HEALTH LAW IN CANADA

Institute of Health Policy, Management and Evaluation
UNIVERSITY OF TORONTO

VOLUME 43, NUMBER 3 LexisNexis® FEBRUARY 2023

IN THIS ISSUE

Editorial

Dear readers,

For our first edition of 2023, we include reprinted articles about the proposed national dental care program, which offers coverage to low-income families; about legal challenges to the amended patented medicines regulations which ultimately can affect the availability and cost of our prescription drugs; and about the continued use of virtual care with an examination of variances in regulation across Canada. We extend our thanks to the authors and law firms that accepted our requests to reprint.

While these articles review important current legal and policy issues in Canadian health care, many pressing concerns are not addressed, including:

- the lack of adequate access to family physicians
- medical assistance in dying based solely on mental illness
- the continuing opioid use crisis; and
- federal standards for long-term care.

And the amounts of the federal health transfer each province and territory will receive under the *Canada Health Act* are currently under negotiation. The provinces and territories want more funding, as usual, but is this the panacea for our health care woes? While more money will definitely help, creative use of funding is crucial. With input from the users of our system — from patients, their families and caregivers — and from front-line health care providers in the various sectors of health care (acute care, emergency services, community and home care, and primary care, to name a few) along with cross-sector collaboration (between health and social services and/or the justice system), perhaps we could create programs and services that ease the unrelenting strain on our health care system.

One recent example of innovative collaboration in Toronto is illustrative. The University Health Network (a network of three teaching hospitals in downtown Toronto), together with its community and municipal partners, created a stabilization and connection site for homeless individuals intoxicated by alcohol.[1] Instead of taking these individuals to hospital to recover, paramedics can take them to the new non-hospital site (staffed by harm reduction, peer support and case workers, with a physician on call) where they can recover and receive follow-up with coordination of social supports.[2] This can reduce the

amount of time paramedics spend in transferring incoming patients to hospital, allowing them to respond to other calls and can decrease the burden on the hospital emergency department, while ensuring that these vulnerable patients receive appropriate care. This is but one example of innovative collaboration that can, and so far, based on early results, is reducing strain on one city's hospital and paramedic resources.[3]

We need more of this innovation, and we know it is occurring across Canada. Please let us know about your successful health care collaboration. If you wish to submit an article, please see our author submission requirements at <https://www.lexisnexis.ca/en-ca/products/health-law-in-canada-journal.page>). Our contact information remains the same <hlcjsubmissions@gmail.com>. We look forward to hearing from you.

Editorially yours,
Simmie Palter
Deputy Editor-in-Chief

---

1. *CTV News*, Toronto, accessed January 18, 2023 at <https://toronto.ctvnews.ca/mobile/new-hospital-program-helps-toronto-s-homeless-cuts-ambulance-offload-time-1.6209499?cache=/7.515546?autoPlay=true>.
2. *Ibid*.
3. *Ibid*.

Patented Medicines Regulations: The Problem is Not in Collecting the Data, but in How You Use It!

Melanie Szweras and Chantalle Briggs

Abstract

The Federal Court of Appeal recently heard a constitutional challenge to the new Patented Medicines Regulations that came into force on July 1, 2022. Several appellants, including Innovative Medicines Canada, challenged the validity of the new list of comparator countries used by the Patented Medicines Price Review Board ("PMPRB") in its price calculations to combat excessive prices on patented medicines. They alleged that the government was pursuing the purpose of setting reasonable prices of patented medicines generally, rather than specifically policing excessive pricing in accordance with excessive price provisions of the *Patent Act*. However, the court accepted the Government's argument that the list of comparator countries was updated to modernize the tools available to the PMPRB. Changing the list of comparator countries only changes the pricing information collected; if the PMPRB were to improperly set reasonable prices generally, this would amount to a misuse of the information collected.

2022 has seen several big changes to the Patented Medicines Regulations under the *Patent Act*, which came into force on July 1st. These changes have already resulted in significant contention, both in terms of the practice guidelines issued by the Patented Medicines Price Review Board ("PMPRB") which were intended to reflect the new Regulations,[1] as well as in terms of successful constitutional challenges to the new Regulations in Federal[2] and Quebec[3] courts. It was recently the turn of the Federal Court of Appeal ("FCA") to consider whether provisions in the new Regulations are constitutional, by also considering the PMPRB's mandate to combat excessive prices on patented medicines.

The Issue

This decision[4] is an appeal of the earlier constitutional challenge at the Federal Court. At the previous judicial review, several parties including Innovative Medicines Canada (the appellants), challenged the validity of several provisions of the new Regulations, including the new list of comparator countries used by the PMPRB in its price calculations.

