

COVID-19 expands health industry to all sectors

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In a year defined by unpredictability and constant change, the COVID-19 global pandemic has pushed health regulatory matters to the forefront of all sectors and industries. Factors such as provincial states of emergency, increased adoption of digital health technologies, a heightened recognition of responsibility for the health and safety of employees and clients, worldwide shortages of personal protective equipment (PPE) and unprecedented initiatives from Health Canada in the form of temporary federal orders have all forced traditional health industry participants to adapt to a continually changing and uncertain environment. Businesses operating outside of the health industry have also been required to seek highly specialized health regulatory advice in response to the impact that the pandemic has had on their operations and business.

Emergency orders and directives: understanding and adapting to constantly changing restrictions

Businesses in all sectors have had to understand and adjust to emergency orders issued under various provincial emergency legislation as a result of states of emergency or states of public health emergency in all jurisdictions of Canada, such as the *[Emergency Management and Civil Protection Act](#)* and the *[Reopening Ontario \(A Flexible Response to COVID-19\) Act, 2020](#)* in Ontario and similar emergency legislation in other provinces. As the pandemic continues, states of emergency and public health emergency have been resolved, and provincial and municipal governments have implemented various other legislative measures and public health guidance to address the ongoing effects of the pandemic, including, most recently, more restrictive lockdown measures in areas of greatest risk.

Understanding the effects and application of the legislation and orders, as well as the recommendations and requirements of applicable federal, provincial and municipal authorities, has been a necessary priority for businesses in 2020 in connection with businesses closing, re-opening, and now in many jurisdictions, closing again. In the process, businesses have had to adapt to the need to adopt cleaning protocols and procedures, as well as other protective measures, such as screening, physical distancing requirements, capacity limits, reducing unnecessary gatherings, face coverings, PPE and safety plans. Guidance from public health authorities continues to evolve as more information becomes known about the COVID-19 virus.

In the more traditional health industry context, health services providers such as hospitals, long-term care facilities and retirement homes were faced with navigating unprecedented developments arising from emergency legislation, such as extraordinary work deployment

powers. In Ontario, for example, the extraordinary work deployment measures include authorizing health services providers to take, with respect to work deployment and staffing, “any reasonable necessary measures to respond to, prevent and alleviate the outbreak of COVID-19.” These powers include, but are not limited to, the authority to, among other things, (a) redeploy staff within different locations in (or between) facilities of the particular health service provider; (b) redeploy staff to work in COVID-19 assessment centres; (c) defer or cancel vacations, absences or other leaves, regardless of whether such vacations, absences or leaves are established by statute, regulation, agreement or otherwise; (d) change shifts and schedules; and (e) employ extra part-time or temporary staff or contractors or volunteers, including for the purposes of performing bargaining unit work.

This has raised considerations relating to healthcare providers’ unique status under occupational health and safety legislation and concerns relating to the reasonable protection of frontline health workers in the rapidly evolving circumstances of the COVID-19 pandemic. This has also highlighted limitations on workers’ rights to refuse work when (a) the circumstance is inherent in the worker’s work or is a normal condition of the worker’s employment, or (b) the worker’s refusal to work would directly endanger the life, health or safety of another person.

Interpreting how various governments’ COVID-19 funding response measures can be applied has also been a challenge for many health industry participants. For example, it has been difficult to assess whether and how Canada Emergency Response Benefit (CERB) payments and temporary pandemic pay could be relied upon within complex employment relationships and arrangements in the hospital context.

Acceleration of digital healthcare delivery

Over the past several years, we have seen an increased emergence of digital healthcare providers across a variety of health industry participants, including, for example, virtual care platforms to facilitate services provided by physicians, nurse practitioners, mental health providers and pharmacies, among others. The COVID-19 pandemic rapidly accelerated the adoption of healthcare delivery through technological and digital means in order to address the limitations of the physical healthcare system infrastructure and its dependence on in-person interactions. While we do not consider digital healthcare delivery to be a 2020 phenomenon, the dramatic accelerated rate of growth in this area, as well as the pace at which it is now being accepted and funded by governments, has significantly increased in part as a response to the COVID-19 pandemic. We anticipate this trend will continue, even after the pandemic is over.

