VIA ELECTRONIC MAIL



November 2, 2022

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

Dear Evan:

RE: Proposed Amendment to O. Reg. 329/04 under PHIPA on the right to access records in electronic format

The Ontario Gazette, published on September 24, 2022, contains a notice by the Minister of Health of a proposed regulation under the *Personal Health Information Protection Act, 2004* (PHIPA) relating to the right of access to records of personal health information in electronic format (the Proposed Regulation).¹ The Office of the Information and Privacy Commissioner of Ontario (IPC) would like to offer the following staff-level comments.

I. Background

Section 52 of PHIPA affords individuals with the right to access their records of personal health information, subject to limited exclusions and exceptions. In March 2020, PHIPA was amended to add a new subsection (1.1) to section 52.² This subsection explicitly provided that the right to access records of personal health information included the right to obtain those records in an electronic format that met the prescribed requirements. Currently, prescribed requirements under subsection 52(1.1) provide individuals with the right to have a health information custodian (custodian) provide the record to the individual in:

- a PDF file; or
- any other electronic format that is agreed to by the custodian and the individual (the Current Regulation).³

It is worth noting that, even before the above amendments and regulatory changes, there was a well-established practice of individuals' exercising their access rights and obtaining records in electronic format.

³ See section 18.0.1 of O. Reg. 329/04, which has been in force since July 1, 2022.



¹ See <u>Ontario Gazette Vol. 155-39</u>, pages 3704-3707. The notice of the Proposed Regulation was also posted in the Ontario Regulatory Registry (<u>Proposal number 22-HLTC027</u>).

² See <u>Bill 188, Economic and Fiscal Update Act, 2020</u>, S.O. 2020, c. 5, Sched. 6, s. 9.

In April 2022, subsection 52(1.1) of PHIPA was amended⁴ so that Ontario Health would have the ability to specify electronic access formats in accordance with regulations:

The right to access a record of personal health information includes the right to access the record in,

- (a) an electronic format that meets the prescribed requirements, subject to any restrictions, additional requirements or exceptions that may be prescribed; or
- (b) an electronic format specified by the Agency⁵ in accordance with the regulations.

When this legislative amendment was proposed, the IPC made a submission containing recommendations with respect to the regulations that may eventually be made authorizing Ontario Health to specific electronic access formats.⁶ This is the Proposed Regulation. As described below, the Proposed Regulation does not incorporate all of the recommendations by the IPC. Further, the Proposed Regulation introduces additional issues warranting comment.

II. Recommendations

Our recommendations are explained below. For ease of reference, we have also included an Appendix setting out all our recommended changes (indicated by an underline for new text and a strikethrough for deleted text).

A. Require Ontario Health to consult with the IPC and the public

1. Introduction

The electronic formats specified by Ontario Health will have significant implications for individuals exercising their access to information rights, and for the IPC in adjudicating those rights. The original version of 52(1.1) of PHIPA required that electronic access formats be prescribed in regulation.⁷ This meant that any draft regulation would have been subject to the public consultation requirements in section 74 of PHIPA. The government should ensure a similarly open and rigorous consultation process for the electronic formats specified by Ontario Health.

2. Consultation with the IPC

As the IPC previously stated, we recommend that the Proposed Regulation be amended to require Ontario Health to consult with the IPC.

⁴ See <u>Bill 106, Pandemic and Emergency Preparedness Act, 2022</u>, S.O. 2022, c. 11, Sched. 4, s. 1.

⁵ "The Agency" is Ontario Health.

⁶ See the IPC's <u>Submission on Bill 106: Obligations and authorities of Ontario Health Teams and access to</u> records in electronic format (April 6, 2022), pages 6-8.

⁷ See s. 52(1.1) of PHIPA <u>as was in force from March 25, 2020</u> to April 13, 2022.

A similar obligation to consult the IPC currently exists when Ontario Health is establishing or amending certain interoperability specifications under sections 26 to 34 of O. Reg. 329/04 under PHIPA. Specifically, Ontario Health is required, for certain interoperability specifications, to "(a) consult with the Commissioner, in a manner [Ontario Health] and the Commissioner mutually consider appropriate in the circumstances; and (b) consider the recommendations, if any, made by the Commissioner...".