The Federal Court determined that this aspect of the new Regulations is constitutional.[5]

The appeal originally challenged three determinations made by the Federal Court, but the Government dropped the other two proposed amendments

to the Regulations. At the time of this decision, the only issue before the FCA was whether the changes to the list of comparator countries are constitutionally valid, as deemed by the Federal Court. The changes to the list of comparator countries are illustrated in Table 1, below, wherein countries removed from the list are shown with ~~strikethrough~~ and countries added to the list are shown in **bold**.

Table 1: Comparator Countries

In Force from March 6, 2008 to June 30, 2022	In Force as of July 1, 2022
France	**Australia**
Germany	**Belgium**
Italy	France
Sweden	Germany
~~Switzerland~~	Italy
United Kingdom	**Japan**
~~United States~~	**Netherlands**
	Norway
	Spain
	Sweden
	United Kingdom

The Arguments

The appellants argued that the Government acted unreasonably when making these changes by selecting certain countries to advance an agenda or a purpose contrary to the purpose of the excessive price provisions of the *Patent Act* and of the Act itself. Specifically, they alleged that the Government was "improperly pursuing the purpose of regulating or controlling prices or setting reasonable prices" in general (para. 17), rather than policing excessive pricing stemming from the abuse of a patent monopoly. In support of this, the appellants presented, among other things, a letter from the Minister of Health which speaks of lowering high drug prices, improving affordability and accessibility of drugs, and modernizing the PMPRB's regulatory framework.

The Government argued that the changes to the list of comparator countries were undertaken to modernize the tools the PMPRB uses to detect excessive pricing. The list had not been changed since 1994, and the Government argued that the markets had changed in the intervening period causing the list to become dated. The Government stated that for the new list, it selected the 11 countries most comparable to Canada according to the following factors:

i. their measures to constrain free-market pricing,
ii. their economic standing, and
iii. their market characteristics.

With respect to the United States and Switzerland, which were removed from the list, the Government argued that unlike Canada, these countries do not have measures regulating free-market pricing of patented drugs, and therefore were bad comparators.

The Outcome

The FCA agreed with the Federal Court and determined that the changes to the list of comparator countries are constitutional.

The FCA relied on its recent analysis from *Alexion Pharmaceuticals Inc. v. Canada* ("*Alexion*"), which also dealt with the purpose of the excessive price provisions of the Act and of the Act itself, as we previously reported.[6] The FCA stated at para. 49 in *Alexion*[7] that "[o]ver and over again, authorities have stressed that the excessive pricing provisions in the *Patent Act* are directed at controlling patent abuse, not reasonable pricing, price-regulation or consumer protection at large". While the FCA reaffirmed this purpose of excessive pricing provisions of the Act at para. 19 of the present decision, the FCA did not agree with the appellants that the changes to the list of comparators were made for, or had the effect of, regulating prices generally.

Rather, the FCA agreed with the reasoning of the Federal Court, which determined that "the sin is not in the gathering of information; if a sin is committed, it will be later when the information is improperly used" (para. 24). The court stated that the changes to the list of comparator countries amounted only to a change in the pricing information collected. The collection of this information helps the PMPRB to determine whether the price of a patented medicine is excessive. **The court cautioned that if, however,**

the Board uses this information to regulate or control prices or to set reasonable prices generally, rather than to police excessive pricing specifically, then a judicial review of those specific PMPRB decisions may be warranted.

The FCA also agreed with the Federal Court in determining that the Government acted reasonably in making these changes to the list of comparator countries. In response to the evidence presented by the appellants, the court noted that a natural consequence of effectively dealing with excessive pricing is to reduce the overall cost of medicines, and thus an overall cost savings resulting from the amendments does not necessarily mean that these savings are the substance of the changes.

As stated by the court, motive, policy, and politics behind a regulation should not be confused with the regulation's substance.

[**Melanie Szweras** is a partner with Bereskin & Parr LLP in Toronto and member of the Life Sciences practice group. She is also co-leader of the Privacy/Regulatory, Advertising and Marketing practice group. Melanie's practice focuses on drafting and prosecution of applications relating to biologics, diagnostics, biotechnology, food, and pharmaceuticals. She can be reached at <mszweras@bereskinparr.com> or 416.957.1678.]

