ONTARIO PHARMACISTS ASSOCIATION

July 22, 2020

Digital Health Division
1075 Bay Street, 12th Floor
Toronto, ON M5S 2B1

To whom it may concern;

RE: proposed changes to O. Reg. 329/04 under the *Personal Health Information Protection Act, 2004*

On behalf of the broader membership of the Ontario Pharmacists Association ('OPA', the 'Association') comprising 10,000 pharmacy professionals as well as the members of OPA's eHealth and Professional Pharmacy Management Systems Task Force ('Task Force'), we are pleased to offer our input and questions toward proposed changes to O. Reg. 329/04 under the *Personal Health Information Protection Act, 2004*.

INTRODUCTION

The proposed regulation would make the following amendments to the PHIPA Regulation:

(1) Establish that Ontario Health shall establish interoperability specifications that pertain to digital health assets, subject to the direction and approval of the Minister.
(2) Establish that health information custodians must ensure that the digital health assets ('DHAs') that they select, develop or use are compliant with applicable interoperability specifications.
(3) Require Ontario Health to establish a certification process by which a list of digital health assets that are compliant with specifications may be published.
(4) Require health information custodians to provide Ontario Health with reports upon request, and to cooperate and assist the Agency to support compliance monitoring.
(5) Require Ontario Health to establish a compliance monitoring process.
(6) Establish that enforcement of the regulation would occur by means of complaint to the Information and Privacy Commissioner, supported by any reports or information collected in the process of compliance monitoring.

FEEDBACK ON THE PROPOSED AMENDMENTS

For purposes of brevity, we are restricting our responses to those areas where we have specific comments, recommendations or questions.

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(1) Establish that Ontario Health shall establish interoperability specifications that pertain to digital health assets, subject to the direction and approval of the Minister

According to the Digital Health Information Exchange Policy, it is understood that "*by the effective date [of October 1, 2020], Ontario Health will have designed and implemented a program to establish interoperability specifications*" and that *"this program would include implementation requirements for [health information custodians ('HICs')] and digital health product vendors to ensure compliance with the regulation and policy is attained* (page 5)". OPA contends that it is very difficult to provide commentary and input on specifications that have not yet been identified and defined. Consequently, we are unable to respond on the regulatory impact of said specifications.

Therefore, the Association recommends the following as it relates to posting of interoperability specifications for digital health assets to be used by a rapidly evolving pharmacy profession:

a) that HICs (pharmacy owners and pharmacy professionals), pharmacy software vendors ('PSVs') and OPA's Task Force be given advance notice of the proposed specifications prior to posting; and
b) that HICs, PSVs and the Task Force be consulted and offered an opportunity to provide feedback on the proposed specifications prior to their finalization and eventual posting on or before October 1, 2020.

(2) Establish that health information custodians must ensure that the digital health assets that they select, develop or use are compliant with applicable interoperability specifications

The Ontario Pharmacists Association supports this concept but requests that further clarity be provided that specifies timelines for compliance. Notably, OPA recommends that HICs and PSVs be given sufficient lead time (e.g., not less than 12 months) to facilitate the necessary internal system modifications for existing DHAs to become compliant with the finalized specifications.

It will also be important for Ontario Health ('OH') to ensure that mechanisms are in place for appropriate version controls to the specification document. This would include provision of a 12-month minimum window of time for HICs and PSVs to modify their DSAs (if needed) in the event of OH updates to posted specifications.

(3) Require Ontario Health to establish a certification process by which a list of digital health assets that are compliant with specifications may be published.

In the absence of a defined process, OPA recommends that a set of guiding principles be established in advance to ensure that DHAs currently in use by pharmacies are neither disadvantaged by any delays in becoming certified by OH nor disabled while going through the certification process in a manner that disrupts the delivery and provision of patient care services.

OPA would also like to inquire if OH will be the only certifying body for DHAs in the marketplace. In the rapidly evolving profession of pharmacy, coupled with the exponential development of new DHAs given the need to shift to more virtual care on account of COVID-19, it is the opinion of OPA that the sheer volume of certifications to be performed may overwhelm OH and lead to long delays in DHA implementation.

(4) Require health information custodians to provide Ontario Health with reports upon request, and to cooperate and assist the Agency to support compliance monitoring.

and

(5) Require Ontario Health to establish a compliance monitoring process.

OPA, its members and the Task Force understand the need for ongoing compliance monitoring against the interoperability specifications, but since they are yet to be developed and published, it is impossible at this time to generically support an immediate, "upon-request" monitoring policy with no timelines attached. Therefore, and acknowledging and respecting the individual workflows of HICs and PSVs, OPA recommends that Ontario Health provide HICs and PSVs with a 30-day window from the date of request for any reports to be generated and 90-days for requests that are more in-depth for purposes of compliance monitoring.

(6) Establish that enforcement of the regulation would occur by means of complaint to the Information and Privacy Commissioner, supported by any reports or information collected in the process of compliance monitoring.

OPA has no additional commentary or questions in this regard.

GENERAL COMMENTARY

The Ontario Pharmacists Association fundamentally supports the Ministry of Health in its desire to establish a solid foundation upon which relevant health information can be shared and exchanged within the patient's circle of care. Interoperability is the key, both from the provider-to-provider perspective as well as between providers and patients. Looking at lessons learned from past years, patients expect that pharmacy professionals – as health information custodians – need to be integrated into these interoperable systems right from the start, rather than being viewed as a "phased-in" stakeholder for inclusion much later on in the process. This is particularly true now with the rapidly evolving role of pharmacists under an expanded scope of practice.

Over the past several years, the relationship and degree of collaboration between the pharmacy profession and eHealth Ontario have grown significantly, brought about through a combination of direct bi-directional communications between government and OPA's Task Force as well as one-to-one dialogues between government and individual PSVs. These interactions have enabled a greater likelihood of achieving a model and approach that respects the unique nature of Ontario pharmacy practice.

We remain optimistic in the ongoing development of the Digital Health Drug Repository and are encouraged by the options provided to PSV to facilitate connectivity. Ultimately, this will lead to even more important clinical information to be added into and shared across the system. There is still much work to be done in this regard, such as the addition of new clinical fields that are relevant to pharmacy and important to be shared in a truly interoperable system. connect to feed additional information into that system. As such, and notwithstanding challenges related to COVID-19, we at the Ontario Pharmacists Association and our Task Force are eager to resume our collaborative discussions with eHealth Ontario and other relevant stakeholders.

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CONCLUSION

Once again, the Ontario Pharmacists Association appreciates the opportunity to comment on the proposed amendments to O. Reg. 329/04 under *PHIPA, 2004* and to support efforts to ensure interoperability specifications are in place for the use and application of digital health assets in the provision of patient care activities.

We would graciously like to offer our availability for a meeting between yourselves and OPA's eHealth and Professional Pharmacy Management System Task Force to discuss these matters, and many others, at your earliest convenience. In the interim, should you have any questions or comments on this submission, please do not hesitate to contact the undersigned by telephone at 416-949-0788 or by email at amalek@opatoday.com.

Yours sincerely,

Allan H. Malek
Executive VP and Chief Pharmacy Officer

cc: Deb Saltmarche, Chair, OPA eHealth and Professional Pharmacy Management System Task Force
Justin Bates, Chief Executive Officer, Ontario Pharmacists Association