Responding to worldwide shortages of PPE and new COVID-19 testing devices

Generally, the COVID-19 pandemic has elevated the importance of employee occupational health and safety for all businesses and materially increased the risk profile for employers. In particular, the unprecedented worldwide surge in demand for PPE created a number of challenges for those conducting business both within and outside of the health industry. Health industry participants have been facing well-documented challenges in securing adequate PPE stock to protect frontline staff. This has resulted in extraordinary government responses, including new temporary federal orders such as the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19 under the *Food and Drugs Act* (the Interim Order).

Due to the overwhelming demand for PPE as the pandemic took hold, provincial

governments began looking to non-traditional manufacturers to produce, reprocess and distribute PPE. For example, governments requested that luxury clothing manufacturers reprocess expired N-95 masks and with a significant shortage of alcohol-based hand sanitizers, liquor distillers began to manufacture hand sanitizers. The industry expanded dramatically as more participants became focused on the production, reprocessing, distribution and supply of PPE. New market participants also became engaged in the development of new COVID-19 testing devices for benevolent and/or financially motivated reasons.

In seeking to get their products to market quickly, these new health industry participants were faced with navigating complex technical and regulatory requirements to obtain Health Canada authorization to manufacture, import and sell regulated Class I (N95 respirators, medical gowns, face shields and medical goggles) and Class II (medical gloves) medical devices and COVID-19 testing devices under the *Medical Devices Regulations* to the *Food and Drugs Act*. The Interim Order created a new streamlined application process, permitting more participants to obtain Health Canada authorization more rapidly.

The PPE shortages have been also exacerbated by supply chain disruptions and rampant fraudulent activity. Unsurprisingly, the PPE supply chain challenges also led businesses to pursue new supply channels and networks, with many industry participants seeking to rely upon *force majeure* provisions in supply contracts.

Return to work strategies: industry-initiated COVID-19 testing

In addition to employee screening and monitoring, employers in a wide variety of industries have implemented private COVID-19 testing for their employees and workers as one of the measures to assist in maintaining or resuming operations.

Privately coordinated COVID-19 testing raises a myriad of issues. In Canada, paying privately for medically necessary insured services raises issues under the *Canada Health Act*. Other relevant concerns include restrictions regarding the training and qualifications needed to administer COVID-19 tests (which may differ depending on the jurisdiction); medical device regulations governing the testing equipment; considerations around the controlled act of communicating a diagnosis to a patient (which typically may only be performed by a physician or other qualified regulated health professional in each jurisdiction); obtaining appropriate consent to report positive COVID-19 test results to anyone other than the person taking the test; and ensuring that positive COVID-19 test results are reported to the applicable public health authority for contact tracing. It is also necessary to navigate privacy rules relating to personal health information in connection with industry-initiated COVID-19 testing.

Planning for worst-case scenarios

In the early days of the COVID-19 pandemic, the Canadian health industry was consumed by fear that Canadian hospitals would be overwhelmed by demand and face similar tragic circumstances to those experienced in other countries and cities worldwide. In response to these fears, we witnessed the business community entering the health industry in an effort to help to fill infrastructure gaps that could arise if the number of COVID-19 cases in Canada reached unmanageable levels.

Many new and unique arrangements were implemented for a variety of purposes. These included (a) the creation of spaces where healthcare workers who contracted or were at high risk of contracting COVID-19 could isolate from their families and continue to attend work; (b)

the establishment of field hospitals to address the potential overwhelming overflow of patients; and (c) the creation of additional temporary morgue space if the death rates became high.

Looking forward to 2021 and beyond

The above examples are just a small sampling of the unique and highly complex work within the health industry that COVID-19 has created for traditional health industry participants and the business community more generally. We believe that the COVID-19 pandemic has created a significant shift, not only in the way that healthcare is delivered in Canada, but also in the way that all businesses think about their operational risks, bringing a health lens to every industry. We anticipate that 2021 will usher in a variety of new challenges and considerations – as well as opportunities – that will require complex health regulatory advice as the COVID-19 pandemic continues.