falling between the cracks altogether.

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³ See comments of the Information and Privacy Commissioner of Ontario on Bill 138, p. 4, <https://www.ipc.on.ca/wp-content/uploads/2019/12/2019-12-bill-138.pdf>.



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