Further to this process, the IPC and Ontario Health have been consulting on interoperability specifications for some time. In our view, the consultation process between Ontario Health and the IPC with respect to interoperability specifications has been highly collaborative and working well. Ontario Health has been providing the IPC with numerous opportunities to review and provide feedback on drafts of interoperability specifications as they are being developed, working towards a better end result.

This consultation process for interoperability specifications provides a useful precedent. Further, we expect that interoperability specifications established by Ontario Health will directly interrelate to the electronic access formats specified by Ontario Health. In short, interoperability specifications should facilitate providing individuals with access to records in electronic format. As such, there should be equivalent consultation requirements to ensure consistency and transparency. It makes little sense to require consultation for one but not the other.

We have provided specific suggestions in the Appendix for how the language about consultation with the IPC in the interoperability context can be adapted for the electronic access format context.

3. Consultation with the public

We recommend that the Proposed Regulation be amended to require Ontario Health to consult the public on the electronic formats under consideration for access to records of personal health information. The right of access to one's own personal health information is of fundamental importance to individuals. However, this right of access will rapidly become outdated and unwieldy if individuals cannot use the personal health information they receive to become active and informed participants in their own health care, and are required to revert to paper records. For Ontario Health to set useful requirements, they need to know how individuals are using, or intend to use, their electronic access rights. And, to know this, Ontario Health needs to actually hear from those individuals. This need not be complicated. For example, the proposed formats could be posted on Ontario Health's website with an invitation for the public to provide submissions. We understand Ontario Health is already doing this in relation to the interoperability specifications.

We have provided specific suggestions in the Appendix for how the language about consultation in the interoperability context can be adapted for the electronic access format context.

B. Keep PDF until there is an equally commonly used alternative

Under the Current Regulation, individuals have an express right to, at a minimum, access records in one electronic format: PDF. The transition to the Proposed Regulation would remove this minimum right, unless: (1) PDF is one of the formats specified by Ontario Health, and (2) this specification is made and posted on the Ontario Health website by the time the Proposed Regulation comes into force.⁸

While the IPC has urged the government to go beyond PDF and pursue other more useful and manipulatable file formats, this does not mean PDF should be abandoned. Indeed, the IPC previously categorized the Current Regulation as a "first step, with many other steps more urgently required to fully realize the promise of digital health for the benefit of Ontarians".⁹ We worry that the Proposed Regulation will be seen as a step back, and potentially lead to arguments that individuals cannot even obtain records of personal health information in PDF anymore (even though this was common practice since well before the Current Regulation came into force). Further, PDF serves a useful purpose as a common file format that permits records to be viewed by many different types of devices.

We note that the Proposed Regulation does not actually require Ontario Health to specify any electronic formats. (In contrast, there is a provision in O. Reg. 329/04 requiring Ontario Health to "establish, maintain and amend" interoperability specifications). We are further concerned that there could be a gap in coverage if the Proposed Regulation comes into force before Ontario Health has specified any electronic formats.

The requirement to provide access to records in PDF should be kept in the regulation until at least there is an equally commonly used alternative format available, and that format has been specified by Ontario Health.

C. Amend the "secure online application, such as a portal" subsection

The Current Regulation and the Proposed Regulation differ with respect to the language used to discuss providing records through a portal. The Current Regulation states:

(2) The reference to an electronic format in clause (1) (b) **includes** the provision of the record of personal health information by the health information custodian through a secure online application, such as a portal.

In contrast, the Proposed Regulation states:

(2) For greater certainty, subsection (1) **may be used to authorize** the provision of a record of personal health information through a secure online application, such as a portal.

⁸ According to page 3704 in the Ontario Gazette posting, the effective date of the Proposed Regulation is July 1, 2023.

⁹ See the IPC's <u>Submission on the Current Regulation</u> (December 1, 2021).

We recommend that the Proposed Regulation be amended by replacing "may be used to authorize" with "may be used to require".

The provisions in the Proposed Regulation that pertain to custodians should be mandatory, not permissive. Any regulation made under subsection 52(1.1), and by extension electronic formats specified by Ontario Health, must be about which electronic formats a custodian is *required* to provide if requested by the individual, not about which electronic formats a custodian is *permitted* to provide. This is because subsection 52(1.1) is framed as a right of the individual; if the individual has the right, then the custodian has a corresponding obligation.

