PRI-TECH PRIMER: What health technology innovators should know

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Draft for Review

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DISCLAIMER

- This is a summary of legal information available from a variety of authoritative online sources: Make sure to review the source documents and check for any updates before relying on this information
- This document does not cover all areas of the law, such as product liability or consumer protection law
- This document should not be considered legal advice – innovators are advised to seek their own legal advice regarding the application of the law to their own particular situation and unique medical device

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Introduction

The policy and regulatory landscape in Canada is complicated and can be challenging for health technology innovators to successfully navigate through. This manual outlines the policy and regulatory processes related to health technology innovation, and provides innovators with an understanding of the work involved in taking an innovation from the research and development stage to the point of adoption and reimbursement.

The process of innovation consists of several overlapping and interconnected phases. This manual is broken into five chapters, each describing one phase of the innovation process. Each chapter outlines the specific details and processes involved in that particular phase.

Health technologies include pharmaceuticals, devices, diagnostics, procedures and other clinical, public health and organizational interventions[1]

Medical devices as defined in the *Food and Drugs Act*, covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition[2]

Research and Development

The innovation process generally begins with research and development of an innovation. Research should inform the innovator about the problem, existing solutions and the target population, or end-user. The initial research should show evidence in support of the clinical effectiveness of the innovation. This research may be necessary for obtaining regulatory licences and approval. The research and development phase continues throughout the entire innovation process to ensure that the product remains competitive with similar innovations, and maintains end-user interest.

Regulatory approval by Health Canada

It is important to determine whether or not the health technology will be considered a 'medical device' early in the innovation process. In Canada, health technologies that are considered 'medical devices' under the Food and Drugs Act, Medical Device Regulations, must be licensed by Health Canada. In order to obtain a medical device license, innovators must submit an application to Health Canada containing the evidence obtained from the research phase, along with application documentation. This manual will help innovators determine if their technology requires a medical device license in Canada.

[1] HTAi. (2015). What is HTA. In *Health Technology Assessment International*. Retrieved October 13, 2016, from http://www.htai.org/htai/what-is-hta.html

[2] Health Canada. (2012). Medical Devices. In *Health Canada - Drugs and Health Products*. Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php

Health Technology Assessment

Health Technology Assessment is a process in which the technology is evaluated for social, economic, organizational and ethical issues in order to inform policy decisions. Health Technology Assessment requires evidence on the therapeutic and cost effectiveness of the device. The outcome of the HTA process is used to inform hospitals, regional health authorities, provincial programs such as the Assistive Devices Program in Ontario, Alberta's Aids to Daily Living Program (AADL), BC's PharmaCare Prosthetic and Orthotic Program, or Quebec's Régie de l'assurance maladie du Québec (RAMQ) and third party payers about the technology, allowing them to determine whether or not the device will be reimbursed.

Reimbursement/Procurement

If the device is reimbursed decisions around procurement and adoption can be made. In the procurement and adoption phase, group purchasing arrangements are made by Shared Service Organizations (SSOs) or provincial level Group Purchasing Organizations (GPOs). Alternatively, regional health authorities, government initiatives, research facilities, teaching hospitals and health care practitioners may provide smaller scale procurement initiatives.

Note:

If the device is not categorized as a medical device, it is not necessary to undergo the regulatory process. In addition, many medical devices and health technologies will not undergo HTA. If these phases are not undergone, the commercialization and marketing of the device may require greater efforts and resources at the expense of the innovators. For these devices, reimbursement will also be different. Regional Health Authorities, provincial programs and Hospitals will likely not reimburse the product. As a result, third party and private payers will have to be explored as a funding option.

Research and Development

Looking Ahead

The research and development phase is the first step in the innovation process. However, this phase often continues throughout the entire process in order to provide current evidence for clinical and cost effectiveness over other new innovations. Continuing this phase throughout the process will enhance the development of the innovation to better align with evolving end-user preferences. In order to facilitate smooth transitions through the innovation process it is important to look ahead, while working through the research and development phase. Innovators in the research and development phase should consider the following:

- Would this technology qualify as a medical device?
- Who is the target end-user?
- How will this device be marketed, and who will it be marketed to?
- How will end-users inform development of the technology?
- What reimbursement opportunities exist for this technology?

During this phase, innovators may begin gathering evidence to support their innovation in the application for a Health Canada Medical Device license (if applicable), Health Technology Assessment, and/or reimbursement opportunities. This evidence generation is called pre-market testing. Before completing the pre-market testing, it is important for innovators to determine what evidence they will need. The evidence needed depends on the process that the innovators intend to take, whether or not their device classifies as a medical device and needs a license, whether they will need to undergo a Health Technology Assessment and what reimbursement opportunities are available to them. For more information specific to these processes, refer to the appropriate section in the manual.

Financing

Many innovations are launched, but few are successfully turned into commercial products and diffused across the health system more broadly.[3] This may be partly due to insufficient funding for health technology innovators, especially those that are not identified as a company. Most funding opportunities are explicitly available for health technology or medical device companies, not for research institutions or independent innovators.

Small, independent companies tend to look for partnerships with venture capital firms, universities and hospitals to provide access to capital. However, these partnerships can be difficult to find because clinical centers are bureaucratic and hard to navigate. Without partnerships, it is hard to access external government research and development (R&D) funding

[3] Ontario Ministry of Research and Innovation. (2015). *Seizing Global Opportunities: Ontario's Innovation Agenda*. Retrieved October 13, 2016, from https://www.ontario.ca/page/seizing-global-opportunities-ontarios-innovation-agenda

which is concentrated in universities.[4] Even university-based innovators face challenges. Government-owned and operated R&D capacities are mainly engaged in non-commercially-oriented research activities, and moving an innovation past the development phase is not seen as a priority within the scope of the funded project.[5] One alternative to this problem is for innovators to partner with small and medium-sized enterprises (SMEs). However, SMEs are often unwilling to partner with universities as they have limited investment ability.[6] In addition, SMEs do not have the capacity to conduct R&D needed to commercialize their ideas and really grow their business.[5] For that reason, SMEs often overlook health technology innovations. Even with business mentorship services and clinical feedback, innovators in Ontario have few options for accessing seed capital required for prototype development, refinement, and commercialization.[7]

Despite these challenges, health technology innovators should investigate all possible funding opportunities. To assist innovators in their search for relevant funding opportunities, a website called Funding Portal provides a comprehensive list of available government grants, tax credits, industrial incentives, and other contributions, including private financing or investment.

The Funding Portal aggregates data on over 15 000 sources of government and private funding in Canada. A search tool uses this data to generate matches between companies and optimal funding programs. This tool will identify and rank funds based on the particular needs of the innovator (e.g. type of organization, industry sector, amount, and geographic location).[8]

Potential additional funding opportunities for innovators are outlined in the table below.

Award	Description	Requirements	Amount
AGE-WELL Catalyst Program[9]	Funds projects in a specific theme area for one-year to support the generation, promotion or acceleration of economic and social benefit in technology and aging.	The competition is open to investigators based at Canadian institutions working in the field of technology and aging. Canadian universities and investigators who are not already members of the	$35,000 - $50,000

[4] Snowdon, A., Zur, R., Shell, J. (2011). Transforming Canada into a Global Centre for Medical Device Innovation and Adoption [white paper]. Retrieved from http://sites.ivey.ca/healthinnovation/thought-leadership/white-papers/transforming-canada-into-a-global-centre-for-medical-device-innovation-and-adoption-june-2011/

[5] Tesfayohannes, M. (2007). The role of federal government funding on the outreach programs of independent industrial R&D establishments in Canada. *Journal of Manufacturing Technology Management*, *18*(4), 461-478. http://dx.doi.org/10.1108/17410380710743815

[6] Bubela, T. M., & Caulfield, T. (2010). Role and reality: technology transfer at Canadian universities. *Trends in biotechnology*, *28*(9), 447-451. doi: 10.1016/j.tibtech.2010.06.002

[7] Conference Board of Canada. (2007). Exploring Technological Innovation in Health Systems, Centre for Health Care and Innovation.

