Health Law in Canada

Author(s): Michael Watts

Health care in Canada is a complex subject, some health care services are public, some are private and there are a number of different entities involved in regulating and providing their delivery. While there is a perception that all health care in Canada is publicly funded, the publicly funded system is generally restricted to “medically necessary” hospital and physician services, and provincial or territorial drug plans that provide access to prescription drugs to residents over the age of 65 or those residents who rely on social assistance programs. Publicly funded services are delivered through a combination of public and private providers and funding comes from the Canadian federal government, which sets national standards, and the provincial and territorial governments, which regulates the delivery of services and determines those services that are deemed “medically necessary” (i.e., publicly funded) within the context of their own unique fiscal and political environment. In addition, there are a wide array of health products and services that are not subject to coverage under the public health insurance plans that are provided on a private payer basis.

CONSTITUTIONAL DIVISION OF POWER

As is the case for many important industries and economic sectors, neither the federal, nor the provincial/territorial level of government has exclusive jurisdiction over health. Instead, the Constitution Act, 1867, divides the legislative powers relevant to the regulation of the delivery of health products and services between the federal and provincial levels of government.

The federal government is responsible for regulating important aspects of various health industries or sectors including the regulation of selling, importing, distributing and marketing of drugs and medical devices and maintains significant influence over health policy and national objectives through the use of its spending power.

The provincial/territorial level of government has comprehensive authority over the delivery of health care services. Other examples of provincial responsibility include the regulation of hospitals and other health facilities, administration of health insurance plans, distribution of prescription drugs and regulation of health professionals.

However, many health industry sectors are subject to at least some degree of regulation or oversight by both levels of government.

CANADA’S NATIONAL HEALTH INSURANCE PROGRAM
Canada’s “national” health insurance program, a publicly funded single-payer system often referred to as “Medicare,” is designed to ensure that all Canadian residents have universal access to medically necessary hospital and physician services. However, it is important to note that there is no single national health insurance plan. Canada’s publicly funded health insurance program actually comprises 13 separate provincial and territorial health insurance plans that are each independently governed and administered based on the requirements and common criteria established by the Canada Health Act.

**THE CANADA HEALTH ACT**

The *Canada Health Act* is the federal legislation that provides the foundation for the Canadian health care system. The Act is administered by Health Canada, the federal department with primary responsibility for maintaining and improving the health of Canadians. However, neither the *Canada Health Act* nor Health Canada have direct authority to regulate the health insurance plans that give effect to the publicly funded health insurance system that is in place across the country. Instead, the Act establishes certain values and principles and sets out criteria and conditions that each publicly funded health insurance plan is required to meet in order to qualify for federal funding through the Canada Health Transfer. As federal funding is critical to the ability to fund “medically necessary” hospital and physician services, each provincial and territorial health insurance plan must satisfy the requirements of: public administration; universality; portability; comprehensiveness; and accessibility.

Notably, these requirements relate only to funding and administration and establish broad principles rather than a prescriptive code. In addition, the *Canada Health Act* is silent with respect to the delivery of health services and does not prohibit or discourage the delivery of insured health services by the private sector. As a result, there is significant variation in the funding and administration of health insurance plans from one jurisdiction to another. However, most provinces permit the delivery of a broad range of publicly funded health services through a combination of both public and private providers. Indeed, many publicly funded services in Canada are privately delivered.

The requirement that publicly funded health insurance plans be comprehensive requires that “medically necessary” hospital and physician services be covered. If a service is determined to be “medically necessary” then the full cost of the service must be covered by the public plan. However, the term is not defined and the services that must be covered are intentionally and broadly defined in order to accommodate the ability of each province and territory to make its own coverage decisions within the context of its unique fiscal and political environment. Typically, such decisions are made in consultation with the relevant medical associations in the jurisdiction. However, determining whether a particular service is “medical necessary” is a determination that has both a fiscal and political dimension. Ultimately, these coverage decisions are decisions about the allocation of scarce public resources.

The products and services available to Canadians through the publicly funded health insurance system are supplemented by a wide array of health products and services that are not, as a general matter, subject to coverage under the public health insurance plans. For example, prescription drug coverage, dental services and vision care are generally provided on a private payer basis. However, many jurisdictions provide coverage for these types of services to seniors and those who face financial or other barriers to privately funded health care. There are also a growing number of providers offering non-medically necessary and other ancillary health services. Examples include elective surgical or cosmetic procedures.
REGULATION OF HEALTH PROFESSIONALS AND HEALTH FACILITIES

Health professionals and health care facilities are subject to federal laws of general application, but the regulation of such matters is largely a matter of provincial jurisdiction.

HEALTH PROFESSIONALS

Through legislation, the provinces have delegated the regulation of health professionals to self-governing professional bodies (with varying degrees of discretion). Such legislation generally seeks to protect the public through a combination of “input regulations” that focus on who is entitled to provide a particular health service and “output regulations” that focus on the quality and delivery of the service being provided. Such regulations also generally include conflict of interest (or anti-kickback) provisions, as such matters are generally dealt with as part of the regulation of health professions rather than the regulation of health facilities.

Health industry participants offering a particular service need to understand how the service is regulated. If the service involves the performance of a regulated or controlled act (i.e., acts that can only be performed by a particular category or categories of regulated health professionals or their delegates) then the involvement of one or more duly qualified health professionals will likely be required. Also, it may be necessary to implement certain protocols and procedures in order to comply with the requirements of the regulatory colleges that govern the practices of any such professionals. Complying with such requirements can have significant commercial implications.