[**Chantalle Briggs** is an associate with Bereskin & Parr LLP in Toronto. Her practice focuses on life sciences and medical device matters, including patents and related regulatory issues under the Food and Drugs Act. Chantalle is currently on the Executive of the Canadian Bar Association's Health Law Section as a Member-at-Large. She can be reached at <cbriggs@bereskinparr.com> or 289.326.4763.]

1. We previously reported on these guidelines at <https://www.bereskinparr.com/doc/pmprb-regulations-saga-coming-to-an-end-new-draft-guidelines-issued>.
2. <https://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/481803/index.do>.
3. <https://www.canlii.org/fr/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?resultIndex=1>.
4. <https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/521063/index.do>.
5. *Supra*, note 2.
6. <https://bereskinparr.com/doc/canadian-drug-price-review-board-reined-in>.
7. <https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do>.

Canada's Proposed Dental Care Program

Lynne Golding, Laurie M. Turner and Rachel Hung

Abstract

The focus of this article is the federal government's national dental care program for low-income families that commenced in December 2022. This article provides a brief history of government funding for dental care in Canada at the federal and provincial level. It also summarizes the information that is available with respect to the new dental program during its first phase (beginning on December 1, 2022, and concluding on June 30, 2023), including the financial eligibility requirements, coverage (*i.e.*, in terms of age (under 12) and covered services (specified dental services)), application process and payment mechanisms. This article also provides an overview of the limited information that has been made publicly available regarding the second phase of the new program, which will begin on July 1, 2023, and conclude on June 30, 2024.

Earlier this year, the federal government released its budget for 2022 (the "2022 Budget").[1] Amongst numerous significant expenditures in the 2022 Budget is the provision for a national dental care program for lower-income families (the "Dental Program").

This article starts by offering a brief history of government funding for dental care in Canada and subsequently, provides an overview of what we know now about the Dental Program, and the uncertainties that still exist.

Background

The Dental Program follows the "Supply and Confidence Agreement" entered into by the Liberal Party of Canada (the current minority government at the federal level) and the New Democratic Party ("NDP") in March 2022. Under that agreement, in exchange for the NDP agreeing to support the Liberal government on confidence and budgetary matters, the Liberals committed to prioritizing a number of actions, including the implementation of a national dental care program (a program for which the NDP has been advocating).[2]

Unlike many physician and hospital services, dental services—other than certain surgical dental procedures performed in hospitals ("Surgical-Dental Services")—are not covered by the *Canada Health Act*.[3] At a high level this means that, unlike most physician and hospital services, the provinces and territories are not required by the *Canada Health Act* to insure (*i.e.*, pay for) dental services other than Surgical-Dental Services in order to receive their complete share of the Canada Health Transfer (being the primary mechanism by which the federal government provides provinces and territories with funding for health care). Though government dental programs do exist, they are available to a limited number of Canadians. By way of example only, the federal government provides funding for a range of dental services to eligible First Nations people and Inuit through its "Non-Insured Health Benefits Program" or "NIHB".[4] At the provincial level, Ontario's Ministry of Health, for example, provides funding for certain dental services rendered to children and youth (under 17 years of age) from low-income families.[5]

Accordingly, and due to the fact that one-third of Canadians do not have private dental insurance, it is estimated that between seven and nine million Canadians are unable to access adequate dental care on account of the cost.[6]

2022 Budget

Through the 2022 Budget, the federal government committed to providing funding of $5.3 billion over five years for the Dental Program, starting with $300 million in the 2022-2023 fiscal year and increasing to $1.7 billion in year five, being the 2026-2027 fiscal year.[7]

While the 2022 Budget provided limited details regarding the implementation of the Dental Program, it did confirm that the program would be restricted to uninsured families with an annual income of less than $90,000, and that families earning below $70,000 annually would not have to make any co-payments.[8] Moreover, the 2022 Budget stated that the funding available through the Dental Program would first be available to eligible individuals under the age of 12 during 2022, and would then be expanded in 2023 to include eligible individuals under the age of 18, seniors, and persons living with a disability, with full implementation by 2025.[9]

Developments Since 2022 Budget

In July, the federal Minister of Health ("Minister") released a "request for information" (the "Dental Program RFI") from the dental industry to support Health Canada's development of the Dental Program. Following the Dental Program RFI, and Health Canada's engagement with provincial and territorial "partners",[10] the federal government introduced legislation on September 20, 2022, to address the first stage of the Dental Care Program. If passed, Bill C-31, the *Cost of Living Relief Act, No. 2 (Targeted Support for Households)* ("Bill C-31"),[11] would enact the *Dental Benefit Act* (the "Act"). Pursuant to the Act, a new "interim" dental benefit plan (the "Dental Benefit") would be established,[12] which would remain in effect until a permanent program is implemented (which the government has committed to doing by 2025[13]). As of the date of this article, Bill C-31 is at second reading in the Senate, having passed third and final reading in the House of Commons on October 27, 2022.