[8] The Funding Portal Inc. (2016). About Funding Portal. In *Funding Portal*. Retrieved October 13, 2016, from https://fundingportal.com/tfportal/About

[9] AGE-WELL NCE. (2016). 2016 Catalyst Funding Program. In *AGE-WELL: Canada's Technology and Aging Network*. Retrieved October 13, 2016, from http://agewell-nce.ca/research/2016-catalyst-funding-program

		AGE-WELL network will be required to sign onto the Network Agreement prior to receiving funds. The applicant's host institution must be eligible to hold Tri-Council funding. Catalyst funds cannot be used for activities funded through other AGE-WELL competitions (e.g. activities that are part of Core Research Projects).	
HTX Resources for Evaluating, Adopting and Capitalizing on Innovative Health Technology (REACH)[10]	The goal of REACH is to help Ontario public healthcare delivery organizations use new ways to evaluate, procure and more rapidly adopt beneficial medical technologies addressing high-priority health system problems	This is a matching grant funding program managed by the Health Technology Exchange (HTX), with support from the Government of Ontario. REACH is a 3.5-year program targeting late pre-market, early post-market, pre-diffusion technologies where procurement and local evidence are challenges. Projects must be led by public healthcare delivery organizations (the "Lead Applicants").	50% matching grant funds, ranging from $300,000 - $600,000, with exceptions up to $1,000,000.
Canadian Foundation for Healthcare Improvement (CFHI)[11]	CFHI plays a unique, pan-Canadian role in supporting healthcare delivery innovation. By supporting organizations across Canada to lead, implement and spread evidence-informed, patient-centred solutions, we accelerate	Varies by project.	Varies by project

[10] HTX: The Health Technology Exchange. (2015). REACH. In *HTX*. Retrieved from http://www.htx.ca/content/what-is-reach

[11] Canadian Foundation for Healthcare Improvement (CFHI). (2016). What We Do. In *Canadian Foundation for Healthcare Improvement*. Retrieved from http://www.cfhi-fcass.ca/WhatWeDo.aspx

	improvements in health and care. We can help you implement the change you need – using appropriate evidence, engaging providers, patients and families, and evaluating and measuring performance – to address your organization's pressing challenges.		
Epic Capitol Management[12]	The Epic Canadian Healthcare Funds are positioned to invest in unique private Canadian healthcare companies on the verge of rapid growth. The funds will focus on Medical Technology companies that have the potential for industry disruption and that can truly improve healthcare delivery globally.	Companies with scalable, non-replicable products/services protected with IP.	The composition of the funds will resemble the venture capital model. The overall strategy of the fund should be considered aggressive for portfolio purposes.
Alberta Innovates Technology Futures[13]	Provides millions of dollars for health research and innovation activities that enhance the effectiveness and efficiency of the health system, improving health outcomes and ensuring research translates into innovative technologies, tools and policies.	Funding varies by project. Search their website for available opportunities.	

[12] EPIC Capital Management Inc. (2014). EPIC Funds. In *EPIC Capital Management Inc*. Retrieved from http://epiccapitalmanagement.ca/epic-healthcare-fund/

[13] Alberta Innovates Technology Futures. (n.d.). About Tech Futures. Retrieved October 13, 2016, from: http://www.albertatechfutures.ca/Corporate/AboutTechFutures.aspx

New Ventures BC[14]	Provides a competition for start-up funding to groups hoping to develop and commercialize an innovative technology	See their website for competition rules and timelines.	The largest and longest running tech competition in British Columbia, offering over $300 000 in cash and prizes
Health Technologies Fund[15]	The Health Technologies Fund (HTF) supports the development of made-in-Ontario health technologies by accelerating evaluation, procurement, adoption and diffusion in the Ontario health system. The fund is part of the Office of the Chief Health Innovation Strategist's mandate to strengthen Ontario's innovation ecosystem.	See website for details on the requirements.	Stream 1: Prototype up to $100K (up to 2 years) Stream 2: Pre-Market Evaluations up to $500K (up to 2 years) Stream 3: Early Adoption up to $500K (up to 2 years)

Incentives

There may be tax credits applicable to your particular medical device company, depending on the province you operate in. Provincial tax credits range from the base credit of 10% in Ontario and British Columbia, to 15% in Newfoundland and Labrador, Nova Scotia, New Brunswick, and Saskatchewan. Ontario has a higher tax credit for companies contracting with business research institutes (20% versus the base credit of 10%) and Quebec has a higher tax credit for companies contracting with universities (28%). Quebec also offers medical device companies a credit on salaries of 35%. Additionally, a federal tax credit offers medical device companies a 35% credit on their first $2 million in revenue, and a 20% tax credit for remaining expenditures.[4]

[14] New Ventures BC (n.d.) Competition Format. In *New Ventures BC*, Retrieved October 13, 2016, from: http://www.newventuresbc.com/

[15] Ontario Centres of Excellence. (2016). *Health Technologies Fund*. Retrieved October 13, 2016, from http://www.oce-ontario.org/programs/commercialization-programs/health-technologies-fund

Licensing/Regulatory Approval

NOT ALL PRODUCTS USED TO PROMOTE THE WELL-BEING OF INDIVIDUALS WILL FALL UNDER THE JURISDICTION OF HEALTH CANADA.

IT IS IMPORTANT TO DETERMINE IF YOUR PRODUCT IS A "MEDICAL DEVICE" UNDER THE *FOOD AND DRUGS ACT*, MEDICAL DEVICE REGULATIONS (MDRS).

NOT ALL AGE-WELL TECHNOLOGIES WILL FIT THE DEFINITION OF A "MEDICAL DEVICE" – TECHNOLOGIES THAT ARE NOT MEDICAL DEVICES WILL NOT NEED HEALTH CANADA REGULATORY APPROVAL AND **SHOULD NOT** SUBMIT AN APPLICATION TO HEALTH CANADA.

STEP 1: Is your product a "medical device" under the *Food and Drugs Act*, Medical Device Regulations (MDRs)?

In order to distinguish between products that need to be regulated as medical devices by Health Canada and those that can be regulated as general consumer products, we must look to the definition of a "medical device" under the regulating law.

The governing regulations are the Medical Devices Regulations (SOR/98-282), which were created under the authority of Canada's *Food and Drugs Act*, RS 1985, c.F-27 (the "Act"). If a device does not fall under the definition of a "medical device", Health Canada does not have the statutory authority to regulate that product. Any application that does not meet the qualifications for licensing under the Act will be rejected by Health Canada.

Definitions

A "medical device" under the Medical Devices Regulations is defined as a "device" within the meaning of Canada's *Food and Drugs Act*, but does not include a device that is intended for use in relation to animals.

"Device" under the *Food and Drugs Act* means any instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in the identified medical purposes.

Identified Medical Purposes

1. diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,
2. restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,
3. diagnosing pregnancy in human beings or animals,
4. caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or
5. preventing conception in human beings or animals

Devices are excluded from the above description if those actions are done solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.

Whether a product is a "medical device" depends on the *intended* use for the product. Health Canada regulates any devices manufacturers label as intended for, or represented for, the indicated medical uses defined under the Food and Drugs Act. If the intended or represented use of the device is for one or more of the medical purposes indicated in the above definition, the device qualifies as a medical device.

For example, if a new device using an existing GPS technology is manufactured, sold or represented (through marketing, packaging claims, or otherwise labelled) for use in mitigating the symptoms of dementia, the technology may fall under Health Canada regulations. In contrast, if a new device using GPS technology is not intended or represented for any medical use, but rather helps all seniors with location finding, it would not necessarily fall under Health Canada regulations and licensing. This would be the case even if certain patients with dementia later decide to use the existing GPS technology to help with their own location monitoring.

Nonetheless, if there is a risk that patients will use non-regulated devices for medical purposes, the necessary warnings should be attached about appropriate use. It is extremely important to monitor and mitigate how your product's intended use is being "represented" both pre- and post-market, and ensure your labeling is in compliance with any relevant regulations.

If at any point, even after distribution begins, that there is a stated intention to manufacture, market, or customize a device for one of the above medical purposes, Health Canada *must* be notified. The purpose of enhanced regulation on these types of products is so that a person suffering from an ailment and relying on a particular product to alleviate that ailment has assurance from Parliament that their reliance is not misplaced or inappropriate.

Software

Software can also be considered a "medical device" if it meets the same description under the Act: software that is intended or represented to be used for one or more of the medical purposes set out in the definition of a device. Examples of software that do not meet the definition of "medical device" include:

- Applications that perform administrative calculations and manipulations (like determining time between appointments, workflow management)
- Wii Fit video game
- Personal BMI calculators
- Pedometer software used for fitness[16] (like the Fitbit)

On the other hand, any software involved in data manipulation, data analysis, data editing, image generation, determination of measurements, identification of a region of interest in an image, or identification (through an alarm/alert) of results from a monitor that are outside of an established range, is considered an "active diagnostic device". Therefore, the manufacturer of that software would be responsible for holding a medical device licence.

Prevention

Note that none of the listed medical purposes, like "prevention" or "mitigation", are defined within the Act. Therefore, each term should be construed broadly and in accordance with generally accepted definitions held by experts in the appropriate fields.

Health Canada, for example, does not explicitly exclude any type of prevention. Therefore, devices intended to be used in primary prevention (preventing the initial development of the disease), secondary prevention (activities aimed at early detection), and tertiary prevention (reducing or minimizing the impact of existing diseases) may all be covered under Health Canada's authority.

STEP 2: What class is your medical device?

If your device fits the definition of a "medical device" under the Medical Devices Regulations, you must then identify which class your product falls under (Class I, II, III, or IV), by determining the appropriate risk classification. This will determine what type of application is needed. For example, if your medical device is a low risk device (Class I), you will not need a Medical Device Licence (MDL). You will however need a Medical Device Establishment Licence (MDEL) to sell your medical device as a manufacturer. The licence you need depends on both your risk classifications and your activities (see Step 3).

[16] Health Canada. (2016). *Notice: Software regulated as a Class I or Class II Medical Device*. Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_notice_software_im_avis_logicels-eng.php

The risk classification rules for non-IVDD (non- in vitro diagnostic devices) medical devices can be grouped into four sets: Invasive Devices, Non-invasive Devices, Active Devices (devices that need an electrical charge to function), and Special Rules that apply regardless of the other rules. It is important to review all of the rules in the event that your device falls under more than one category: the highest possible classification will determine your medical device class.

A step-by-step guide for classifying your device follows further in this document: both an outline and detailed steps are provided.

Classification of your device is crucial to the licensing process because it determines whether you have to get a medical device licence at all. It also indicates the number of regulatory submissions required as part of your application, and level of review that is involved.