HEALTH FACILITIES

Operating a regulated health facility can be challenging and often involves a degree of regulatory risk. Purchasers, lenders and investors must have a thorough understanding of the legal framework and broader policy objectives of the system in order to adequately assess the risks and to take advantage of opportunities in this sector.

Residential health care facilities other than hospitals, such as nursing homes, long-term care facilities, pharmacies, laboratories and specimen collection centres are, in most jurisdictions, privately owned and operated pursuant to provincial licences and oversight. However, the degree to which such health facilities and other providers are regulated generally depends on the nature of the products and services being provided.

The operation of health facilities by private sector entities still typically involves some element of reimbursement through public funds. Where public funds are being used to acquire goods and services, additional accountability measures such as procurement requirement requirements often apply. Such accountability measures, as well as the significant role played by shared service organizations and other buying groups, can give rise to complex commercial, legal and regulatory issues.

Structuring a successful health investment or supplying certain health products and services generally requires sophisticated commercial and legal advice. This is particularly true in the case of investments or supplies involving multiple jurisdictions, as both the nature and scope of regulations generally varies from one jurisdiction to another.

REGULATION OF DRUGS AND MEDICAL DEVICES
The process of obtaining marketing authorizations and approvals of prescription drugs and medical devices is administered by Health Canada’s Therapeutic Products Directorate (TPD).

The TPD applies the Food and Drugs Act and the regulations applicable to prescription drugs and medical devices to ensure that drug products and medical devices sold in Canada are safe and effective. Except for low risk medical devices, no medical device or drug product can be offered for sale in Canada unless and until, after review, it is issued a marketing authorization by Health Canada.

In addition to its review of drug products and devices, Health Canada is responsible for the ongoing monitoring of drug products and medical devices being sold in Canada, as well as the regulation of good manufacturing practices and establishment licences, which are required in connection with the import, manufacture, distribution and/or sale of drug products and medical devices.

THE PATENTED MEDICINES PRICES REVIEW BOARD

In the United States, the price of pharmaceutical drugs is set by the market forces largely without government interference. This is not the case in Canada. The Patented Medicines Prices Review Board (PMPRB) is an independent quasi-judicial body created in 1987 under amendments to the Patent Act. The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drugs sold in Canada. Based on a review of the information required to be filed by a patentee, the PMPRB considers whether the price of a medicine appears excessive based on certain factors including: (i) the prices that the patented medicine is sold in the Canadian market; (ii) the prices at which other medicines in the same therapeutic class are sold in the Canadian market; and (iii) the prices at which the medicine and other medicines in the same therapeutic class have been sold in other countries other than Canada. If the PMPRB considers the price of a medicine appears excessive, revised pricing is the usual outcome.

PUBLIC MARKET ACCESS

Each province has a provincial drug plan that allows certain individuals to access drugs at a reduced cost. Products that will be paid for by the provincial government (in some provinces, for all residents, while in others for certain prescribed individuals such as seniors and individuals receiving social assistance), are typically listed on provincial formularies. For innovator products, the manufacturer negotiates the pricing for inclusion on the provincial formulary with the provincial government. For generic products, the price to be paid for the generic product is determined by a sliding scale of fixed prices related to when such products enter the market and the price of the innovator product (i.e., a percent of the price of the innovator pharmaceutical product depending on whether they are first, second or third entry products). If a drug is a generic product and listed as interchangeable on the provincial formulary, a pharmacist is permitted to dispense the interchangeable product for the innovator product. Under most provincial benefit plans, interchanging a generic product for the innovator product by pharmacists is mandatory and generally most provinces will only reimburse the pharmacist for the lowest cost interchangeable product. Government drug plans account for approximately 50% of all sales of prescription drugs in Canada.

TELEMEDICINE AND EHEALTH

TELEMEDICINE
Telemedicine and mobile technology are having a profound impact on the accessibility and delivery of health care services. However, when a health industry participant wishes to make a health service available through the use of mobile technology or other advanced information and communication systems complex legal and regulatory issues often arise. Various national organizations are working to develop common standards. However, the delivery of a health service that crosses a domestic or international border often involves complex regulatory and compliance issues. Managing compliance with the rules of a single health care system can be difficult. Developing efficient business solutions that comply with the varying requirements of multiple jurisdictions requires deep legal and industry knowledge and a sophisticated understanding of commercial issues.

**EHEALTH**

Canadian governments, at all levels, are actively pursuing eHealth initiatives with varying degrees of scope and complexity. The federal government is playing a significant role in supporting funding and setting national priorities through Canada Health Infoway, a federally funded, independent, not-for-profit organization, which works with provinces and territories to invest in eHealth projects. It is widely expected that significant investment in eHealth projects and initiatives will continue and may ultimately exceed investments in other health care infrastructure costs.

Health industry participants pursuing opportunities in Canada should avail themselves with legal counsel who possess a comprehensive knowledge of the complex Canadian health care system, a strong commercial perspective and expertise in the relevant industry sector. Successfully investing or participating in Canada in any health industry sector can present challenges for even the most sophisticated health industry participants, particularly where an investment or participation crosses a provincial or national border.