Bill C-31 provides that the Dental Benefit will be available in 2022-2023 to families with an "adjusted income" of under $90,000 per year and who do not have access to dental insurance ("Eligible Families"), in respect of children under the age of 12.[14] More specifically:

- for the purposes of determining the income of Eligible Families, the term "adjusted income" is used by Bill C-31. Bill C-31 provides that this term *generally* has the same meaning as it has in s. 122.6 of Canada's *Income Tax Act*;[15]
- the Dental Benefit will only be available in respect of eligible individuals (during the first period of December 1, 2022 to June 30, 2023 and the second period of July 1, 2023 to June 30, 2024, children under 12) who have received or will receive dental care services (as defined below) during the applicable period and in respect of whom the eligible parent[16] is in receipt of a Canada child benefit on that date;[17]
- the Dental Benefit may be available to persons who are covered by another government program or plan, but only to the extent that the person's dental care services are not (or will not be) fully paid or reimbursed by such program or plan;[18] and
- the Dental Benefit will be a direct, up-front, tax-free payment to Eligible Families who make an application for the Benefit, with the amount of such payment over the two years being dependent on the family's income as follows:

Adjusted Income of Eligible Family	Dental Benefit Payable PER YEAR
Below $70,000	$650 for each eligible child
Between $70,000 and $79,999	$390 for each eligible child
Between $80,000 and $89,999	$260 for each eligible child

The Dental Benefit will be applied for through the Canada Revenue Agency. As part of the application, applicants will need to attest that the person in respect of whom the application is made:

- does not have access to private dental coverage (*i.e.*, coverage for dental care services under a contract of insurance, whether obtained on the basis of employment, purchased privately or otherwise); and
- has received dental care services during the relevant period to which the Dental Benefit applies or, that the applicant intends for such person to receive dental care services during such period.[19]

As noted above, the Dental Benefit will be paid directly to Eligible Families who apply for same and will not necessarily be paid on a reimbursement basis. While an applicant may apply for the Dental Benefit in respect of past dental care services (such that the Dental Benefit could be used as reimbursement for costs already incurred), an application may also be made in respect of future dental care services. However, in either event, Eligible Families who have received the Dental Benefit will be required to provide documentation (*e.g.*, receipts) evidencing their proper use of the Dental Benefit for dental care services, upon request of the Minister. Bill C-31 confers the Minister with broad authority to require persons to provide any information or document in order for the Minister to: (i) verify compliance with; or (ii) prevent non-compliance with, the provisions of the Act.[20]

Bill C-31 defines the "dental care services" in respect of which the Benefit may be applied as "[…] services that a dentist, denturist or dental hygienist is lawfully entitled to provide, including oral surgery and diagnostic, preventative, restorative, endodontic, periodontal, prosthodontic and orthodontic services".[21] Notably, if an Eligible Family incurs expenses for dental care services that are less than the amount of Dental Benefit that they have received, there does not appear to be any mechanism whereby they are able to return the unused portion of the Benefit. However, persons who knowingly report false or misleading information when applying for the Dental Benefit (which, as noted above, requires an attestation to be made that the person with respect to whom the application for benefits is made has received or will receive dental care services during the time period to

which the Benefit applies), or apply for and receive the Dental Benefit knowing that they are ineligible to receive it, could face a fine of up to $5,000.[22]

In 2023, until the time that the Dental Benefit is fully implemented in 2025, the Dental Benefit will be available in respect of children under the age of 18, seniors, and persons living with a disability.

The CRA's application portal for the Dental Benefit became available following Royal Assent of Bill C-31, and is now operational. The Benefit retroactively cover expenses for dental care services incurred on or after October 1, 2022.[23, 24]

Looking Ahead

Although details of the first phase of the Dental Program have now been released, it remains to be seen how exactly the federal government will develop a comprehensive national long-term dental care program, which they have committed to doing by 2025, and what such program will look like. As noted above, the government has solicited input from industry and other stakeholders via an RFI to support the government's creation of the longer-term dental program, including what role industry can play in the program. However, at the date of this article, the government has not yet released the results of the RFI. The government has also stated that provinces and territories have been engaged in the design and timelines of the full program;[25] yet, it currently appears that this will be a stand-alone, federally administered initiative. This is how the NDP, who first conceived of the dental care program, had intended it to be.