Class I medical devices do not have a medical device licence requirement and are not subject to pre-market review (only needing an MDEL), while Class II-IV medical devices do have a medical device licence requirement. Class II devices are licensed by attestation of safety and effectiveness by the manufacturer, while Class III and IV medical devices undergo pre-market review and generally involve the intervention of a practitioner.[17] In general, the application for Class II devices is administrative in nature, while applications for class III devices are based on the submission of summary documents. Applications for class IV devices are based on more extensive data, including study reports, quality plan, and risk assessments. More details about the requirements can be found below, as well as within each respective Health Canada application form.

STEP 3: What are your intended activities? (Are you a manufacturer, importer or distributor?)

Are you a manufacturer, distributor/seller, or importer, of an unlicensed or licensed medical device? Is your name listed on the label as the manufacturer? The answers to these questions will help determine whether you need a Medical Device Licence or whether you need a Medical Device Establishment Licence.

17 MaRS (2012). *Healthcare product development: Study protocols, reports and amendments.* Retrieved October 13, 2016, from: https://www.marsdd.com/mars-library/healthcare-product-development-study-protocols-reports-and-amendments/

- *Importers, distributors and listed manufacturers* of **Class I** medical devices require an MDEL to operate in Canada (unless selling through a licensed importer/distributor). This is necessary for the government to assure the identity of medical device distributors and manufacturers of Class I medical devices, and to assure that the necessary regulatory requirements are being met.
- *Distributors* of **Class I** medical devices do not need an MDEL if the importer already has an MDEL.
- *Listed manufacturers* of **Class II, III, and/or IV** medical devices require an MDL (but not an MDEL) to distribute in Canada.

Manufacturer: "a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf." - *Medical Device Regulations*

STEP 4: Alternatives: Do you fall into an alternative application process? (Special Access Programme, Investigational Testing, Private Label Medical Device)

Special Access Programme (SAP)

If you are a medical professional, you may qualify for the Special Access Programme.[18] Health Canada's Special Access Programme (SAP) allows doctors to gain access to medical devices not yet approved for sale in Canada (through importation or sale in Canada) or custom-made devices. Special Access can only be requested by medical professionals (and not medical device companies) in emergency use cases or when conventional therapies have failed, are unavailable or unsuitable to treat a patient.

Health care professionals must be licensed to practice in Canada in order to apply for Special Access authorization. They can apply to the Medical Devices Bureau (MDB) to import and/or sell a Class II, III, or IV medical device, or a Class III or IV custom-made device, provided that the device is not already licensed for sale in Canada, and that the application satisfies the criteria set out under the Regulations.

Investigational Testing

If you only want to sell a medical device for the purpose of investigational testing on humans, with a patient's informed consent, you can apply to Health Canada for approval to do so.[19]

[18] Health Canada. (2016). *Medical Devices – Special Access Programme*. Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/acces/md-im/index-eng.php.

[19] Health Canada. (2015). *Preparation of an Application for Investigational Testing – Medical Devices*. Retrieved October 13, 2016 from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_ita_im_ld_aee-eng.php

Private Label Medical Device

If you are a person who sells a medical device under your own name or trademark, but the medical device is identical in every way to a medical device that is already licensed, you must apply for a Private Label Medical Device licence.[20] This can be done only after an MDL has been issued to the original manufacturer.

STEP 5: Based on Steps 2-4: Determine the appropriate application forms and fees to submit to Health Canada

Given the above, determine what the appropriate form and fees are for your medical device.[21]

Complete the application form for a Medical Device Establishment Licence (MDEL)[22], or a **Medical Device Licence (MDL)**[23]:

Pay the appropriate fees

For the appropriate MDL fees, refer to the MDL Application Fee Form and Guidance document on Cost Recovery - Fees for the Review of Medical Device Licence Applications. An indication of the appropriate fees depends on medical device classification.

Detailed Fee Outline[24]

Fee Category	Notes	Fee as of April 1, 2016
Class I – Medical Devices Establishment Licence (MDEL)*	Your establishment may qualify for a fee remission.**	$7,794 (without fee remission)
Class II – New Medical Device Licence (MDL) Application	Your establishment may qualify for a fee remission or deferred payment.***	$389
Class III – New MDL Application	Your establishment may qualify for a fee remission or deferred payment.****	$5,579
Class IV – New MDL Application	Clinical studies required. Your establishment may qualify for a fee remission or deferred payment.****	$12,975

* The following are exempt from holding an MDEL: a retailer; a healthcare facility; a manufacturer of Class II, III or IV medical devices that only sells (i) medical devices for which they hold a valid licence, or (ii) medical devices subject to Parts 2 and 3 of the *Medical Devices Regulations;* a manufacturer of a Class I medical device that imports or distributes solely through a licensed establishment; a person solely selling medical devices subject to Parts 2 and 3 of the Regulations; and a dispenser.

[20] Health Canada (2011). *Guidance Document – Private Label Medical Devices.* Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/label_marque_pri-eng.php

[21] Health Canada (2016). Forms. In *Drugs and Health Products.* Retrieved October 13, 2016, fromhttp://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/index-eng.php.

[22] Health Canada. (2013). Medical Device Establishment Licence Application: Form and Instructions (FRM-0292). Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/form/frm-0292-eng.php

[23] Health Canada. (2015). *Guidance Document – How to Complete the Application for a New Medical Device Licence*. Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_licapp_im_ld_demhom-eng.php

[24] Health Canada. (2016). Medical Device Licence Application Review Fees as of April 1, 2016. Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/finance/fees-frais/mdlae_edhim-eng.php

** Access the MDEL fee calculation chart at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/calcul-chart_md-im-eng.php , print the result (a PDF is created with form completion) and submit along with your MDEL application. Note that if you'd like to be considered for a Fee Remission, select "yes" on this form and include a Certified Statement of Revenue – the maximum fee allowed is 1% of gross revenues for last calendar year.

*** Detailed information on possible remissions (for example, where fees for your application or amendment application are greater than 2.5% of actual gross revenue from the medical device during the fee verification period) or deferred payment option (if not yet completed first fiscal year) can be found at: http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/guidedoc_feesmd_docorient_fraisim-eng.php

**** Notice: Software regulated as a Class I or Class II Medical Device: http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_notice_software_im_avis_logicels-eng.php

Be sure to consult the most recent MDL Application Fee Form[21] for full fee information. For further information on the applicable fees, refer to the Guidance Document - Fees for the Review of Medical Device Licence Applications.

STEP 6: Review Process: Target review times are 15-90 days depending on the device Class

Health Canada review stages are as follows:

1. Administrative completeness
2. Application validation (validity of regulatory information for the type of application in question)
3. Screening for technical completeness
4. Comprehensive review

Your response time will depend on the risk classification of your device and the complexity of your application. The target timelines stated by Health Canada by Class are:

- Class II – 15 days
- Class III – 75 days
- Class IV – 90 days

In practice, these timelines may not be met and can vary depending on the device.[25]

STEP 7: Receive Response / Licence Issued

Health Canada may approve your application and issue a licence, or ask you for more information. For guidance on the review process, see Management of Applications for Medical Device Licences and Investigational Testing Authorizations.

If your application was not approved at some point throughout the review process, you also have the following options:

- Appeal the decision[26]

[25] Health Canada. (2009). *Interim target performance standards for management of applications for medical device licences and investigational testing authorizations.* Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pol/mdlapp_demhim_pol-eng.php#Attachment1

[26] Health Canada. (2009). Appeal Procedures. In *Management of Applications for Medical Device Licences and Investigational Testing Authorizations.* Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pol/mdlapp_demhim_pol-eng.php#a12

- Resubmit your application with additional information – be sure to check the appropriate response deadlines[27], as missing a deadline to supply additional information will often mean a rejection letter.

STEP 8: Compliance: ensure your device remains safe and effective

Compliance and Enforcement is undertaken by the Health Products and Food Branch Inspectorate. [28] If a device is found to be no longer safe and effective, the licence can be suspended, and/or the manufacturer may be requested to recall or refit the device.

Recent Bill C-17 amendments to the *Food and Drugs Act* have given the Minister increased powers when a safety issue is identified.[29] This includes ordering the company to carry out a mandatory recall of the medical device or perform additional tests. The amendments also create an obligation on healthcare institutions to report medical device incidents to the Minister of Health. Currently, a reportable medical device incident is defined as an incident, where a device contributed to that incident, leading to one of the following outcomes:

- Death of a patient, user, or other person (report within 10 days)
- Serious deterioration in health of a patient, user, or other person (report within 10 days)
- Potential for death or serious deterioration in health of a patient, user, or other person (report within 30 days)

Section 59 of the Medical Device Regulations provides details about the process of "Mandatory Problem Reporting":

> *Mandatory Problem Reporting*
>
> 59. (1) Subject to subsection (2), the manufacturer and the importer of a medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring inside or outside Canada and involving a device that is sold in Canada and that
>
> (*a*) is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its the directions for use; and
>
> (*b*) has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur.
>
> (2) The requirement to report an incident that occurs outside Canada does not apply unless the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action, or unless the regulatory agency has required the manufacturer to take corrective action.

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[27] Health Canada (2009). Management of Applications for Medical Device Licences and Investigational Testing Authorizations. Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pol/mdlapp_demhim_pol-eng.php

[28] Health Canada (2015). Guidance on Medical Device Compliance and Enforcement (GUI-0073). Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/gui-0073-eng.php

[29] Health Canada. (2015). Amendments to the *Food and Drugs Act*: Guide to New Authorities (power to require and disclose information, power to order a label change and power to order a recall). Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-amendments-modifications-eng.php

For further information on the interpretation of the above terms and some examples of reportable medical device incidents, review Health Canada's Mandatory Problem Reporting Guidance Document.

