Supply Chain Considerations: Shipping Medical Devices to Canada

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Contents

Introduction

In late 2021 Medtech Canada, a national association representing Canada's medical technology industry, issued a report highlighting some of the challenges that became apparent in Canada's medical device supply chain during the pandemic. Like many countries, Canada experienced shortages of essential products including personal protective equipment (PPE), surgical supplies, and ventilators, which exposed vulnerabilities in the nation's ability to meet residents' health care needs.

Among the many recommendations included in the Medtech report, two have clear implications for U.S. manufacturers:

1. Although there is growing support for increasing the volume of products manufactured in Canada, "we need to be realistic about what Canada can, and cannot, do."
2. "Supply chain resiliency almost certainly includes an important role for the United States."

The United States has long had an important role in Canada's healthcare supply chain. In the medical device sector, for example, Canada imports roughly 75% of its total supply. Of that amount, nearly 45% come from U.S. manufacturers. And in the critical clinical laboratory sector, despite strong advancement in Canada's domestic capabilities, research by Frost & Sullivan notes a "substantial amount of tests" are outsourced to U.S. providers, with several U.S. labs maintaining commercial operations in Canada.

Demand for U.S. devices is expected to remain strong, as factors including Canada's aging population strain supplies of healthcare services and products. A 2021 report by the Fraser Institute found the country's senior citizens (aged 65+) will account for 23.4% of the overall population by 2040. This population shift will come at a cost, with the typical senior citizen accruing health care costs of roughly $12,000 per year, versus $2,700 for non-seniors. By 2040, seniors will account for 71.4% of the country's total healthcare expenditures.

According to the Fraser Institute, this dramatic shift is challenging policymakers to identify and implement "new techniques and procedures that will provide healthcare services more economically to seniors without sacrificing efficacy."

U.S. manufacturers are well-positioned to help provide those techniques and procedures. Because of this and other market opportunities the U.S. International Trade Association (ITA) lists the medical device industry as a "best prospect industry" for U.S. businesses looking to export. "Canada's healthcare industry is experiencing demand increases resulting from the advance of chronic diseases and an aging population," an ITA analysis noted. "The substitution of new and more expensive products, rising prices for existing products and more per-patient use of medical supplies continue to contribute to the industry's growth. As the country shifts its focus towards emerging medical devices, technologies such as robotic surgery, surgical simulation, mobile health, and wearables are expected to experience significant growth."

Learn how to optimize your healthcare supply chain and add efficiency to your medical device deliveries.

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Any U.S. company considering an expansion to the Canadian market though, must have an understanding of how critical processes and systems function within that country. This includes an awareness of the intricacies involved in shipping medical products across the border, and an understanding of Canada's healthcare system, which the ITA defines as a "mixed public-private" system. Each of the country's provinces and territories administer their own healthcare plans, with funding from the federal government. Canada's healthcare system, called Canadian Medicare, ensures universal coverage for all "medically necessary" services, but benefits and accessibility vary. In addition, since many services do not fall within the scope of "medically necessary," most Canadians – about two-thirds—have private insurance.

Businesses must also understand the regulatory process. In many ways Canada's regulatory protocols for medical devices mirror those of the United States, but there are important differences. Health Canada, the federal agency responsible for reviewing all devices sold in Canada describes its approach as "one of the best regulatory systems in the world for medical devices, with some of the most stringent requirements." U.S. businesses must ensure not only that their products are safe and effective, but that they successfully comply with all customs-related documentation, duties/taxes, and permit requirements.

Finally, businesses must have a viable logistics strategy for ensuring the safe, timely, and efficient deliveries of their products across the Canadian market. Many devices require special services including temperature control, extra security, or fragile handling. U.S. manufacturers must ensure products arrive in time to meet strict time-specific requirements for deliveries to healthcare facilities, while simultaneously accommodating increased demand for deliveries direct to patients' homes. This includes patients who live in remote areas not serviced by most major delivery carriers.

The following discussion will shed light on each of these topics. The discussion will provide insight about Canada's sophisticated medical device and laboratory sectors, and the tremendous opportunities available to U.S. manufacturers. But, as the analysis will make clear, success in the Canadian market depends on many factors, including a Canada-specific, customized logistics strategy.

Need More Information?

Another Purolator white paper, "Medical Device Shipping: Navigating Supply Chain Challenges to Meet Patient Needs," which provides even more information about shipping within the Canadian market.

Get white paper

Canada’s Medical Device Industry – Overview and Opportunities for U.S. Businesses

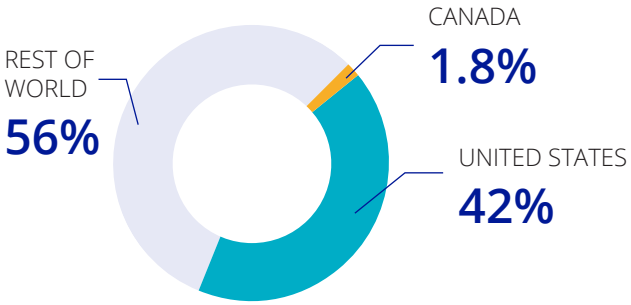
Canada's Medical Device Industry – Overview and Opportunities for U.S. Businesses

Any discussion of Canada's medical device industry should begin with a fundamental understanding of what, precisely, is considered a medical device. The World Health Organization (WHO) defines a medical device as "an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting of modifying the structure or function of the body for some health purpose."

According to WHO, more than 2 million different types of medical devices are produced worldwide, and categorized into more than 7,000 generic device groups. Medical devices include a broad scope of products ranging from syringes, bandages, contact lenses and dentures, to more complicated devices including pacemakers, artificial joints, respiratory ventilators and cardiac assist devices.