We will continue to monitor for any further updates.

[**Lynne Golding** is a partner at Fasken's Toronto office and the Co-Leader of the firm's national Health Law Group. Lynne is a corporate / commercial lawyer, who is highly regarded in the health regulatory space. Lynne is a frequent speaker on issues affecting the health sector and has been recognized for her expertise in healthcare law, including by Chambers Global and the Canadian Legal Lexpert Directory.]

[**Laurie Turner** is a partner at Fasken's Toronto office and the co-leader of the firm's national Health Law Group. Laurie is a corporate / commercial lawyer who regularly advises both for-profit and not-for-profit clients in the healthcare sector. Laurie has been recognized for her expertise in healthcare law, including by Chambers Global. Laurie can be reached at <lturner@fasken.com> or preferably at (416) 868-3446.]

[**Rachel Hung** is an associate at Fasken's Toronto office and is part of the Litigation and Dispute Resolution Practice Group. While Rachel maintains a broad civil litigation practice, she is particularly interested in serving clients in the health sector.]

---

1. The 2022 Budget is available here: <https://budget.gc.ca/2022/report-rapport/toc-tdm-en.html>.
2. See the NDP's "It's time for a national dental plan that covers everyone", online: <https://www.ndp.ca/dentacare>.
3. <https://laws-lois.justice.gc.ca/eng/acts/c-6/page-1.html>.
4. See Government of Canada's "Dental benefits for First Nations and Inuit", online: <https://www.sac-isc.gc.ca/eng/1574192221735/1574192306943>.
5. See Ontario's Ministry of Health's "Healthy Smiles Ontario", online: <ontario.ca/healthysmiles>. Notably, the Health Smiles Ontario program is not mandatory for dental professionals, and it appears that a significant disparity exists in some cases between the amount payable by the program to dental professionals for covered services, on the one hand, and the customary fees for such services, on the other hand.
6. Message from the Minister of Health regarding Request for Information from Industry on Proposed National Dental Care Program, online: <https://www.canada.ca/en/health-canada/news/2022/07/message-from-the-minister-of-health-regarding-request-for-information-from-industry-on-proposed-national-dental-care-program.html>.
7. See The 2022 Budget, Chapter 6, Section 6.1.
8. The Canadian Dental Association defines a "co-payment" as that portion of a bill for services that is the responsibility of the insured. See: <https://www.cda-adc.ca/en/oral_health/talk/copayment.asp>. However, despite the fact that the 2022 Budget includes co-payments being required from families earning between $70,000 and $89,999.99 annually, the concept of co-payments does not appear in Bill C-31.
9. *Supra*, note 7.
10. *Supra*, note 6.
11. <https://www.parl.ca/DocumentViewer/en/44-1/bill/C-31/third-reading> ("Bill C-31").
12. Bill C-31, Part 1, Preamble.
13. See Government of Canada's "Making Dental Care More Affordable: The Canada Dental Benefit", online: <https://www.canada.ca/en/department-finance/news/2022/09/making-dental-care-more-affordable-the-canada-dental-benefit.html>.
14. *Ibid*., note 13.
15. Bill C-31, Part 1, s. 2(2). More specifically, Bill C-31 provides that the term "adjusted income" has the same

meaning as is given to that term by s. 122.6 of the *Income Tax Act*, except that the reference to "at the end of the year" in s. 122.6 is to be read as a reference to "on December 1, 2022 in the case of an application made under section 5 or paragraph 7(a) and on July 1, 2023 in the case of an application made under section 6 or paragraph 7(b)". See s. 122.6 of the *Income Tax Act*: <https://laws-lois.justice.gc.ca/eng/acts/i-3.3/page-95.html#h-299563>.

16. Bill C-31, Part 1, s. 2(1) provides that the term "eligible parent" has the meaning given to the term "eligible individual" in s. 122.6 of the *Income Tax Act*.
17. Bill C-31, Part 1, ss. 5-6.
18. Bill C-31, Part 1, s. 4(1)(d).
19. Bill C-31, Part 1, s. 10(1).
20. Bill C-31, Part 1, s. 16. Notably, the term "Minister" is defined by the Act to mean "Minister of Health". However, it is unclear whether the authority conferred by s. 16 on the "Minister" is intended to refer to the Minister of Health (as the use of the term "Minister" in this case suggests) or the Minister of Revenue (who is referenced in numerous sections in Bill C-31 leading up to this s. 16).
21. Bill C-31, Part 1, s. 2(1).
22. Bill C-31, Part 1, s. 23.
23. See Government of Canada's "Government of Canada introduces legislation to make life more affordable for Canadians", online: <https://www.canada.ca/en/department-finance/news/2022/09/government-of-canada-introduces-legislation-to-make-life-more-affordable-for-canadians.html>.
24. *Supra*, note 13.
25. *Ibid*., note 13. See also Government of Canada's "Canada Dental Benefit": <https://www.canada.ca/en/revenue-agency/services/child-family-benefits/dental-benefit.html>.