Health Canada's website urges consumers that experience adverse events to contact their health professional or local health authority.

Recalls and advisories can be found here: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php

STEP 9: Renew your licence annually

Medical Device Establishment Licence (MDEL)

Medical Device Establishment Licences no longer expire (as of April 1, 2011) but you must submit a completed Annual Review application by April 1 of each year. To do this, submit the same MDEL Application Form 0292, indicating the reason for the application ("annual review") and noting any changes. Note that you must submit this form each year even if there are no changes to your licence. Your licence remains valid as long as you submit this application before the deadline each year.

The fee for the review of an annual review MDEL application was most recently $7,641 (increasing 2% each year), but some establishments may be eligible for a reduced fee (be sure to consult fee remission). The fee is due with the application.

Medical Device Licence (MDL)

You must renew your Medical Device Licence annually.[30] In order to have the right to sell Class II, III, and IV medical devices, you will be invoiced (in February) for an annual fee, payable at the time of licence renewal. Manufacturers who have not completed their first calendar year of selling their medical device in Canada will have their fee deferred and have the right to sell that device to the end of that year.

You may qualify for a reduced fee by submitting a Reduced Fee Request and Certification Form with your renewal, certifying that the AGR from the medical device sales is less than $20,000 before January 20th of the first renewal year.

STEP 10: Report any important changes to your medical device or the manufacturing process

Have you made any important changes to the medical device or the manufacturing process? You may need to apply to modify your MDL. Read Health Canada's guidance on the

[30] Health Canada. (2013). Guidance Document - Medical Device Licence Renewal and Fees for the Right to Sell Licensed Medical Devices. Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_licren_mm_homren-eng.php

interpretation of a “significant change” of a medical device to determine if your change requires additional submissions.[31]

The Medical Device Regulations define a “significant change” as “a change that could reasonably be expected to affect the safety or effectiveness of a medical device”. It includes a change to any of the following:

(*a*) the manufacturing process, facility or equipment;

(*b*) the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture;

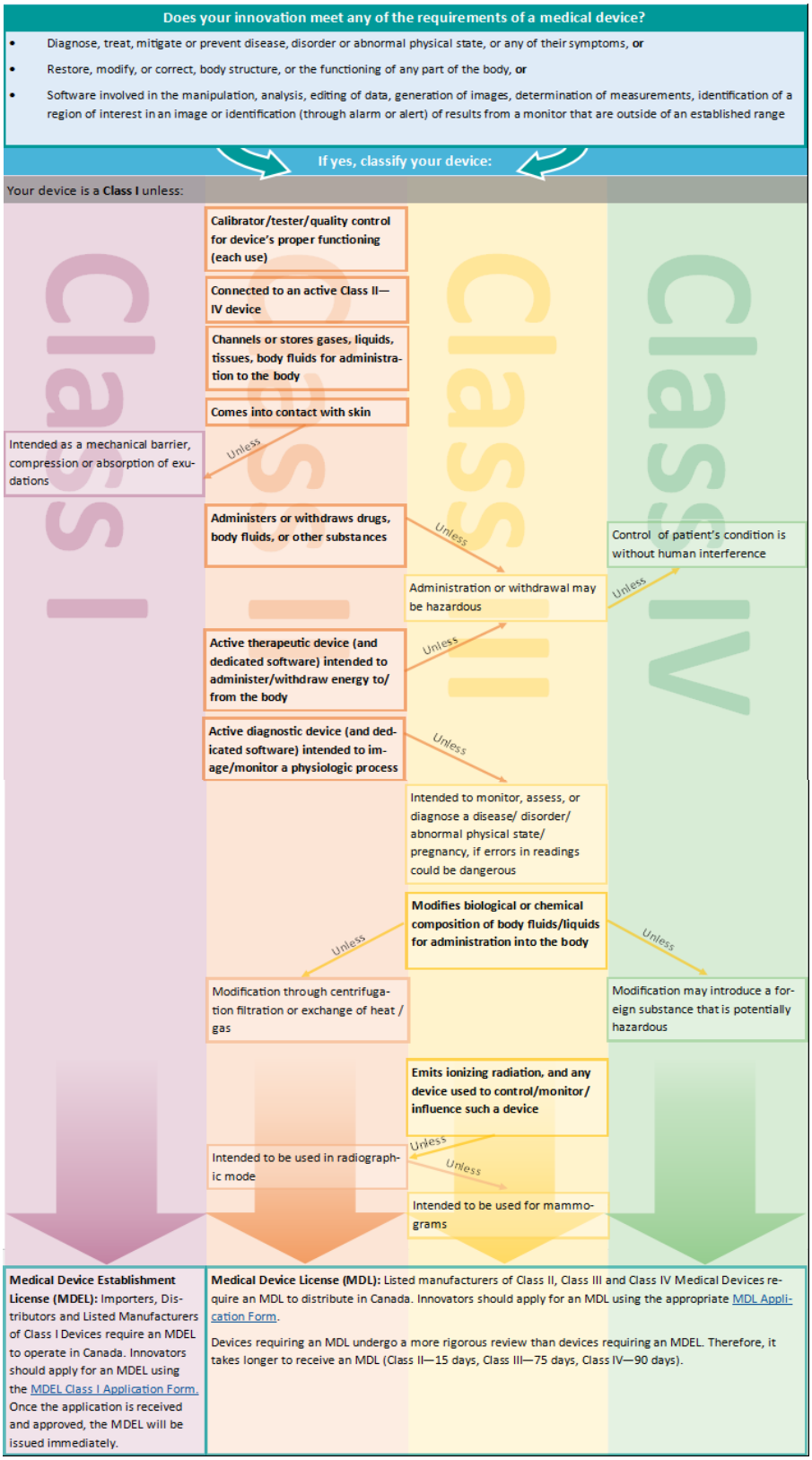
(*c*) the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and

(*d*) the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication for the device and any change to the period used to establish its expiry date.

For further information, consult Health Canada’s Medical Device Guidance Documents.

[31] Health Canada. (2011). Guidance for the Interpretation of Significant Change of a Medical Device. Retrieved October 13, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/signchng_modimportante-eng.php

Classification of Risk- Overview



Classification of Risk – Detailed Guide

You must determine which classification your device falls under prior to submitting your application. The above outline can be the first step in determining which class your device may fall into. Detailed review of risk classification criteria, along with expert consultations, is recommended.

Health Canada's "Guidance Document - Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs)" was created to provide assistance to industry and health care professional on how to comply with the governing statutes and regulations (see the Appendix of this document for Health Canada's description of the rules). Health Canada notes that their guide is one way to interpret the regulations – alternative approaches may be acceptable if they are supported by adequate justifications, and should be discussed in advance with the relevant program area.

Rules for non-IVDD medical devices

1. **Invasive Devices (Rules 1 - 3)**
2. **Non-invasive Devices (Rules 4 - 7)**
3. **Active Devices (Rules 8 - 12)**
4. **Special Rules (Rules 13 - 16)**

You must first determine if your device is subject to the Special Rules (Rules 13-16). If not, you should determine whether device is:

- Invasive (Rules 1-3)
- Non-invasive (Rules 4-7)
- Active (Rules 8-12)

Your device may fall into more than one category. Make sure to check all the rules to find the highest classification possible. If more than one rule applies (i.e. both non-invasive and active) the rule that assigns the higher risk determines the final classification. Also note that the manufacturer's "intended" use of the device will determine the risk category.

Special Rules

- Breast implants or tissue expanders for breast reconstruction and augmentation – always Class IV (Rule 16)
- Material sold to provide for the configuration/arrangement of an individualized shape or mould – same class that the finished medical device falls under (Rule 15)
- Intended to be used to: disinfect or sterilize blood, tissues or organs intended for transfusion or transplantation – Class IV (Rule 13)
  - Intended to be used to disinfect or sterilize a medical Device – Class II (Rule 13)
- Manufactured using animal or human cells or tissues or their derivatives or produced through the use of recombinant DNA technology – Class IV (Rule 14)

- Unless only intended to come into contact with *intact* skin (example leather strap) – Class I (Rule 14)

Invasive Devices

- Special Rules for Invasive Devices: Despite Rules 1 and 2,
  - All denture materials and orthodontic appliances, and their accessories - Class II (Rule 3)
  - All surgical or dental instruments - Class I (Rule 3)
  - All latex condoms - Class II (Rule 3)
- All surgically invasive devices – Class II (Rule 1)
  - Unless:
    - Intended to be absorbed by the body – Class III (Rule 1)
    - Long term (30+ days) surgically invasive – Class III (Rule 1)
    - Intended to diagnose, monitor, control, or correct a defect of the CVS/CNS or fetus *in utero* – Class IV (Rule 1)
    - All surgical or dental instruments – Class I (Rule 3) – Reduced risk only if:
      - It is intended for use during a surgical or dental procedure and is generally not an accessory to another medical device (e.g., orthopedic implant trial);
      - It is reusable [that is (i.e.), not disposable/single use];
      - It is not connected to an active/powered device; and
      - It is intended to be used to perform one of the following actions: cutting, drilling, sawing, scraping, clamping, hammering, puncturing, dilating, retracting or clipping.
    - (All other surgical or dental use instruments are likely Class II (Rule 1 or 2))
- All devices invasive via a body orifice or come into contact with the surface of the eye – Class II (Rule 2) (examples – contact lens, surgical glove)
  - Unless:
    - Placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum – Class I (Rule 2) – Reduced risk (example – manual toothbrush)
      - Except: All denture materials and orthodontic appliances and their accessories – Class II (Rule 3)
    - Long term (30+ days) invasive – Class III (Rule 2) (example – IUD)
      - Except: All denture materials and orthodontic appliances and their accessories – Class II (Rule 3)
    - Intended to prevent the transmission of infectious agents during sexual activities or reducing the risk thereof – Class III (Rule 2)
      - Except: All latex condoms – Class II (Rule 3)

