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HEALTH SCIENCES & TECHNOLOGIES

Health Canada's approach to the COVID-19 pandemic, amendments to Ontario's health information legislation

FOREWORD

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THE COVID-19 PANDEMIC has been a highly disruptive event for all industries in Canada, but perhaps none has been hit more dramatically than health care. Medical professionals, institutions and suppliers have been expected to react at breakneck speed in a time of crisis.

Luckily, with more attention comes more support. Governments across Canada have stepped up to fast track the execution of public health initiatives by amending the regulatory environment and injecting money into key health care priorities. Health tech innovators have also stepped up, collaborating with competitors and retooling to prioritize urgent requirements.

As Sara Zborovski and Ian Trimble at Stikeman Elliott LLP outline in this special report on health sciences and technologies, Health Canada has implemented measures through the Food and Drugs Act that facilitate faster access to new categories of medical devices, drugs and foods amid the COVID-19 pandemic.

These measures allow the minister of health to make an interim order when they believe immediate action is required to deal with a significant risk to health, safety or the environment. The recent interim orders outlined in this report include those that help facilitate the importation and sale of medical devices; the production of drugs, medical devices and foods for a special dietary purpose; and help with clinical trials for medical devices and drugs, all in relation to COVID-19.

At the time of writing, 131 medical devices and 38 drugs, 45 clinical trials for COVID-19 drugs, including vaccines, and six clinical trials for COVID-19 medical devices have been authorized by Health Canada under the new rules.

While these streamlined processes will help our health care sector manage the moving target presented by COVID-19, moving too fast is not without risks.

As Charles S. Morgan and Daniel Glover from McCarthy Tétrault LLP outline, the Ontario government has recently amended its health information legislation to bring new obligations and penalties.

While these streamlined processes will help our health care sector manage the moving target presented by COVID-19, moving too fast is not without risks.

As these lawyers outline, several of these changes have important implications for those in the health care industry and businesses that collect personal health information.

The legislation grants new powers for the province's privacy commissioner; introduces higher penalties for offences under the Personal Health Information Protection Act; creates new obligations to maintain an electronic audit log; introduces the concept of "consumer electronic service providers"; and introduces the ability to impose requirements related to information de-identification.

While these changes were introduced in March, just as the COVID-19 crisis hit Canada, they serve as a reminder for those operating in the health care sector that innovation and progress cannot come at the expense of fundamental rights. In other words, governments are not ignoring the privacy rights of Canadians even in times of crisis.

The health care sector faces a daunting task in managing a pandemic that will likely be with us for many months, if not years. A sound understanding of the regulatory landscape — both how it looks now and as it will evolve — must be a key priority for the sector and those who support it. With this knowledge, this sector will be well positioned to deliver health services to the public in these unprecedented times.

Health Canada's approach to the COVID-19 pandemic

Amid the COVID-19 pandemic, Health Canada implemented measures through the Food and Drugs Act that facilitate faster access to new categories of medical devices, drugs and foods

AS THE GLOBAL pandemic hit, Health Canada launched an expedited review and approval pathway to bring COVID-19-related products to the Canadian market. This includes both the approval of products that are similar to existing products (preventing critical shortages) and the approval of new products specific to COVID-19.

Pursuant to s. 30.1(1) of the Food and Drugs Act, the minister of health is empowered to make an interim order when they believe immediate action is required to deal with a significant risk to health, safety or the environment. In this article, we outline three interim orders put in place in response to the COVID-19 pandemic, respecting:

1. the importation and sale of medical devices for use in relation to COVID-19;
2. drugs, medical devices and foods for a special dietary purpose in relation to COVID-19; and
3. clinical trials for medical devices and drugs relating to COVID-19.

Sale of medical devices

On March 18, the federal minister of health approved the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, providing an expedited pathway to approval for the importation and sale of medical devices. This order enables Health Canada to expedite the review of submissions and applications for medical devices used to diagnose, treat, mitigate or prevent COVID-19, thus providing Canadians with increased access to novel investigational treatments, once available.

This order also provides:

- expedited market access to COVID-19-related diagnostic laboratory test kits and other marketed COVID-19-related medical devices, and
- manufacturers with the ability to submit test kits and related medical devices through an expedited approval process.

To date, several diagnostic tests have been approved through this mechanism.

Medical devices used in relation to COVID-19 include ventilators; testing devices; sterilizing devices; continuous or remote monitoring devices used to reduce direct patient interaction; and personal protective equipment (PPE) such as medical masks, N95 respirators, gloves and gowns. The order provides an expedited authorization pathway that is available for new medical devices that are not yet licensed in Canada or other jurisdictions, existing approved medical devices whose intended use was not originally COVID-19-related and COVID-19

medical devices that have received approval from a trusted foreign regulatory authority.