In Canada, the domestic medical devices industry (excluding in vitro diagnostics) was valued at US$7.5 billion during 2020, and accounted for roughly 1.8% of the global market. By comparison, the United States is the world's largest and most developed market, with a 2020 value of US$177 billion and a 42% global market share.

Global market share of the medical device industry

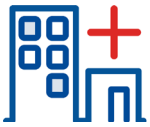


The Canadian medical device industry employs more than 35,000 people and is home to approximately 1,500 corporate facilities. The industry is comprised of small, medium and large-sized facilities, with large facilities (100+) employees representing 43% of total employment. Much of the research that fuels these companies is conducted in Canadian universities and research centres, and eventually spun-off into medical device companies. The industry is primarily based in the provinces of Ontario, Quebec, Alberta, and British Columbia, with 80% of the device industry located in Ontario and Quebec.

Canada's medical device industry is export-oriented, with roughly 80% of domestically produced devices sold to international buyers. Sales to the U.S. account for 68% of Canadian device exports, followed by sales to the Netherlands (4%), Germany (3%), and China (3%).

The Canadian medical device industry employs more than

35,000



The Canadian medical device industry is home to approximately

1,500

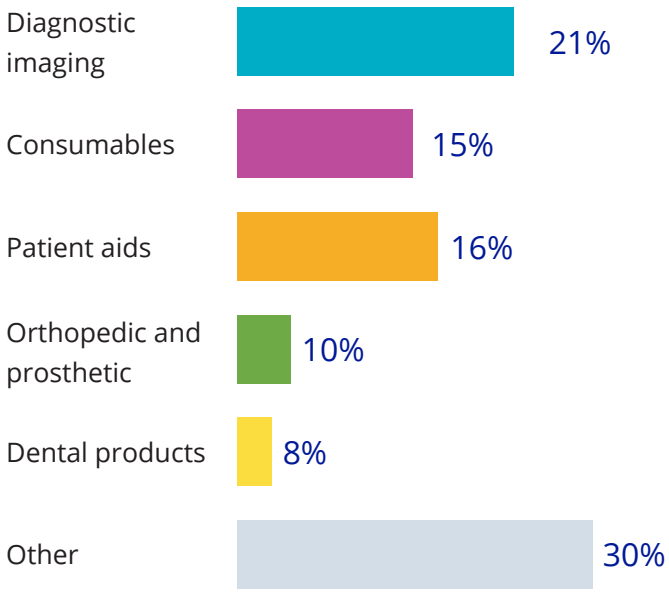
corporate facilities

Of Canada's total employment, the medical device industry represents

43%

At the same time, the country is heavily dependent on imports to meet its domestic device needs. According to the U.S. International Trade Administration, Canada imports roughly 75% of the devices it uses. Of that number, 45% comes from the United States, followed by China, Mexico and Germany.

Canada's largest import categories, based on 2020 data, include:



(Includes wheelchairs, ophthalmic instruments, anesthesia apparatus, dialysis equipment, blood pressure monitors, endoscopy apparatus, and hospital furniture.)

Medical device regulatory requirements

Medical devices in Canada are regulated by Health Canada's Medical Devices Directorate. Regulations are rooted in the Food and Drugs Act and accompanying Medical Devices Regulations. Health Canada claims to have "some of the most stringent requirements in the world for the licensing of medical devices."

Before any device can be sold in Canada, it must be registered, with certain products required to obtain a Medical Device License. According to Health Canada, to determine which devices need a License, products are categorized based on the risk association with their use. Devices are categorized into four distinct classes, with Class I devices presenting the lowest risk (e.g., a thermometer or tongue depressor), and Class IV devices presenting the greatest potential risk (e.g., pacemakers).

Manufacturers of Class II, III and IV devices must obtain a Medical Device License before they can be sold on the Canadian market. While Class I devices do not need a Medical Device License, they are monitored through Establishment Licenses. According to Health Canada, "Medical Device Establishment Licenses (MDELs) are issued to Class I device manufacturers as well as importers or distributors of all device classes to permit them to import or distribute a medical device in Canada."

The MDEL ensures that devices sold in Canada meet applicable safety requirements, and allows the government to maintain a listing of all licensed establishments. Such a listing is maintained to protect the public should a problem with a specific device become known.

Canada's strict regulatory requirements were strengthened via a 3-part "Action Plan" which was phased in during the 2019-2021 period. Among other provisions, the Action Plan increases reporting requirements, with manufacturers required to inform Health Canada within 72 hours if a foreign regulatory agency has issued a warning about their device, and to submit information about label changes. In certain situations, Health Canada may compel a manufacturer to conduct assessments, tests, or studies.

Labeling requirements

Medical devices sold in Canada must meet specific labelling requirements as required by Health Canada's Food and Drugs Act, and Medical Devices Regulations. While many of these provisions mirror U.S. Food and Drug Administration regulations for sales within the United States, there are several that are unique to the Canadian market.

A few examples include:

- **Language requirements:** Certain information, including labels and directions for use, must be supplied in both English and French. This is to accommodate Canada's status as a bi-lingual country, with both English and French recognized as official languages.
- **Temperature information.** Temperature-sensitive devices must provide storage requirements, with temperatures listed in degrees Celsius.

Although there are similarities between U.S. and Canadian regulations, exporters must be careful to meet specific requirements. Efforts are underway to align aspects of U.S. and Canadian medical device regulations, with a working group expecting to harmonize certain pre-market technical review requirements for moderate-risk devices.

Regulatory mandates can be confusing. And mistakes can be costly. Learn about common mistakes – and how to avoid them.