Non-Invasive Devices

- All non-invasive devices are **Class I** (Rule 7) (e.g., mechanical hospital bed, mechanical wheelchair, hand splint) unless intended to:

- Act as a calibrator, tester, or quality control support to another medical device prior to/during *each use* of the device to ensure proper functioning (as opposed to repair/periodic maintenance) – Class II (Rule 7) (note: no physical contact with patient or only with intact skin)
- Connect to an *active* device classified as Class II, III, or IV – Class II (Rule 7) (note: no physical contact with patient or only with intact skin)
- Channel or store gases, liquids, tissues or body fluids for eventual administration into the body – Class II (Rule 5) ("Indirectly invasive")
- Modify the biological or chemical composition of body fluids or liquids for eventual administration into the body – Class III (Rule 6) ("Indirectly invasive") – also see Rule 11(2):
  - Unless: Modification may introduce a foreign substance that is potentially hazardous – Class IV (Rule 6)
  - Unless: Modification accomplished through centrifugation, filtration, or the exchange of heat or gas – Class II (Rule 6)
- Come into contact with injured skin – Class II (Rule 4) (e.g., promote healing, provide pain relief, provide a moist wound healing environment, like hydrogel wound and burn dressing)
  - Unless: Intended to be used as a mechanical barrier, for compression or for absorption of exudations – Class I (Rule 4) (example – gauze bandage)

Active Devices

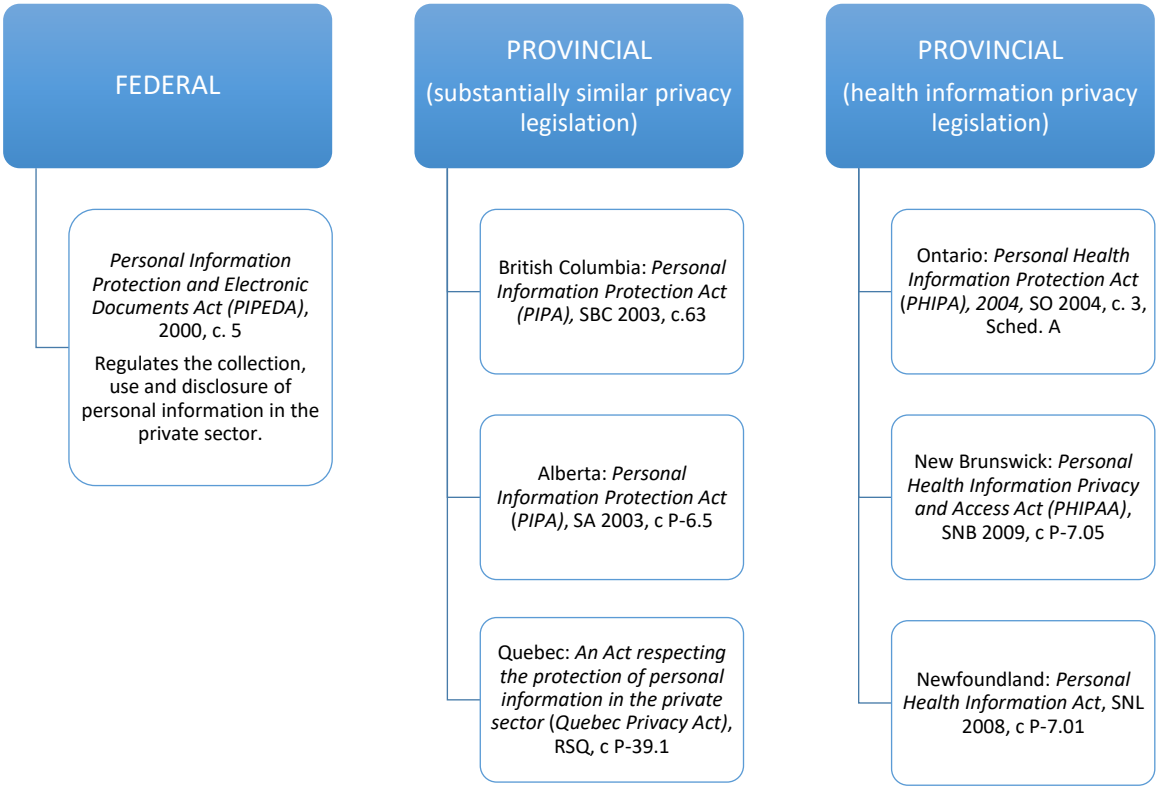
(Active devices are devices that require a source of energy to work)

- All active devices are **Class I** (Rule 12) (ex. Hydraulic adjustable hospital bed, powered wheelchair), unless they are:
  - An active diagnostic device (and dedicated software) intended to image or monitor physiological processes – Class II (Rule 10)
    - Unless: Intended to monitor, assess or diagnose a disease, a disorder, an abnormal physical state or a pregnancy, if erroneous readings could result in immediate danger – Class III (Rule 10)
      - (Remember the "Highest possible classification" rule – if Rule 1(2) applies, such as with *invasive* fetal monitoring, as well as Rule 10(2), then use highest classification – Class IV)
  - An active therapeutic device (and dedicated software) intended to administer or withdraw energy to or from the body – Class II (Rule 9) (ex. Powered toothbrush)
    - Unless: Administration or withdrawal is potentially hazardous (taking into account: nature of administration/withdrawal, intensity of energy, and part of body concerned) - Class III (Rule 9)
      - Unless: *Additionally*, control of patient's condition is through a closed loop system (a system capable of sensing, interpreting, and treating a patient without human interference at any point in the procedure) – Class IV (Rule 9)

        - (Remember the "Highest possible classification" rule – if Rule 1(2) applies as well as Rule 9(2), then use highest classification – Class IV)
- An active device intended to administer or withdraw drugs, body fluids or other substances from the body – Class II (Rule 11)
    - Unless: Administration or withdrawal is <u>potentially hazardous</u> (taking into account: nature of administration/withdrawal, nature of the substance involved, and part of body concerned) - Class III (Rule 11)
        - Unless: *Additionally*, control of patient's condition is through a <u>closed loop system</u> – Class IV (Rule 11) (ex. A closed-loop blood glucose controller)
- An active device intended to emit ionizing radiation, including any device intended to control, monitor, or influence such a device – Class III (Rule 8)
    - Unless: Intended to be used in radiographic mode – Class II (Rule 8)
        - Unless: *Additionally*, intended to be used for <u>mammographies</u> – Class III (Rule 8)

Privacy Laws

Medical devices that store a patient's personal health data in order to better monitor, diagnose, or care for a patient fall under Canada's privacy legislation. Below is an overview of the key privacy legislation, noting that other legislation, regulatory guidance, and privacy best practices should also be consulted depending on your particular device.



Federal

The *Personal Information Protection and Electronic Documents Act (PIPEDA)* regulates the collection, use and disclosure of personal information in the private sector. It also applies to federal works, undertakings or businesses. Personal information is broadly defined under *PIPEDA* and includes any information about an identifiable individual, with some exceptions.

Provincial

In provinces where legislation is deemed to be "substantially similar" privacy legislation (British Columbia, Alberta, and Quebec), *PIPEDA* does not apply in those provinces (except in the case of federal works, undertakings or businesses). Health information custodians in provinces with specific health information protection legislation deemed "substantially similar" to *PIPEDA* (Ontario, New Brunswick, and Newfoundland and Labrador) are similarly not subject to *PIPEDA*.

While *PIPEDA* does not specify which security safeguards must be used, the organization has a responsibility to use appropriate security safeguards depending on:

- the sensitivity of the information
- the amount of information
- the extent of distribution
- the format of the information (electronic, paper, etc.)
- the type of storage.[32]

A helpful guide, the *PIPEDA* Privacy Toolkit can be found here. A useful self-assessment tool that allows your organization to assess your privacy and security risks can be found here: Securing Personal Information: A Self-Assessment Tool for Organizations.

Other Relevant Legislation

There are also a number of provincial "health information" acts that govern the collection and use of health information. For example, Alberta's *Health Information Act* provides patients with the right to request their health records and provides health custodians with a framework for using, collecting and disclosing health information.[33]

Additionally, each province has some form of public sector "access to information" legislation. For example, Ontario's *Freedom of Information and Protection of Privacy Act* (*FIPPA*) now applies to hospitals, with the exclusion of personal health information protected under *PHIPA*. It is important to be aware that each province has their own access to information legislation, and access to your organization's records may be requested if under the custody or control of the applicable institutions.

Cloud Computing Privacy Considerations

When using cloud computing services, privacy regulators recommend transparency about outsourcing processes. It is also recommended to provide proper notice to affected individuals when such use involves transferring their personal information across borders.