Additionally, Health Canada is expediting the review and issuance of Medical Device Establishment Licenses for companies that require them for COVID-19-related devices. The Special Access Program remains available prior to approval and allows doctors to gain access to drugs and medical devices that have not yet been licensed.

Supplies that may slow the spread of COVID-19

Health Canada has implemented an interim measure allowing for expedited market access to certain products. Subject to certain notification requirements, products including hand sanitizers, disinfectants, PPE and medical swabs can be sold in Canada under the interim measure despite not fully meeting regulatory requirements such as labelling, licensing or packaging.

At this time, 490 hard surface disinfectants and hand sanitizers have been authorized for sale under this interim measure.

Exceptional importation pathway to address COVID-19-related shortages

On March 30, the federal minister of health approved the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19, which provides an exceptional importation pathway to prevent and alleviate critical supply issues as a result of the pandemic. This order allows for the exceptional importation and sale of:

- drugs (including hard surface disinfectants and hand sanitizers);
- medical devices (including PPE); and
- foods for special dietary purposes (such as infant formulas) to address anticipated or existing shortages related directly or indirectly to COVID-19.

Manufacturers and importers must apply to obtain approval from Health Canada and have an MDEL or Medical Device Licence (MDL) before being authorized to use the exceptional importation and sale pathway. Subject to notification requirements, products governed by this order may be imported and sold in Canada despite not fully complying with Canadian regulatory requirements, provided they were manufactured according to comparable standards as those required for Canadian-approved products. Up-to-date lists of the drugs, medical devices and foods for special dietary purposes eligible for this exceptional importation pathway are available on the Health Canada website.

At this time, 131 medical devices and 38 drugs have been authorized by Health Canada under the exceptional importation pathway.

This order also introduced a mandatory requirement for manufacturers of medical devices critical during the COVID-19 pandemic to notify the minister of health of anticipated or existing shortages within five days of becoming aware of such shortages. This helps inform the minister of which products to allow through the exceptional importation pathway.

Clinical trials for COVID-19-related medical devices and drugs

On May 23, the federal minister of health approved the Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19, creating an expedited pathway to prioritize reviews and approval for COVID-19 clinical trial applications for pharmaceutical and biologic drugs, as well as medical devices. This order is intended to facilitate the conduct of clinical trials relating to the diagnosis, treatment, mitigation or prevention of COVID-19 while ensuring participants' protection and valid trial results.

This order is intended to:

- reduce certain administrative requirements;
- allow alternate means of obtaining patient consent in light of COVID-19 realities;
- allow a wider range of health professionals (such as nurse practitioners) to be involved in running clinical trials;
- broaden the criteria for qualified health professionals who can carry out qualified investigator duties at remote sites; and
- expand the range of applicants who are can apply for a medical device clinical trial authorization.

Forty-five clinical trials for COVID-19 drugs, including vaccines, and six clinical trials for COVID-19 medical devices have been authorized by Health Canada, either under the regular authorization process or the Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19.

Duration of expedited pathways created via interim orders

All three aforementioned interim orders have been approved by the Governor General in Council and will remain in force until the earliest of (i) the day on which the interim order is repealed; (ii) the day on which regulations having the same effect come into force; or (iii) one year after the day on which the interim order is made.

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Amendments made to Ontario's health information legislation

New powers for the province's privacy commissioner and higher penalties for offences under PHIPA are among the changes

ON MARCH 25, a new law passed by the Ontario legislature made significant amendments to the province's personal health information legislation, the Personal Health Information Protection Act ("PHIPA"). Several changes have important implications for those in the health care industry and businesses that collect personal health information ("PHI"). Among these changes are:

- new powers for the province's privacy commissioner;
- higher penalties for offences under PHIPA;
- new obligations to maintain an electronic audit log;
- introduction of the concept of "consumer electronic service providers"; and
- the ability to impose requirements related to information de-identification.

Most amendments are in force as of March 25, 2020, while a few amendments will come into force on a later date to be declared by the government.