Read article

Canada's Diagnostic Laboratory Sector – Overview and Opportunities for U.S. Businesses

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The world became a lot more familiar with the medical and diagnostic laboratory industry during the COVID-19 pandemic, when industry leaders including Abbott and Quest Diagnostics were at the forefront of efforts to develop reliable testing. These companies, along with others, impressed the world with the speed at which tests were not only developed, but manufactured and delivered to healthcare providers and patients worldwide. In doing so, diagnostic lab companies demonstrated their vital role in health care, and the tremendous advances in capabilities that have been made in recent years.

Diagnostic products and services play a vital role in identifying health problems and informing medical interventions. According to the Centres for Disease Control, 14 billion lab tests are ordered annually in the United States, and 70% of medical decisions depend on laboratory results. In Canada, approximately 1.2 million laboratory tests are performed each day. Those tests are performed in a range of settings including private labs, hospitals, provincial health centres, physicians' offices, pharmacies and increasingly, in patients' own homes.

Within the industry, point-of-care (POC) diagnostics, in which testing occurs at-or-near the site of patient care, has grown at a rate of 7% annually, fueled largely by sales of technology-enabled "smaller, cheaper, and more sophisticated" options, including "lab-on-a-chip" devices which require just a few drops of blood. POC sales have also been driven by over-the-counter self-testing products including glucose tests, genealogy tests and home pregnancy tests.

The diagnostic industry falls into key categories that include:

- **In vitro diagnostics (IVDs).** In vitro diagnostics are clinical tests that analyze blood, urine, saliva, tissue and other samples taken from the human body. IVD tests are regulated in Canada by Health Canada as medical devices, and must meet all applicable regulatory requirements.
    - Examples of IVDs include reagents, blood sugar monitoring systems, pregnancy tests, cholesterol tests, Hepatitis and HIV tests, and coagulation test systems.

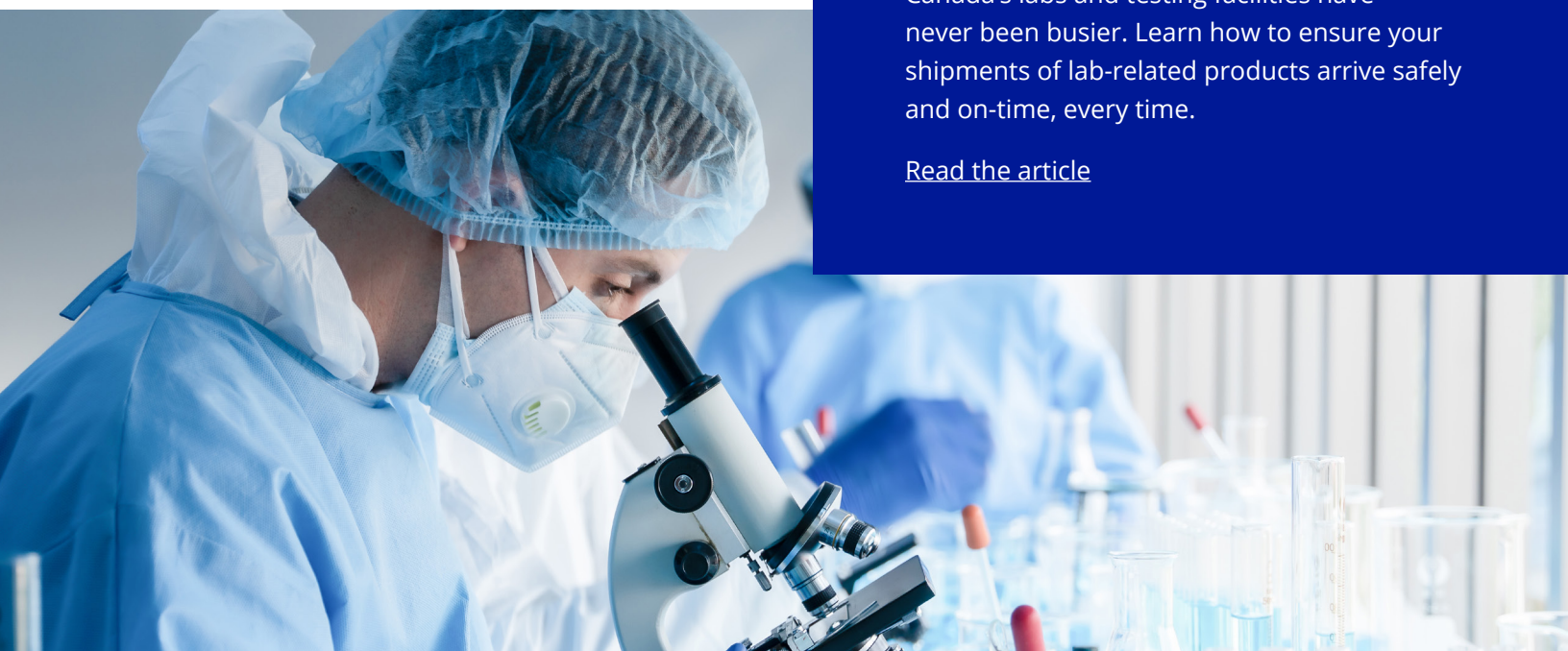
- **In vivo diagnostics**. In vivo diagnostic tests refer to more invasive tools and equipment typically used for imaging or monitoring of targets within the body (as opposed to in vitro tests which are performed outside the body on samples taken from the patient). In vivo tests vary from simple skin tests for determining antigens that cause allergic diseases to highly technical PET scans and other types of imaging.
- **Molecular diagnostics.** According to the Yale School of Medicine, molecular diagnostics, also called molecular pathology, nucleic acid-based testing, and polymerase chain reaction (PCR), "involves taking DNA or RNA, the unique genetic code found in our cells, and analyzing the sequences for red flags that can pinpoint the potential emergence of a specific disease." Examples of common molecular diagnostics tests include testing for gene mutations associated with breast cancer, leukemia, cystic fibrosis, and ALS. In addition, molecular testing has been a factor in helping to diagnose COVID-19, with Health Canada calling the associated test "the gold standard."
- **Laboratory-Developed Tests (LDTs).** According to PEW, "any IVDs that are developed and used within the same laboratory" are often referred to as laboratory developed tests (LDTs). LDTs are designed and used in a single laboratory, Pew notes, "in facilities ranging from physicians' offices, hospitals, and academic medical centres to large testing companies." LDTs have been allowed to evolve with relatively little regulatory oversight. In the United States, the Food and Drug Administration has historically viewed LDTs as posing a lower risk to patients than most commercial testing kits, and has exempted them from nearly all regulatory requirements. Similarly, Health Canada also not regulate lab-developed tests.