The Evolving Regulatory Landscape of Virtual Care in Canada

Michael Watts, Susan Newell and Lauren Hebert

Abstract

This article discusses key changes in the health regulatory landscape applicable to virtual care across Canada. The approach to licensing requirements differs across jurisdictions, but most health regulatory authorities in Canada require that a health professional is licensed in the same jurisdiction that the patient is located. In certain jurisdictions of Canada, standards of care established by health regulatory authorities require that a health professional offering virtual care to their patients must also ensure that they personally offer timely in-person care to their patients, which can have significant implications on the ability of patients to access the services of a health professional that is not located in their geographic region. The scope of government health insurance plan coverage of virtual care services and the conditions that must be met to bill for services also raises practical considerations for physicians providing virtual care services. While there were a number of changes to the applicable rules in 2022, we anticipate that the virtual care landscape will continue to evolve in the coming years.

With several years of experience, including more than two years during the pandemic alone, virtual care is no longer considered a novel health service in Canada. However, the legal framework for virtual care remains inconsistent and varied among health professions and across the provinces and territories. Changes implemented by many health regulatory authorities during 2022 created a disjointed patchwork of rules. This suggests that further deviation is likely in the coming years, and it may be some time before a consistent approach to the virtual care regulatory landscape emerges in Canada.

As a result, regulated health professionals, health technology platforms and other industry stakeholders in the health industry that facilitate the delivery of virtual care services in various jurisdictions of Canada or that offer interdisciplinary health services through virtual care have a challenging task of understanding and complying with a variety of different legal frameworks. And these regulatory landscapes are continuously evolving.

Virtual Care Defined

The terms "virtual care", "telemedicine" and "telehealth" do not have universally accepted definitions. For example, in a report of the Virtual Care Task Force,[1] a joint task force of the Canadian Medical Association, the College of Family Physicians of Canada and the Royal College of Physicians and Surgeons of Canada, "virtual care" was defined as "any interaction between patients and/or members of their circle of care, occurring remotely,

using any form of communication or information technologies with the aim of facilitating or maximizing the quality and effectiveness of patient care".

The terms "telemedicine" and "telepractice" are generally considered to refer more narrowly to clinical services delivered by a health professional to a patient through electronic communications or information technologies. Conversely, the term "telehealth" is often considered to have broader application to include telemedicine and provider-to-provider communication through electronic communications or information technologies.

Virtual care services may be provided synchronously in real time, for example, through telephone or video communications that provide the ability for a patient and a healthcare professional to engage in a live discussion. Interactions may also be asynchronous, *i.e.*, communications that do not provide real-time interaction, such as messaging or email that can be accessed and read at any time.

Evolution of the Virtual Care Regulatory Landscape in Canada

The delivery of health services in Canada is governed by the provinces and territories. In each jurisdiction, standards of care for each health profession are established by a self-governing regulatory body. Prior to the onset of the COVID-19 pandemic, there were many established virtual care providers and health technology platforms in Canada. However, as a result of the pandemic, virtual care throughout 2020 suddenly represented a majority of patient interactions. Accordingly, all health regulatory authorities were forced to consider the appropriateness of their existing virtual care policies or quickly react to implement new ones. Governments also had to rapidly ensure that physicians could bill applicable government health insurance plans for virtual care services, albeit on a limited or temporary basis, without the luxury of time to consider the broader potential impacts on the health system.

Throughout 2021 and 2022, as virtual care providers became more experienced, a variety of organizations and task forces undertook studies and published reports on virtual care in Canada, including physician associations,[2] provincial working groups and Health Canada.[3] As lockdowns eased and in-person services resumed, many health regulatory authorities had a chance to reflect on the successes or deficiencies of their virtual care policies and to consider approaches to billing for physician virtual care services. This resulted in a number of health regulatory authorities updating their virtual care policies throughout 2021 and 2022. For example, in 2022, the virtual care policies published by health regulatory authorities for physicians in British Columbia, Alberta, Manitoba, Ontario and New Brunswick were updated. Some provinces also updated their approach to the remuneration of physician virtual care services, such as Ontario, New Brunswick, and Newfoundland and Labrador.