PIPEDA does not restrict transfers of personal information outside Canada, but requires organizations to provide a comparable level of protection by ensuring transfers are reasonable for the purpose for which the information was initially collected, and protecting that information using contractual means. It is also important to note that US authorities may use the *USA Patriot Act* to obtain Canadians' personal information if located or accessible from the US.

Provincially, only Alberta's *PIPA* requires notification to affected individuals and requires company policies to include their outsourcing practices. Quebec's *Privacy Act* requires organizations to consider the potential risks of transferring personal information outside of the

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[32] Office of the Privacy Commissioner of Canada. (2015). A Guide for Businesses and Organizations: Privacy Toolkit, Canada's Personal Information Protection and Electronic Documents Act. p. 23, Retrieved from https://www.priv.gc.ca/information/pub/guide_org_e.asp.

[33] Office of the Information and Privacy Commissioner of Alberta (2016). What We Do. Retrieved October 13, 2016, from https://www.oipc.ab.ca/action-items/what-we-do.aspx

province, and if there is not a comparable level of protection, it should not be transferred. British Columbia and Nova Scotia impose restrictions, but only on public bodies.

Note that the storage of health information tends to involve a higher level of sensitivity and risk of harm than storage of other types of personal information. It is your responsibility to use the appropriate safeguards for the type of information being used by your medical device. Organizations must only collect, use and disclose personal information for purposes that a reasonable person would consider appropriate in the circumstances, even if the individual has consented to the collection, use and disclosure. Whichever safeguards you deemed appropriate for your particular organization, it is important to ensure that all users have easy access to your organization's privacy policies and practices.

Canadian Standards Association

Innovators should ensure end-users that their product, and each of its parts, are safe and reliable. The Canadian Standards Association (CSA) group provides products with certification marks that provide consumers, retailers and end-users with certainty that the product has been independently tested and has met the required standards for safety and performance.

In order to sell electrical and electronic products, gas-fired products, and many other products in North America, they must be approved by a third party testing agency, like the CSA Group.

To gain certification from the CSA group, innovators must contact them by phone, email or a request for quote. The CSA Group will ask the innovator to provide them with the following information:

- Contact and company information
- Information about the product
    - How and where it will be used
- The countries where the innovator intends to sell the product
- A list of all other approvals that the innovator has already received, or is pursuing
- The standards that the device has been designed to meet, or the standards that the innovator would like the product to be tested against
- Marketing brochures or data sheets describing the product
    - What is it? What does it do? What does it look like?
- Photograph of the product
- A list of all components and materials used in the product, including
    - Manufacturer's names
    - Model catalogue designations
    - Electrical ratings
    - CSA group file numbers
        - If components were certified by a group that is not CSA, the agency listing number and part names must be included
- The alternate materials or components that may be used in manufacturing
- The schematics and/or wiring diagrams
- The model or catalogue numbers, including any similarities or differences between models
- The full names and addresses of all manufacturing facilities and the contact person

Once the CSA group has received this information, a representative will contact the innovator to begin the certification process.

*CSA works to ensure complete confidentiality of all the information provided.

Certification Process

In the first step of the certification process, the innovator will receive an information packet containing the information in the table below.

Information	Description
Project Reference Number	To be used for all future communications about the project.
Product Service Agreement (PSA)	If it is the first time the innovator has worked with the CSA Group they will need to sign and return the PSA, outlining the working relationship.
Request for Product Samples	The innovator will be asked to send product samples to the laboratory indicated in the information packet. If the sample is large, or the production run is limited, a CSA representative will visit the facility.
Request for Technical Information	Any additional technical information should be provided at this time. If products have been tested by other accredited organizations, those test results can be included.

Once this information has been received, the technical representative assigned to the project will contact the innovator to inform them that testing will begin, and provide a timeline for the testing.

When all the requirements outlined in the standards have been met, the CSA Group will issue a certification report and a certificate of compliance. The innovator will then sign and return a service agreement indicating that the product is licensed to use the appropriate CSA mark on the product.

Below is a chart describing the available CSA Group certification marks.

CSA Mark	Type of Mark/Label	CSA Mark/Label Definition	Country
	Certification mark	Indicates that the product was tested and has met the certification requirements for electrical, plumbing and/or mechanical products.	Canada U.S.

	Certification mark	Indicates that the product was tested and has met the certification requirements for electrical, plumbing and/or mechanical products.	U.S.
	Certification mark	Indicates that the product was tested and has met the certification requirements for gas-fired products.	U.S.
	Certification mark	Indicates that the product was tested and has met the certification requirements for electrical, plumbing and/or mechanical products.	Canada
	Certification mark	Indicates that the product was tested and has met the certification requirements for gas-fired products.	Canada
	Certification mark	Indicates that the product was tested and has met the certification requirements for component products.	Canada
	Certification mark	Indicates that the product was tested and has met the certification requirements for component products.	Canada U.S.
	Certification mark	Indicates that the product was tested and has met the certification requirements for component products.	U.S.
	Sustainability mark	Indicates that the product has been tested and has met the environmental performance requirements for product specific sustainability standards.	Canada U.S.
	Special inspection label	Indicates that the electric healthcare product was tested and has met the Provincial Guidelines for the Field Approval of Health Care Equipment plus any applicable CSA health care product requirements for installation and use.	Canada
	Special inspection label	Indicates that the electric, non-healthcare product was tested and has met CSA Group Special Publication SPE-1000, Model Code for the Evaluation of Electrical Equipment, and the Canadian Electrical Code for installations and use.	Canada

Source: http://www.csagroup.org

Wireless Communication Licensing

Devices that utilize any form of radiocommunication, wireless communication using WIFI or any frequency on the electromagnetic spectrum must consider the licensing options through Industry Canada and the FCC.

Industry Canada

Industry Canada (IC) is the regulatory body responsible for certification, permits and licensing of devices using the electromagnetic spectrum for communication and monitoring in Canada.[34]

Local Area Networks (LAN) are transmitters that typically operate between 2.4 GHz - 5.8 GHz and that send and receive signals over WIFI. These transmitters are divided into Category I and II, and are considered low-power licence-exempt transmitters, meaning that no licence is required to own or operate the device.[35] However, the device still must comply with the regulations outlined in RSS-Gen.

Category I equipment must comply with RSS-210 and the manufacturer must apply for a Technical Acceptance Certificate (TAC), which certifies that the device meets all of the standards outlined in RSS-210. Manufacturers receive TACs through the Minister or a Certified Body. Category II equipment to must comply with RSS-310 and no TAC is required. More information on TACs can be found in sections 21-25 in the Radiocommunication Regulations. Both Category I and II devices must also comply to RSS-102. Refer to the Category I Equipment Standards List and the Category II Equipment Standards List to classify a transmitter. These lists also provide a link to the set of standards that are applicable to each specific category. If the equipment also has an antenna, it may be subject to regulations in CPC 2-0-03.[34]

If the device is purchased from a supplier in Canada, it is the supplier's responsibility to ensure the transmitter and antenna meet IC regulations. However, if a device is created by the innovator, or an existing device is modified the innovator must ensure it complies with all IC regulations and the innovator must apply for certification or recertification. If the innovator is purchasing hardware for their technology from another country, it must have an IC Certification number or the innovator must apply for IC certification to use the hardware in Canada.[34]

Technologies that will be using sensors, Infra-red waves, or if a transmitter conveys waves of a higher frequency than 5.8 GHz, they may be subject to licence regulations and further permits, such as the ICES regulations. Innovators should refer to the heading under Radiocom on the Industry Canada website that pertains to their device for more information.

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[34] Innovation, Science and Economic Development Canada. (2016). Our Organization. Retrieved October 13, 2016, from https://www.ic.gc.ca/eic/site/icgc.nsf/eng/h_00007.html

[35] Innovation, Science and Economic Development Canada. (2016). How are licence-exempt radio devices regulated for use in Canada? In *Low-Power Licence-exempt Radiocommunication Devices – Frequently Asked Questions*, Retrieved October 13, 2016, from https://www.ic.gc.ca/eic/site/smt-gst.nsf/eng/sf08655.html#Q4

Further questions can be brought to the nearest Industry Canada district office. Innovators should expect correspondence from IC on their application within 14 days.

Federal Communications Commission

The Federal Communications Commission (FCC) is an independent U.S. government agency that regulates communication by radio, television, wire, satellite and cable for all of the U.S. [36] The FCC works with other bodies across North America to provide regulatory oversight, leadership, and cooperation and is responsible for managing and licensing electromagnetic spectrum for commercial and non-commercial use. [35]

If an innovator is creating or modifying any type of transmitter to access any frequency in the electromagnetic spectrum, then they must license the device through the FCC. [36] Please consult Title 47 of the Electronic code of Federal Regulations to determine what licensing options exist for each type of transmitter. If a transmitter is being bought or imported for use in the United States, it is the responsibility of the innovator to ensure that it complies with FCC regulations.

Much like Industry Canada, the FCC has regulations surrounding low-powered, non-licensed transmitters that send and receive signals over WIFI.[37] No licence is needed to own or operate this type of transmitter. For more information, please consult Part 15 of the Electronic code of Federal Regulations. Please see Part 15.3 of the Electronic code of Federal Regulations to discern if your device uses a low-power, non-licensed transmitter.
Antennas also require subsequent licensing. Please consult Part 17 of Title 47 of the Electronic code of Federal Regulations.