In general, the industry relies on reagents, analytical instruments, and accessory products that are needed to perform diagnostic laboratory tests:

- **Reagents** are solutions of biological or chemical substances that react with target substances in samples. This process will result in a measurable outcome.
- **Analytical instruments** are the various machines and equipment that bring samples and reagents together and measure results or other qualities in samples.
- **Accessory products**, such as the software that manages and checks the performance of the systems are also produced by the industry.

Canada's labs and testing facilities have never been busier. Learn how to ensure your shipments of lab-related products arrive safely and on-time, every time.

Read the article



Canadian testing practices – public and private labs, physicians' offices, patients' homes

Approximately 1.2 million laboratory tests are performed each day in Canada. Those tests are performed in a range of settings including hospitals, private facilities, provincial health centres, physicians' offices, pharmacies and increasingly, in patients' own homes.

The Canadian IVD market is expected to grow at an annual rate of more than 5% through 2027. According to Mordor Intelligence, factors behind this growth include:

- Ongoing presence of COVID-19 will continue to drive demand for testing.
- Increased use of point-of-care (POC) diagnostics, which are generally easy to use and produce fast results.
- Ease of procurement, with provincial and territorial governments offering broad coverage of diagnostic tests. Public Health Ontario, for example, offers 282 different tests. [See below for more information about Canada's healthcare system.]
- Advanced technologies including biosensors, lab-on-a-chip, and wearable devices allow patients to easily perform tests and services that previously required a trip to a physician's office or testing facility.
- Increasing awareness and acceptance of personalized medicine.

Discover more about the impact of COVID-19 on Canadian health care in our infographic.

See infographic

The Canadian IVD market is considered "moderately competitive," according to Mordor Intelligence, and consists of several major players. In terms of market share, a few of those major players (Becton Dickinson, BioMerieux, Bio-Rad Laboratories, Danaher and Fisher Scientific) dominate the market. In addition, the growing need for diagnostics due to the rising prevalence of disease, combined with IVD advances, is helping a few smaller players find success.

Canada is a world leader in conducting clinical trials

Canada has emerged as a significant player in the critically important clinical trials sector. As defined by Roche, a clinical trial is "a research study conducted in human beings with the goal of answering specific questions about new therapies, vaccines or diagnostic procedures, or new ways of using known treatments. Clinical trials are used to determine whether new drugs, diagnostics or treatments are both safe and effective."

According to Business and Industry Canada, Canada accounts for 4% of global clinical trials, and is fourth in its number of clinical trial sites. "All major global pharmaceutical companies conduct a large portion of their clinical trials in Canada," the government agency notes, drawn by Canada's prestigious research universities, accomplished researchers and scientists, and by the government's investments in research & development."

Canadian labs and test facilities import a significant volume of materials used for patient care and research purposes. Imports increased by 38.6% over the April 2019 – April 2020 period, although much of that increase was attributable to the pandemic, and the resulting need for COVID-19 testing.

Canada's diagnostic laboratory sector - regulatory requirements

Diagnostics developed as "test kits" and sold to laboratories, hospitals and clinics are considered medical devices, and are subject to regulatory oversight by Health Canada. Diagnostic test kits and other supplies are addressed in the same governing documents as other devices -- the Food and Drugs Act and the accompanying Medical Devices Regulations.

Medical devices are grouped into four classes:

Class I – lowest risk devices that require an establishment license, but not a medical device license.

Class II – low-to-moderate risk devices that require a medical device license. Class II devices include contact lenses, denture materials and "non-invasive devices that come into contact with injured skin.

Class III – medium-to-high-risk devices such as hip implants, glucose monitors, ultrasound diagnostic imaging equipment, and surgically invasive devices that are intended to be absorbed into the body or that are intended to remain in the body for at least 30 consecutive days. Class III devices require a medical device license and must provide a valid ISO 13485 certificate.

Class IV – high-risk devices such as pacemakers and surgically invasive devices that diagnose, control, or correct a defect in the central cardiovascular system. Class IV devices require a medical device license and must provide a valid ISO 13485 certificate.

Activities that take place within laboratories are regulated by individual provinces and territories, and not by the federal government. According to a report by the independent Canada's Drug and Health Technology Agency (CADTH), "Canada does not have national mandatory accreditation for clinical pathology laboratories and point-of-care testing. Laboratory quality is largely a provincial responsibility; therefore, laboratory regulation and accreditation vary across the country."

As the following overview of Canada's healthcare system will make clear, provinces and territories are responsible for developing and administering local health care. This has resulted in differences in coverage, payment models, and procurement practices.