1. New powers for privacy commissioner

Ontario's privacy regulator, the Office of the Information and Privacy Commissioner (the "IPC"), gained new powers as part of the amendments:

- Section 61 of PHIPA is amended and s. 61.1 is introduced to provide the IPC with authority to order a person to pay an administrative penalty if they have contravened PHIPA. The purpose of the penalty is to encourage compliance with PHIPA and to prevent a person from deriving, directly or indirectly, any economic benefit by contravening PHIPA or any of its regulations. The amount of the administrative penalty should reflect these purposes and is determined by the IPC, subject to the regulations.
- Other amendments to s. 61 of PHIPA provide the IPC with the power to make an order requiring a health information custodian ("HICs") or a class of HICs to cease providing PHI to a "consumer electronic service provider." This is a new concept that is discussed further in this blog.

With these amendments, the IPC has additional enforcement powers. The administrative penalty is a new power that did not exist previously in PHIPA. Once regulations are introduced, this provision will be another tool for the IPC in its enforcement toolkit.

2. Higher penalties for offences

Penalties for offences also increased with amendments to s. 72(2) of PHIPA:

a) fines for an individual found guilty of an offence doubled to $200,000 from a maximum of $100,000;
b) fines for an organization found guilty of an offence doubled to $1 million from a maximum of $500,000; and
c) individuals found guilty of an offence may now also face imprisonment of up to a year.

3. Electronic audit log

The amendments add a new obligation for HICs under a new s. 10.1 to PHIPA (which is not yet in force at the time of publication), whereby HICs that use electronic means to collect, use or disclose PHI will be required to maintain an electronic audit log that records the viewing, handling and modification of PHI. HICs will also be required to audit and monitor the electronic audit log. The IPC will have the power to order production of electronic audit logs from HICs.

The new section mandates that the electronic audit log must contain sufficient amounts of information about the record, including recording when and by whom a record was created and altered and every time that a record was viewed. For every instance in which a record or part of a record of PHI that is accessible by electronic means is viewed,

handled, modified or otherwise dealt with, the electronic audit log must document:

a) the type of information that was viewed, handled, modified or otherwise dealt with;
b) the date and time on which the information was viewed, handled, modified or otherwise dealt with;
c) the identity of all persons who viewed, handled, modified or otherwise dealt with the PHI;
d) the identity of the individual to whom the PHI relates; and
e) any other information that may be prescribed.

As enacted, s. 10.1 may present some difficulties to HICs when the provision comes into force and which HICs may need to address prior to the provision coming into force. For instance, HICs will need to ensure that they have sufficient time to implement the technological infrastructure required to maintain electronic audit logs as required under s. 10.1. Notably, the amendments are silent on whether HICs will be allowed to grandfather existing systems or whether HICs will be given a transition period for compliance.

4. 'Consumer electronic service providers'

The amendments introduced a new "consumer electronic service providers" concept under a new s. 54.1 to PHIPA (which is not yet in force at the time of publication).

Section 54.1 of PHIPA defines "consumer electronic service provider" as "a person who provides electronic services to individuals, at their request, primarily for, (a) the purpose of allowing those individuals to access, use, disclose, modify, maintain or otherwise manage their records of PHI or (b) such other purposes as may be prescribed under regulation." Potential examples of such consumer electronic service providers could include entities that provide services related to the processing of PHI to individuals through their mobile apps, online portals or event smart devices providers.

With this amendment, the Ontario government will recognize a new category of organizations that are subject to legal compliance obligations, which are distinct and separate from the obligations applicable to HICs, under PHIPA. However, at the time of publication, the Ontario government has not provided any draft regulations or any other indications as to what the applicable obligations will be for consumer electronic service providers under PHIPA. The obligations applicable to consumer electronic service providers, therefore, remain to be seen.

5. Requirements for de-identification and re-identification

The amendments will change the definition of "de-identify" under s. 2 of PHIPA (which is not yet in force at the time of publication) such that the Ontario government can prescribe, via regulations, requirements and standards for the de-identification of PHI. The change to "de-identify" will affect a number of provisions in PHIPA that mandate the de-identification of PHI. No draft regulations have been made at the time of publication, so the requirements for de-identification under PHIPA remain to be seen. These provisions complement re-identification provisions in s. 11.2 of PHIPA that were passed in 2019 but are not yet in force. Those provisions prohibit attempts to re-identify information that has been previously de-identified, except for a limited class of persons including HICs and prescribed entities.

Key takeaways

The Ontario government introduced a number of key amendments in its latest amendment to PHIPA on March 25. Among these, new enforcement and inspection powers are added to existing powers of the IPC. Other amendments bring more severe penalties, new obligations to keep electronic audit logs, as well as the introduction of the new concept of the "consumer electronic service provider" and possible regulations setting out standards for de-identification.

For more information about PHIPA or any other Canadian privacy laws, please contact the authors and visit the McCarthy Tétrault Cybersecurity, Privacy & Data Management group page.

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