For low power, non-licensed transmitters (or Part 15 transmitters), there are three procedures to receive authorization through the FCC: Verification, Certification and Declaration of Conformity.[38] For more information, please consult Part 2, Subpart J of the Electronic code of Federal Regulations.

The FCC provides a wide variety of other wireless communication services. For a full list, please consult the FCC website. The following table outlines some of the wireless communication services relevant to medical devices.

[36] Federal Communication Commission. *What We Do*. Retrieved June 02, 2016, from https://www.fcc.gov/about-fcc/what-we-do

[37] U.S. Government Publishing office. (2016). *Part 15: Radio frequency devices*. Retrieved June 02, 2016 from http://www.ecfr.gov/cgi-bin/text-idx?SID=5cf478bd19de51af958b5821435cd416&mc=true&tpl=/ecfrbrowse/Title47/47cfr15_main_02.tpl

[38] U.S. Government Publishing office. (2016) *Part 2: Frequency allocations and radio treaty matters*. Retrieved June 02, 2016 from http://www.ecfr.gov/cgi-bin/text-idx?SID=5132f55e8ccaaeacbf2200bc2cdc908d&mc=true&node=sp47.1.2.j&rgn=div6

Name of Service	Frequency	Description	Website link
Intelligent Transportation Systems[39]	902-928 MHz	Two types of ITS radio services: The Dedicated Short Range Communication (DSRC) service which primarily deals with vehicle to vehicle communication, and the Location and Monitoring Service (LMS) which involves non-voice radio techniques to monitor the location and status of mobile radio units.	Find more information here
Medical device Radiocommunications service (MedRadio)[40]	401 – 406, 413 – 419, 426 – 432, 438 – 444, 451 – 457 MHz	This spectrum is mainly used for devices that are implanted or worn on the body and that are used for diagnostic or therapeutic purpose.	Find more information here
Wireless Medical Telemetry Service (WMTS)[41]	608 – 614, 1395 – 1400, and 1427 – 1432 MHz	This service is mostly used for remote patient monitoring and include devices that measure patient's vitals or other indicators of health.	Find more information here

IC and FCC Compatibility

If an innovator wishes to commercialize their device in both Canada and the United states, they must apply for authorization through both the FCC and IC. Both regulatory bodies work collaboratively, so often test results that meet standards for one body will be accepted by the other. It is recommended that the innovator consider the standards of the test facility that must be met for both regulatory bodies before choosing a lab location to complete the appropriate testing of a device.

Industry Canada has indicated they will accept a FCC test report if it meets the following conditions:

- The test report must be less than one year old;
- If the type of measurement was "radiated", the laboratory who did the testing must have their Test Site (OATS or Anechoic chamber) approved by Industry Canada;
- If the type of measurement was "conducted", the laboratory who did the testing is not required to have their test site approved by Industry Canada;
- A cross-reference table must be submitted with the test report to show that the equipment meets all of the applicable Canadian requirements.

[39] Federal Communication Commission (2004). *Intelligent Transportation Systems*. Retrieved June 02, 2016 from http://wireless.fcc.gov/services/index.htm?job=service_home&id=intelligent_ts

[40] Federal Communication Commission. (2006) *Medical Device Radiocommunications Service (MedRadio*). Retrieved June 02, 2016 from https://www.fcc.gov/general/medical-device-radiocommunications-service-medradio

[41] Federal Communication Commission. (n.d.). Wireless Medical Telemetry Service (WMTS). Retrieved June 02, 2016 from https://www.fcc.gov/general/wireless-medical-telemetry-service-wmts

Health Technology Assessment

A Health Technology Assessment (HTA) consists of a systematic evaluation of the properties and effects of a health technology. The assessment evaluates the intended effects of the technology, and investigates the unintended consequences.[42] HTAs are completed by interdisciplinary groups that use analytical frameworks and various discipline-specific assessment methods.[42] These groups compare the clinical effectiveness and cost effectiveness of the health technology with existing technologies or methods using a post-market, evidence-based economic analysis. The goal of an HTA is to inform policy decision makers on the technology's safety, efficacy, potential for health innovation and return on investment.[Error! Bookmark not defined.] This information is used to facilitate reimbursement decisions.

An HTA is not required for sale of a medical device or health technology in Canada. However, senior management and health care decision makers often request an HTA to ensure that they make an informed decision about whether a health technology should be funded and adopted into practice.[Error! Bookmark not defined.] Any person or organization can request an HTA to be conducted, with the exact framework depending on the organization conducting the HTA and the relevant evidentiary standards.[Error! Bookmark not defined.] HTAs can be conducted at a provincial or hospital level, or through programs like MaRS EXCITE.[Error! Bookmark not defined.]

Health Technology Assessment International (HTAi)

HTAi is a global scientific not-for-profit agency representing professionals who produce or encounter HTA.[Error! Bookmark not defined.] This group contains over 1200 members from 65 different countries representing researchers, policy makers, industry, academia, health service providers and patients/consumers.[Error! Bookmark not defined.] HTAi holds regular meetings, interest groups and policy fora which serve as information sharing venues.[Error! Bookmark not defined.] Currently, HTAi has an interest group in patient and citizen involvement in health technology assessment.[Error! Bookmark not defined.]

HTA in Canada

The Canadian Agency for Drugs and Technologies in Health (CADTH) is a not-for-profit organization which provides evidence-based information about health technologies.[43] CADTH was created in 1989 by federal and provincial Health Ministers to develop a systematic approach to evaluating health technologies and drugs. The agency is funded through provincial and federal contributions.[43] All the reviews CADTH completes are freely available on their

[42] HTA Glossary. (n.d.). Health Technology Assessment (HTA). Retrieved October 13, 2016, from http://htaglossary.net/Health+Technology+Assessment+%28HTA%29&highlight=health%20technology

[43] The Canadian Agency for Drugs and Technologies in Health. (2016). *About CADTH.* Retrieved October 13, 2016, from www.cadth.ca

website and on some topics, such as “Evidence on Topics Related to Long-Term Care” there are evidence bundles which include a variety of tools and resources.[43]

Decision makers can request CADTH’s services through their website including those working in ministries and departments of health, publically funded organizations responsible for health service delivery (health authorities, hospitals or long-term care facilities), public health agencies and drug manufacturers.[43] CADTH can provide advice, recommendations or tools to inquiries that pertain to a health care decision or policy. CADTH can also be contacted through Liaison Officers located regionally in each province.[43]

CADTH’s services are available to all Canadian provinces and territories outside of Ontario and Quebec (which operate their own HTA agencies). CADTH acts as the primary body for preforming provincial HTAs in all provinces and territories that do not have their own provincial HTA agency: Saskatchewan, Manitoba, Nova Scotia, New Brunswick, Prince Edward Island, Newfoundland and Labrador, Yukon, Northwest Territories and Nunavut.[43] In Alberta and British Columbia, CADTH works to perform HTAs in collaboration with provincial bodies that formulate the recommendations for use.[43]

Types of HTA

CADTH provides different HTA services under their Health Technology Management Program. The Rapid Response Service provides decision-makers with the most relevant information in a time-sensitive manner.[43] A more in-depth assessment can be completed with CADTH’s HTA Program. The HTA Program provides 2 services: (i) a full HTA, involving a comprehensive review of both clinical and cost effectiveness and an examination of ethical, legal and social implications of the technology, or (ii) a Technology Review, consisting of an assessment of either clinical or cost effectiveness, but not both.[43] These HTA Program assessments include the evidence and information necessary for decision makers, but do not include a set of recommendations for the technology. However, CADTH provides an Optimal Use Service that provides decision makers with a complete HTA and a set of recommendations developed by a panel of experts.[43]

Eligibility

CADTH preforms HTAs on health technologies, which they define as drugs, diagnostic tests and medical, dental and surgical devices and procedures.[43]

Data Requirements

In completing an HTA, CADTH evaluates clinical and cost effectiveness of the technology. This might include ethical, legal and social implications for patients and for the broader healthcare system.[43]

Provincial HTA

Provincial HTA processes do not involve an application process from the manufacturer.[Error! Bookmark not defined.] These provincial organizations identify technologies through regular environmental scanning and passive surveillance, or through communication with hospital administrators.[43]

British Columbia

The Health Technology Review begins with the completion of a business case by the Health Technology Review Office. This business case is then evaluated by the Health Technology Assessment Committee (HTAC).[44] Business cases are reviewed by HTAC 4 times a year, and recommendations are made twice a year.[44]

Eligibility

Non-drug health technologies (tools, devices, diagnostics and procedures) being considered for public reimbursement are eligible for the review process.[44] All new non-drug health technologies that are being considered for reimbursement at a cost threshold of $25,000 per patient or $1,000,000 province wide, undergo the review process in British Columbia.[44] Technologies that have already been adopted are also reviewed if requested by leadership.[44]

Data Requirements:

The province of British Columbia examines the social and system demographics, clinical effectiveness and costs of technologies in their HTA process.[Error! Bookmark not defined.] More specifically, the disease burden, impact on the population, implementation plan and training and credentialing required for adoption of the technology are examined under the social and system demographics.[Error! Bookmark not defined.] Clinical effectiveness is considered in terms of the health effects, non-health effects and the quantity and quality of life improvements caused by the adoption of the technology.[Error! Bookmark not defined.] The incremental cost (as defined by CADTH), budget impact and cost of implementation are evaluated to understand the overall cost of the technology.[Error! Bookmark not defined.]