Operating in Canada – the Canadian Healthcare System

Operating in Canada – the Canadian Healthcare System

The Canadian government describes its healthcare system as a publicly-funded system that provides "universal coverage for medically necessary healthcare services provided on the basis of need, rather than the ability to pay." Responsibility for the system, known as Canadian Medicare," is shared by the federal government and the country's 10 provinces and 3 territories. The federal government sets overall directives, ensures safety of devices and pharmaceuticals, and provides some funding. Each province/territory offers an insurance plan, maintains a healthcare system, and delivers services. Private insurance is available to cover costs for services and products that do not fall within the scope of "medically necessary."

While benefits, accessibility, and delivery approaches may vary between provinces and territories, all citizens and legal residents receive "medically necessary" hospital and physician services free-of-charge, at the point-of-use.

Canada's healthcare system is a source of great national pride. A survey by the Association for Canadian Studies found 73% of respondents cited universal health care as "a very important source" of Canadian pride. The next highest response was for citizens' actual Canadian passport, about which 70% felt most proud. And an Ipsos survey conducted in late 2021 – while the country was in the midst of the COVID-19 pandemic – found two-thirds of Canadians were satisfied with their province's health system.

How does it work?

Analysis by The Commonwealth Fund provides the following breakdown of Canada's healthcare system:

"Canadian provincial/territorial governments have primary responsibility for financing, organizing, and delivering health services and supervising providers. The jurisdictions directly fund physicians and drug programs, and contract with delegated health authorities (either a single provincial authority or multiple sub provincial, regional authorities) to deliver hospital, community, and long-term care, as well as mental and public health services.

"The federal government co-finances provincial/territorial universal health insurance programs and administers a range of services for certain populations, including eligible First Nations and Intuit peoples, members of the Canadian armed forces, veterans, resettled refugees, and inmates in federal prisons. It also regulates the safety and efficacy of medical devices, pharmaceuticals, and natural health products, funds health research and some information technology systems, and administers several public health functions on a national scale."

Learn more about shipping medical devices to Canada. Our white paper takes a deep dive into direct-to-patient shipping needs as well as present strategies and considerations for ensuring medical devices reach patients receiving care at home.

Get white paper

What are "medically necessary" services?

The Canada Health Act is the federal legislation that became law in 1984 and provides the blueprint for Canada's publicly funded health insurance. A core provision of the law is that provincial and territorial health plans must "insure all medically necessary services."

The Act does not, however, define what those medically necessary services include.

"Medically necessary services are not defined in the Canada Health Act," notes the federal government's analysis. "It is up to the provincial and territorial health insurance plans, in consultation with their respective physician colleges or groups, to determine which services are medically necessary for health insurance purposes.

"If it is determined that a service is medically necessary, the full cost of the service must be covered by the public health insurance plan to be in compliance with the Act. If a service is not considered to be medically required," the analysis notes, "the province or territory need not cover it through its health insurance plan."

13 unique health plans and 13 different procurement strategies

A direct result of Canada's approach to health care has been the establishment of 13 unique healthcare plans, one in each of Canada's 10 provinces and 3 territories. Each province and territory develops its own "best practices" with regard to covered services and products. These "best practices" also extend to procurement and pricing practices, and requirements for receiving, storing and distributing medical supplies.

Currently there is no consistent model for procurement. The rules are different in each province and are often different within regions or among specific providers. However, as provincial and territorial governments seek to contain costs and maximize efficiency, several common procurement initiatives have been implemented that include:

- **Group Purchasing Options (GPOs).** Group purchasing involves healthcare facilities using their combined buying power for leverage in securing lower prices and other supplier concessions. HealthPRO is such an example. HealthPRO includes

more than 260 members representing over 800 healthcare facilities across 7 provinces and territories and has reportedly achieved millions of dollars in savings for members.

- **Shared Service Organizations (SSOs).** SSOs seek to reduce costs and improve efficiency by consolidating processes and functions among member units and leveraging the resulting economies of scale. Participating healthcare facilities outsource functions such as human resources, finance, and procurement to an external SSO, which assumes managerial responsibility. This allows each member unit to reduce operating costs and, presumably, ensure these functions are handled by a provider well-versed in current practices and trends.

  An example of a SSO operating in Canada is Ontario-based Plexxus, which operates on behalf of more than 20 hospitals located throughout the province. Since 2006, Plexxus has helped hospitals achieve $350 million in savings.

- **Bundled Care.** Under a "bundled" model, a single payment is issued to cover all aspects of a medical procedure. That bundle will then be broken down and divided among all stakeholders.

  A patient who undergoes a hip replacement, for example, will need a range of services including a surgeon, anesthesiologist, operating room, x-rays, hospital stay, hip replacement device, additional devices including a walker and cane, and physical and occupational therapy, among other services. Under the old scenario, each stakeholder would submit a separate claim for reimbursement. But in the new environment, a single "bundled" payment is issued to the hospital, and each stakeholder paid a negotiated fee from that sum.

  For device manufacturers, the new process means additional pressure to control costs, including an increased awareness of the price of materials used in new designs.

U.S. businesses should understand each entity's procurement rules and practices before attempting to establish a relationship. The U.S. International Trade Administration provides the following listing of provincial and territorial procurement offices:

Province/Territory	Procurement Office	Notes
Alberta	Alberta Purchasing	Online tool that lets public and private sector users explore tender opportunities for goods and services in Alberta.
British Colombia	BC Bid Portal	Portal that provides direct supplier access to all provincial procurement opportunities.
Manitoba	MERX	Provides access to all Manitoba goods and services tenders.
New Brunswick	Service New Brunswick	New Brunswick Opportunities Network posts tender notices for the province.
Newfoundland and Labrador	Public Procurement	Website advertises tender bidding opportunities.
Northwest Territories	NTContracts	Information about all procurement opportunities.
Nova Scotia	Nova Scotia Procurement	Provincial website that details comprehensive tendering opportunities.
Nunavut	Nunavut Tenders	Website that lists all procurement opportunities.
Ontario	Ontario Tenders	Online system that hosts procurement opportunities and award notices for the Ontario government.
Prince Edward Island	PEI Tenders	Provincial site that provides suppliers with information about all procurement opportunities available in PEI.
Quebec	SEAO	Electronic tendering system approved by the government of Quebec. Provides access to government contracting opportunities from public and municipal agencies in health networks.
Saskatchewan	SaskTenders	Website that lists all procurement opportunities available in the province.
Yukon	Yukon Procurement	Government contracts and procurement opportunities.