Key Differences in the Regulation of Virtual Care Across Canada

As outlined below, there are a number of ways in which regulation of virtual care in Canada differs by jurisdiction.

Where does virtual care take place?

The location where a health service is deemed to be rendered is an important factor in the approach to regulation. The majority of health regulatory authorities consider the health service to be rendered in the jurisdiction where the patient is located.

However, there are some exceptions to this interpretation. For example, the College of Physicians and Surgeons of Newfoundland and Labrador considers the practice of medicine to take place in Newfoundland and Labrador when a physician practises medicine while physically located in Newfoundland and Labrador.[4]

Licensing of Extra-Provincial Virtual Care Providers

Each health regulatory authority takes a different view regarding licensing requirements. Most health regulatory authorities permit their health professionals to provide services to patients in other jurisdictions if the health professional complies with the rules in the

jurisdiction where the patient is located and holds the necessary professional liability coverage.

However, there are certain differences in each health regulatory authority's approach to whether a health professional licensed in another jurisdiction of Canada may provide services to individuals located in their jurisdiction. For example, the College of Physicians and Surgeons of Ontario ("CPSO") recently updated its virtual care policy to say that physicians must be registered by the CPSO to provide virtual care to patients located in Ontario unless the provision of virtual care from a physician licensed elsewhere is in the patient's best interest.[5] Examples of acceptable circumstances that reflect the patient's best interest referenced by the CPSO include where the care sought is not readily available in Ontario, such as specialty care, or where the care sought is provided within an existing physician-patient relationship and is intended to bridge a gap in care. Exceptions may also be available for urgent or emergency assessment or treatment of a patient.

In other jurisdictions, such as British Columbia,[6] physicians licensed in other provinces do not need to be licensed by the College of Physicians and Surgeons of British Columbia to provide services to patients in British Columbia. By contrast, New Brunswick has established a Telemedicine Provider List that allows out-of-province physicians to register to provide virtual care services to patients located in New Brunswick.[7]

Need for in-person options

Most virtual care policies state that virtual care is meant to be a complement to, and not a replacement for, in-person care. In certain provinces, such as Manitoba,[8] New Brunswick[9] and Nova Scotia,[10] medical regulatory authorities have interpreted this to mean that each physician's practice must include timely in-person care when clinically indicated or requested by the patient. These types of requirements can have significant implications on the provision of virtual care in the province because health professionals are only able to provide virtual care to patients within a reasonable geographic proximity to their location.

Other regulators have determined that requiring physicians to make in-person care available to all patients has the effect of limiting patient choice or access to services for patients in rural areas. As a result, they have adopted policies that permit in-person care requirements to be satisfied through other means. For example, in British Columbia, physicians are required to have a pre-established agreement or formal affiliation with other health professionals who can make in-person care available to patients if the physician is not able to personally provide in-person care to a patient.

Other provinces, such as Alberta, have adopted specific standards of practice regarding episodic care to ensure that patients are able to obtain the follow-up care needed.[11] Still other provinces, such as Ontario, do not explicitly require that physicians offer in-person services at all, as long as the physician is able to provide or arrange for appropriate follow-up care for the patient.

Scope of permitted virtual services

Most virtual care policies require health professionals to continue to meet the same standard of care for the applicable health service when providing in-person or virtual care.

Certain health regulatory authorities have imposed specific requirements regarding the services that are or are not appropriate for virtual care. For example, the prescription of opioid medication outside a longitudinal relationship or without satisfying specific criteria is not permitted through virtual care in some jurisdictions.

Billing for virtual care services

Billing of virtual care services to government health insurance plans is an important consideration for the provision of virtual care by physicians. Although all jurisdictions in Canada have included virtual services as part of their insured services, the criteria that must be met for a service to be insured differ across Canada. For example, certain provinces have only included telephone or video interactions as insured virtual care services.

Some provinces have implemented billing structures that pay physicians different amounts for a virtual service than the amount that would be paid to render the same service through an in-person visit. There are further deviations in billing structures based on type of interaction or the nature of the physician-patient relationship. In Ontario, as of December 1, 2022, when there is no pre-existing relationship between a physician and a patient, Ontario will pay the physician less for certain services rendered through virtual care than would be payable if the service were rendered through virtual care to a patient with a pre-existing physician-patient relationship or if the service were rendered in-person. Fees paid to physicians are also lower when the service is rendered by telephone than would be payable for in-person services or services rendered by video. If the physician provides certain insured services to a patient by phone, the amount payable would only be 85 per cent of the in-person fee. Introducing different payment structures for the same service will likely impact the way physicians make care available to their patients.