Even before the introduction of subsection 52(1.1) and the Current Regulation, many custodians already provided individuals with access to their records in electronic format (including through portals), and PHIPA can be read to require this access.¹⁰ No amendment to PHIPA or its regulation was or is needed to "authorize" this to happen.¹¹ Section 54 of PHIPA, which covers custodians' responses to access requests, does not make any distinctions about format types.

D. Improve drafting consistency with existing provisions of the regulations to PHIPA

The IPC notes that several provisions in the Proposed Regulation are inconsistent with similar phrases that already exist in the regulations to PHIPA. This is especially a concern, as the regulation appears to be intending to have the same effects, but through slightly different language. This could create statutory interpretation arguments and challenges that are neither necessary nor desirable. In the Appendix, we have shown our proposed solutions to these drafting inconsistencies, together with an explanation of the inconsistency.

III. Conclusion

We appreciate the opportunity to make this submission. One of the IPC's strategic priority areas for 2021-2025 is "Trust in Digital Health", and one of our goals in this area is to promote confidence in the digital health care system by guiding custodians to respect the access rights of Ontarians.¹²

Please let us know if you have any questions.

¹⁰ The practice of providing records in electronic format in response to requests for access under PHIPA is not new. PHIPA defines "record" to mean "a record of information in any form or in any medium, whether in written, printed, photographic or electronic form or otherwise."

¹¹ Along the same lines, in the "Summary of Proposal" section of the <u>Regulatory Registry posting</u>, this sentence is inaccurate: "Alternatively, the proposed regulation would authorize HICs to provide access in another electronic format that is agreed to by the HIC and the individual." No regulation is needed to "authorize" this to happen.

¹² See <u>IPC Strategic Priorities 2021-2025</u>, page 2.

In the interest of transparency to the people of Ontario, we will make this submission available on our website.

Sincerely,

Andrew Drumment

Andrew Drummond Director of Health Policy

Appendix: the Proposed Regulation with IPC recommended changes

1. Section 18.0.1 of Ontario Regulation 329/04 is revoked and the following substituted:

Right to access record in electronic format

18.0.1 (1) For the purposes of subsection 52 (1.1) of the Act, the right of an individual to access a record of personal health information about the individual that is in the custody or under the control of a health information custodian includes the right to have the health information custodian provide the record to the individual in,

- (a) an electronic format specified by the Agency-and posted on the Agency's website;¹³ or
- (b) any other electronic format that is agreed to by the health information custodian and the individual.

(2) For greater certainty, subsection (1) may be used to <u>authorizerequire</u> the provision of a record of personal health information through a secure online application, such as a portal.

(3) The Agency shall make the electronic format referred to in clause (1) (a) available to the public by posting it on the Agency's website.

(4) The Agency shall ensure that the most up-to-date electronic formats, including any amendments to the formats, are posted in accordance with subsection (3).¹⁴

(5) The Agency shall consult, in a manner the Agency considers appropriate, with any health care provider organizations, individuals, stakeholders and other parties that the Agency considers appropriate, in order to inform its decisions concerning the specification or amendment of the electronic format referred to in clause (1) (a).

(6) Where the Agency is specifying or amending the electronic format referred to in clause (1) (a), the Agency shall,

- (a) make the proposed electronic format available to the public by posting it on the Agency's website and allow at least 30 days for members of the public to make recommendations;
- (b) consult with the Commissioner, in a manner the Agency and the Commissioner mutually consider appropriate in the circumstances; and
- (c) consider the recommendations, if any, made by the public and the Commissioner before providing the electronic format to the Minister for approval.

(3)(7) The Agency shall obtain the approval of the Minister before specifying or amending¹⁵ the electronic format under clause (1) (a).

¹³ We suggest that "and posted on the Agency's website" be replaced by a separate subsection to be consistent with s. 29(1) of O. Reg. 329/04.

¹⁴ We suggest the addition of this subsection to be consistent with s. 29(2) of O. Reg. 329/04.

¹⁵ We suggest this addition to be consistent with s. 27(1) of O. Reg. 329/04.

(4)(8) The Minister may direct the Agency to specify or amend the electronic format referred to in clause (1) (a).

(5)(9) If the Minister issues a direction to the Agency under subsection (4)(8), the Agency shall comply with that direction.

Commencement

2. [Commencement]