Operating in Canada – the Customs Clearance Process

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In addition to compliance with Health Canada regulatory requirements, U.S. manufacturers must successfully navigate the U.S.-Canadian customs clearance process. This includes compliance with U.S. export requirements, as managed by U.S. Customs and Border Protection (CBP), and Canadian import requirements, managed by Canada Border Services Agency (CBSA).

With regard to the import process, shippers must be aware not only of documentation requirements, and duty and tax obligations, but must also have a high level of confidence that information provided to CBSA is accurate and complete.

To provide a better understanding of the process, CBSA offers the following checklist:

- Obtain a business number from the Canada Revenue Agency.
- Identify the type of goods to be imported.
- Determine if the services of an external customs broker will be used.
- Determine the country of origin for the goods to be imported.
- Verify whether the goods are eligible to be imported into Canada, and if they are subject to regulation by any other government department (OGD). [Medical devices are subject to Health Canada compliance requirements and may also be regulated by additional agencies.]
- Ensure the goods are properly marked and labeled.

  Determine the 10-digit tariff classification number and the applicable rate of duty for each item using the Canadian Customs Tariff schedule.
- Determine whether the goods are subject to any other duties or taxes including the goods and services tax (GST).
- Determine the value of the goods to be imported (for use in assessing the amount of duty owed).
- Select the preferred terms of shipping (Incoterm) and communicate with the logistics provider or transportation about cross-border requirements.

Because the customs process is time consuming, most shippers choose to outsource the process to an experienced customs broker or qualified logistics provider. While an experienced third party can seamlessly manage the customs process, it's important to keep in mind that a shipper is ultimately responsible for all documentation submitted to CBSA on its behalf.

Deliveries to the Canadian Market – Building a Healthcare-Specific Logistics Strategy

Deliveries to the Canadian Market – Building a Healthcare-Specific Logistics Strategy

Similar to the United States, Canada's healthcare system is under significant pressure to reduce costs, and has implemented fundamental changes in all sectors, including procurement practices and supplier requirements. This includes a shift to leaner inventories and fundamental changes in where healthcare services are provided. Most notably, Canadians are increasingly able to manage chronic conditions from their homes, or receive treatment at a local community health centre.

Consider, for example, that 63% of Canadians have selected home and community care as preferred priorities in senior health care. In Ontario alone, a network of 100+ community health centres care for the province's population – young and old -- with a range of services and programs. This way, community members avoid hospital visits by having their needs met locally – often in their own homes. In addition to providing a convenience for residents, community healthcare helps manage costs, since 1% of Ontario's population uses one-third of its healthcare resources.

Device suppliers must accommodate strict requirements imposed by hospitals, surgical centres, physicians' offices, long-term care facilities, pharmacies, and other facilities that treat patients.`

This means suppliers servicing the Canadian market must have core logistics competencies that include:

- **Reliable and consistent service.** Device manufacturers must meet stringent delivery requirements whereby products must arrive within a narrow window of time. Hospitals, surgical centres, and long-term care facilities no longer maintain inventory stockpiles, and instead rely on regular replenishments to meet each day's requirements. Device manufacturers require flexible and reliable logistics services that allow them to meet these deadlines, with the ability to accommodate evening pickups, since many medical offices do not know their next-day needs until late afternoon.
- **Time-definite deliveries.** In some instances, the need for reliable service extends to time-definite deliveries. Hospitals and surgical centres have adopted "just-in-time-like" delivery models, whereby surgical kits and other devices required for surgeries must arrive shortly before they are scheduled to be used. Delayed deliveries not only risk cancellation of such procedures but put device makers at risk of fines and penalties. Guaranteed, time-definite morning deliveries allow device makers to meet these deadlines, thereby allowing medical facilities to perform scheduled procedures.

- **Geographic reach.** Device manufacturers require on-time deliveries across Canada, including to healthcare facilities and consumers' residences located in all provinces and territories. But finding a logistics provider that offers comprehensive service across Canada can be quite difficult. This is because, for many reasons, most Canadian companies offer only regional service to select geographic areas. As a result, companies with customers located in multiple provinces and territories often enlist several providers, with each handling a specific region. Such a patchwork approach means multiple shipment transfers, shipment delays, increased risk of theft/damage, loss of visibility, inconsistency of service, higher costs, and general chaos.

  A far better solution is to enlist a logistics provider that services the entire country and has a proven track record for on-time deliveries and exceptional efficiency.

- **An omni-channel strategy** that accommodates both B2B deliveries to health facilities, and deliveries to consumers' homes. Advanced device capabilities now allow many patients to manage chronic conditions and surgical rehabilitations from their homes, thereby avoiding costly in-patient stays and doctor's office visits.

  Device makers must have confidence in their logistics provider's ability to deliver to consumers' homes and when needed, to perform special tasks including in-home deliveries, deliveries to apartments, and in some cases, set-up and maintenance of certain pieces of equipment.

- **Special delivery accommodations.** Medical facilities increasingly require deliveries to specific locations, including use of a specific door, or to a specific area within a hospital or care facility. Device makers depend on their logistics provider to meet these accommodations and to abide by all facility security and procedural protocols.