Technology standards for virtual care

Provincial and territorial governments have also begun to implement technology standards for the provision of virtual care. In 2022, Ontario Health introduced a virtual visit verification standard for virtual care technology solution providers.[12]

Under the new Ontario Schedule of Benefits for Physician Services, physicians will be required to use a technology solution provider with verification status in order to bill the government health insurance plan for virtual care services provided by video. Other jurisdictions in Canada may implement similar mandatory technology requirements that must be met, either to satisfy the appropriate standard of care in the jurisdiction or to be eligible to charge the government health insurance plan for services rendered. The previous approach taken by health regulatory authorities was limited to regulating a health professional's use of technology and not the technology itself.

Establishing a verification system for technology solutions may have unintended practical consequences by expanding the role of health regulatory authorities to include regulation of health technology outside the medical device context.

Protection of personal health information

Personal health information associated with the provision of health care services is often highly sensitive. As a result, it remains critically important for virtual care providers to understand and comply with applicable privacy requirements in each jurisdiction in which they operate.

Although virtual care is not considered new, health professionals are required to explain the appropriateness, limitations and privacy risks related to virtual care to their patients. While generally similar, the requirements for these communications differ in each jurisdiction.

[**Michael Watts** is a corporate commercial lawyer with a focus on mergers and acquisitions, and corporate commercial matters in the health and cannabis industries. Michael is Chair of Osler's Health Industry Group and Co-Chair of the Cannabis Group. He advises clients in respect of a wide spectrum of matters, including purchase and sale transactions, healthcare corporate restructuring and integrations, corporate governance, shareholder agreements, commercial agreements, digital health regulatory opinions and structuring solutions, privacy and data security, clinical trials, public and private healthcare industry regulatory compliance and business structuring advice. Michael can be reached at <mwatts@osler.com> or 416-862-6605.]

[**Susan Newell** is a corporate commercial lawyer in Osler's Health Industry and Cannabis groups. Susan regularly provides strategic advice to health industry stakeholders in connection with mergers and acquisitions, healthcare corporate restructurings and integrations, corporate governance matters, shareholders agreements, commercial agreements, outsourcing, clinical trial agreements and regulatory opinions in connection with federal and provincial health and cannabis statutes. Susan can be reached at <snewell@osler.com> or 416-862-6797.]

[**Lauren Hebert** is an associate in Osler's Health Industry and Cannabis groups. Her practice is focused on commercial, corporate and regulatory matters in the health and cannabis industries as well as other regulated industries. Lauren can be reached at <lhebert@osler.com> or 416-862-4855.]

1. <https://www.cma.ca/sites/default/files/2022-02/Virtual-Care-in-Canada-Progress-and-Potential-EN.pdf>.
2. *Ibid*.
3. <https://www.canada.ca/en/health-canada/corporate/transparency/health-agreements/bilateral-agreement-pan-canadian-virtual-care-priorities-covid-19/policy-framework.html>.
4. <https://cpsnl.ca/wp-content/uploads/2022/09/Virtual-Care-2021.pdf>.
5. <https://www.cpso.on.ca/en/Physicians/Policies-Guidance/Policies/Virtual-Care>.
6. <https://www.cpsbc.ca/files/pdf/PSG-Virtual-Care.pdf>.
7. https://cpsnb.org/en/find-physicians/telemedicine-providers
8. <https://cpsm.mb.ca/assets/Standards%20of%20Practice/Standard%20of%20Practice%20Virtual%20Medicine.pdf>.
9. <https://cpsnb.org/en/medical-act-regulations-and-guidelines/guidelines/888-virtual-medicine>.
10. <https://cpsns.ns.ca/resource/virtual-care/>.
11. <https://cpsa.ca/physicians/standards-of-practice/episodic-care/>.
12. <https://www.ontariohealth.ca/system-planning/digital-standards/virtual-visits-verification>.

HEALTH LAW IN CANADA

HLiC is published four times a year by LexisNexis Canada Inc., 111 Gordon Baker Road, Suite 900, Toronto, Ontario M2H 3R1

ISBN (Print) 978-0-433-50959-7 **ISBN** (PDF) 978-0-433-50961-9
ISBN (Print & PDF) 978-0-433-50962-7 **ISSN** 0226-88411

Subscription rates: $755 (Print or PDF), $950 (Print and PDF)