- **Technology-based solutions** that ensure real-time visibility and tracking. Device manufacturers must have the ability to track critical shipments, with electronic updates as shipments move through the transit process. In addition, manufacturers rely on Proof of Delivery (POD) verification to help minimize risk of product loss and theft.

- **Hold for Pick up locations/regional access points.** Healthcare professionals who provide in-home visits, or who rotate among various community clinics must have daily access to the materials they will need for each day's scheduled visits. These professionals must have early morning access to needed devices so they can be assured of being able to meet each patient's specific needs.

- **Automated inventory tracking.** Device makers typically have products located in multiple locations ranging from hospital storage closets to fulfillment/kitting locations to sales representatives' car trunks. As bottom-line accountability has become more important than ever, manufacturers must have a way to track all inventory, and the ability to know for certain where a device is located at any given time.

- **Cross-Border Capabilities.** With products from the U.S. accounting for more than 40 percent of imported devices used in Canada, manufacturers clearly need to prioritize cross-border efficiency. This includes solutions that address unique requirements for medical devices, ensure direct service to the border, and a seamless customs clearance followed by direct end-delivery throughout Canada.
- **Global Sourcing Considerations.** Beyond the U.S., Canada relies on device imports from European countries, along with Mexico and China to meet domestic demand. This means an efficient supply chain is needed for bringing goods into Canada and ensuring fast distribution throughout all provinces and territories.
- **Damages.** A medical device that arrives damaged is unusable – and unacceptable. A single damaged part can result in a surgery cancellation, or a medical facility being unable to perform critical procedures. Therefore, prioritizing shipment safety is a paramount concern that requires appropriate packaging and a minimal number of touches and in-transit transfers.

Some helpful tips...

Time-definite deliveries, flexibility, and scalability are just some ways logistics efficiency can improve your medical device shipping strategy.

Get ebook

Prioritize Canadian Expertise and Healthcare Experience in Choosing a Logistics Partner

Prioritize Canadian Expertise and Healthcare Experience in Choosing a Logistics Partner

U.S. device companies have a lot at stake in choosing a logistics provider to manage their Canada-bound shipments. As the above list makes clear, shipping medical devices requires special skills and capabilities. But shipping medical devices across an international border adds a layer of complexity, and potential obstacles to overcome.

Which is why the choice of logistics provider is so important -- and the need to take the time to carefully consider a logistics provider's capabilities within the Canadian market. Many U.S. companies have learned the hard way that not all providers can deliver on their promises and that for some, servicing the Canadian market is simply not a priority.

Instead, insist on a logistics company that does prioritize Canada, and that also prioritizes healthcare-based shipments. Purolator for example, has decades of experience in the Canadian market and capabilities that are well-suited for the unique needs of the medical device industry. This includes an extensive portfolio of service options – courier, freight, air, hybrid – that enable customized solutions that address the unique needs of each shipper. Of special appeal to device manufacturers, Purolator's offers extensive Mission Critical services that satisfy the need for time-definite deliveries with minimal risk of shipment damage.

For cross-border shipping, Purolator provides logistics solutions that prioritize speed and efficiency, along with secure packaging and other device-related requirements. In many instances, shipments arrive at the border on the same day they are picked up!

Shipments arrive at the border with all documentation pre-filed and pass-through Canadian customs with minimal risk of delay.

Once in Canada, shipments continue within the Purolator network. Purolator's Canadian distribution network ensures in-network service to 99.9% of postal codes, with most deliveries made within two days. Delivery times can often be even faster if mission-critical air or express ground services are used – or a combination of the two.

Purolator's capabilities are well-suited for the medical device industry, and offer benefits that include:

- **A network that includes just about all of Canada.** Purolator's distribution network includes every province and territory, and reaches 99.9% of all Canadian postal codes. This includes addresses – including regional hospitals, patient's homes and healthcare centres -- located in rural or remote regions of the country that depend on air service, or require vehicles that can navigate unpaved roadways. Since Purolator's network is so extensive, there is no need to enlist regional providers. Purolator serves as a single-source provider, with all shipments remaining within the Purolator network for the duration of the delivery process.
- **Multiple service options** that ensure fast service across all of Canada. These options include:
    - Expanded early morning service including 7:30am delivery.
    - Extensive same day/next day offerings.
    - Evening pickups, which allow additional time to accommodate late-day orders from medical facilities.
    - Saturday/Evening deliveries.

- **Flexibility** to accommodate medical facility delivery requirements:
  - Deliveries via specific elevators to designated locations.
  - Inside deliveries to regional clinics and surgical centres.
  - Deliveries to consumers' homes.
  - Temperature-sensitive product solutions.
- **Mission Critical Air and Freight Services.** Purolator offers extensive air and freight services that ensure fast, guaranteed delivery. These "mission critical" solutions are customized for each shipper's specific needs.
  - Our Purolator Express® service offers guaranteed overnight service from the United States, with deliveries throughout Canada by 9am, 10:30am, noon, end of day, or evening. This allows a device manufacturer the flexibility to meet each customer's specific needs.
  - Less time-sensitive shipments may benefit from an express freight solution, whereby shipments travel uninterrupted to the border, and move seamlessly to their end destination.
  - Shipments may also benefit from a hybrid solution. In this case, a U.S. shipment might travel via a ground solution to the border, and use air service to reach its ultimate destination. This approach has been very effective in ensuring service to healthcare facilities located in remote regions of Canada.
- **Comprehensive supply chain management.** Medical device manufacturers can rely on Purolator as their comprehensive supply chain expert. Purolator will build a logistics strategy for each company that solves distribution and transportation needs and addresses the unique requirements of the healthcare industry.
- **Convenient pickup options** ensure healthcare workers have on-time access to the products needed for each day's schedule of patients.
  - Hold for Pickup services ensure healthcare professionals will have access to required supplies by 7:30am, with materials delivered overnight to a convenient Purolator access point.
- **Technology-based solutions** for the highest levels of automation and efficiency:
  - Enhanced tracking/traceability capabilities via Purolator E-Ship Web Services.
  - Automated inventory capability serves as a "control tower" in keeping tabs on the multiple locations in which device inventories tend to be located – places including hospital supply closets, fulfilment/kitting centres, and even sales rep vehicles.
  - Easy integration of device makers' data to ensure accurate and fast label generation and account management.

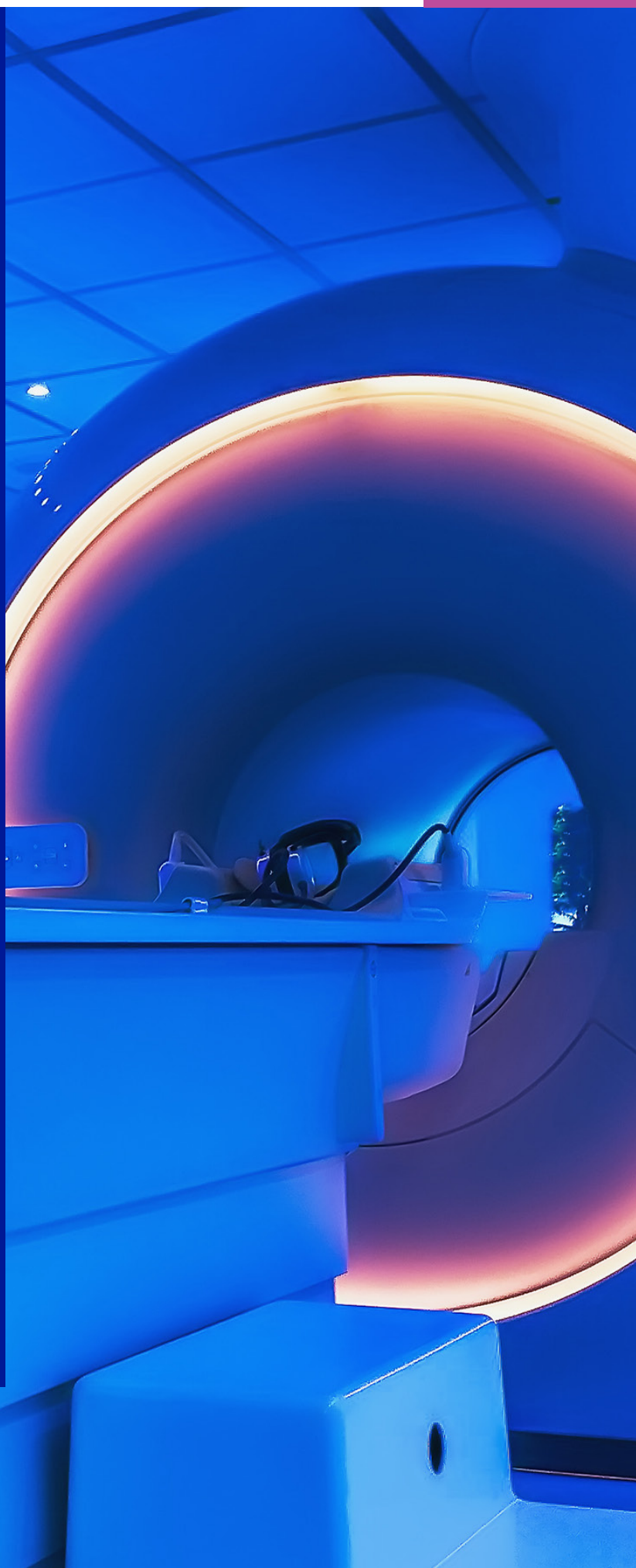
Learn more about our suite of healthcare solutions

Purolator has the ideal solution for every shipping need – even if we have to build the solution just for you!

Our extensive healthcare services include:

- Time-Definite Services for shipments that must arrive by a certain time.
- Dangerous Goods protocols and procedures for sensitive shipments.
- Digital Healthcare Indicator that prioritizes the needs of healthcare shipments from the moment they enter the Purolator network.
- Chain of Signature captures all required signatures as shipments move through the transit process.
- Special Handling for products that don't meet regular package specifications.
- Mobile App tracking allows 24/7 status updates from the convenience of a mobile device.
- Adult Signature captures for designated packages.
- Inside deliveries that accommodate surgical centre and other health facility requirements.
- Last Mile Services that provide peace of mind that medical supplies will arrive on time, undamaged, and with the highest levels of efficiency.

Read more about our capabilities for healthcare-related shipments

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Conclusion

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Among the many "lessons learned" from the COVID-19 pandemic, is the need for countries to reduce reliance on single-source providers of essential products. As the world came to learn, China is the leading source of supplies including ventilators, masks, gowns, and pharmaceuticals. When China's production and supply chains came to a screeching halt, many countries voted "never again," and initiated steps to expand supplier networks or improve domestic production capabilities.

As Medtech Canada made clear in its post-pandemic analysis, there will always be an important role for U.S. manufacturers in Canada's healthcare industry. Perhaps now more than ever, U.S. companies have an opportunity to enter the Canadian market or, to expand an already-established presence. But critical to success, will be a logistics strategy that ensures on-time deliveries across Canada, and takes into account the unique needs of the healthcare industry.

Trust Purolator for Innovative Medical Device Cross-Border Solutions

Learn more about our portfolio of solutions, which provide the flexibility and capabilities needed for success in today's changing healthcare industry

Contact us

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Promises delivered™

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