[44] Government of British Columbia. (n.d.) Health Technology Review. In *About B.C.'s Health Care System.* Retrieved October 13, 2016, from http://www2.gov.bc.ca/gov/content/health/about-bc-s-health-care-system/partners/health-authorities/health-technology-review

Alberta

Alberta Health Technologies Decision Process uses all appropriate evidence and information to consider which health services should be publically funded.[45] Based on the scope of previously set Alberta Health priorities, new technologies and services are identified for review by Ministry staff, or through referral from stakeholders or the general public.[45] An HTA will be completed on these identified technologies by partner organizations.[45] Alberta Health uses the HTA to develop policy options. Through consultations with stakeholders and considerations of broader health systems impacts, recommendations are developed and presented to the Minister or Deputy Minister for final decisions.[45]

Eligibility

Health technology assessments are conducted by partner organizations and referred to Alberta Health Technologies Decision Process. As such the eligibility of a technology is dependent upon the referring agency.[45]

Data Requirements

For the Health Technologies Decision Process, four categories of data are examined: social and system demographics, clinical effectiveness, costs, and political and public policy considerations.**Error! Bookmark not defined.** Under social and system demographics, the review examines the incidence and prevalence of the health issue addressed by the technology, and the capacity of the system to deliver the new service.**Error! Bookmark not defined.** To examine the clinical effectiveness, the review evaluates the health effects and the non-health effects of the technology.**Error! Bookmark not defined.** Cost and political and public policy considerations are examined more broadly.**Error! Bookmark not defined.**

[45] Alberta Health. (2016). *Alberta Health Technologies Decision Process*. Retrieved October 13, 2016, from http://www.health.alberta.ca/initiatives/AHTDP.html

Ontario

In Ontario, HTAs are performed by the Ontario Health Technology Assessment Committee (OHTAC), a subcommittee of Health Quality Ontario (HQO).[46] OHTAC identifies, appraises and interprets existing evidence surrounding new health technologies to provide recommendations about the uptake, diffusion, distribution or removal of the technology from the health system.[46] These recommendations are provided to decision makers at the Ontario Ministry of Health and Long-Term Care, as well as to identified stakeholders and the general public.[46]

Eligibility

OHTAC indicates that technologies and treatment strategies eligible for the HTA process can include "new and existing diagnostic- and treatment-related medical devices, equipment and supplies, and clinical procedures used in any health care service delivery setting."[46] Reviews of technologies and treatment strategies that have not yet been diffused into the health care system are completed before those that have been diffused.[46] The exception to this preference occurs when OHTAC considers the technology to warrant assessment because it is being considered as an alternative to a new technology or treatment, there are safety concerns, or it has a new application.[46]

Data Requirements

OHTAC examines the social and system demographics, the feasibility of adoption into the health system, the clinical effectiveness, the value for money and the political and public policy considerations within the scope of the HTA.**Error! Bookmark not defined.** To evaluate the social and system demographics, OHTAC considers the burden of the illness being addressed by the technology and the need for the technology.**Error! Bookmark not defined.** The feasibility of adoption into the health system is examined by assessing the economic feasibility, as well as the organizational feasibility.**Error! Bookmark not defined.** The clinical effectiveness of the technology is considered in terms of the effectiveness of the technology and the safety of the technology.**Error! Bookmark not defined.** The value of the technology is considered in comparison to the cost of the technology.**Error! Bookmark not defined.** Political and public policy considerations are evaluated based on the consistency of the technology with expected societal and ethical values.**Error! Bookmark not defined.**

[46] Health Quality Ontario (2016). Reviews and Recommendations. In *Health Technology Assessments.* Retrieved October 14, 2016, from http://www.hqontario.ca/Evidence-to-Improve-Care/Recommendations-and-Reports/Recommendations-from-the-Ontario-Health-Technology-Advisory-Committee

Quebec

The Institut national d'excellence en santé et en services sociaux (INESSS) works to promote clinical excellence and the efficient use of resources in health and social services by assessing the clinical and cost effectiveness of health innovations.[47] The assessments are completed by a multi-disciplinary team of professionals, managers, patients and beneficiaries. These assessments result in a set of recommendations concerning their adoption, use and coverage.[47] In addition, guides for best clinical practice are developed to ensure optimal use of the innovation.[47]

Eligibility

Health technologies, medications and interventions are assessed by Universities and other external organizations, who collaborate with INESSS to produce recommendations.[47] These partnering bodies have differing criteria for eligibility.[47]

Data Requirements

The data requirements for review by organizations partnered with INESSS varies according to the type of technology.[47] However, clinical effectiveness and social and system demographics are always evaluated.**Error! Bookmark not defined.**

[47] INESSS. (2016). *About the Institut*. Retrieved October 13, 2016, from https://www.inesss.qc.ca/en/home.html

Local HTA (Payer Level)

HTA bodies exist at a local level within most provinces, most often within hospitals. Typically, reimbursement decisions are made at this level, as such HTAs are often conducted at this level[Error! Bookmark not defined.]. However, hospital administrators can request advice from formal assessment organizations at a provincial level.[Error! Bookmark not defined.] An overview of local HTA bodies in each province is provided in the table below.

Province	Local HTA (Payer Level)[4]
Alberta	• Alberta Health Technology Decision Process (Province) • Institute of Health Economics (Province) • Health Technology Assessment Unit (Province) • Health Technology and Policy Unit (Province)
British Columbia	• Health Technology Review (Province) • Centre for Clinical Epidemiology & Evaluation (Region)
Manitoba	The Manitoba Centre for Health Policy Research provides some of these functions for the province, although it is not officially viewed as an "HTA" body
New Brunswick	Horizon Health Network HTA Program (Region)
Newfoundland and Labrador	Newfoundland and Labrador Center for Applied Health Research (Region)
Nova Scotia	(In Development)
Nunavut	None
Ontario	• HQO's Evidence Development and Standards division (Province) • London Health Sciences center/High Impact Technology Evaluation (Hospital) • Programs for Assessment of Technology in Health)/McMaster University (Province) • Toronto Health Economics and Technology Assessment Collaborative/University of Toronto (Province) • Technology Assessment at Sick Kids /Toronto Sick Kids Hospital (Hospital) • The Ottawa Hospital Technology Assessment Program (Hospital) • The St. Joseph's Healthcare Hamilton (SJHH) Health Technology Assessment Appraisal & Review Program (Hospital) • Ontario's Institute for Clinical Evaluative Sciences (ICES) also provides some of these functions for the province, although it is not officially viewed as an "HTA" body

Prince Edward Island	None
Quebec	• Institut national d'excellence en santé et en services sociaux (INESSS) (Province) • Technology Assessment Unit McGill University Health Center (Hospital) • Centre hospitalier universitaire de Sherbrooke(Hospital) • Direction de l'évaluation des technologies et des modes d'intervention en santé/Centre hospitalier universitaire de l'Université de Montréal (Hospital) • Centre hospitalier universitaire Sainte-Justine (Hospital) • Centre hospitalier universitaire de Québec (Hospital)
Saskatchewan	Health Quality Council (Province)
Northwest Territories	None
Yukon	None

Hospital-Based HTA

Approaches taken by hospitals vary greatly by organizational complexity.**Error! Bookmark not defined.** Most teaching hospitals have HTA bodies to facilitate their reimbursement decision making, given their greater funding allocations. In Quebec, all teaching hospitals are required to have HTA bodies.**Error! Bookmark not defined.** These bodies may support hospital-wide decisions or may be contained within certain departments. As such, they may have varying levels of support from senior administration and varying impacts on decision-making.**Error! Bookmark not defined.**

Alternative HTA Options

A medical device company can conduct their own assessment of their technology's clinical and cost effectiveness to inform decision-makers, as long as the quality of the evidence presented remains high and valid in the eyes of the decision makers.

Provincial policy may create programs based on their strategic directions or changes in federal funding. These resulting programs may provide opportunities for HTA for health innovations.**Error! Bookmark not defined.** Similarly, decisions to fund or investigate health technologies may be impacted by political decisions.**Error! Bookmark not defined.**

Reimbursement

Within the Canadian healthcare system, resource allocation decisions ultimately determine if a medical device will be reimbursed in Canada. The Medical Devices Bureau (MDB) of Health Canada's Therapeutic Products Directorate (TPD) regulates medical devices for human use in Canada[48]. Devices that are approved by the MDB are then communicated to the provincial ministries. This information is then communicated to the Regional Health Authorities, who communicate with hospital administrators.**Error! Bookmark not defined.**

Health Canada is only directly responsible for reimbursement and purchasing decisions for specialized programs that it administers, such as for First Nations and Inuit populations.[48] There are also other federal departments and programs responsible for reimbursement decisions in specialty populations. These include the Department of National Defence (Canadian Forces Health Services Group), Correctional Services Canada (Health Services), and Veterans Affairs Canada (Health Care Benefits).[48]

The vast majority of reimbursement decisions for approved health technologies are made at the hospital level, by senior level management.[49] As such, regional or national consensus by physicians through existing professional networks can be a strong influence on the decision to reimburse a technology.**Error! Bookmark not defined.** However, these decision makers are often exposed to pressures from industry and patients, impacting their final decisions.[50] To counter act this, innovators can implement on-line framing strategies that highlight the cost-effectiveness of their innovation, and influence the decisions of purchasers.[51]

[48] International Society for Pharmecoeconomics and Outcomes Research. (2016). Canada - Medical Devices & Diagnostics. In*ISPOR Global Health Care Systems Road Map*. Retrieved March 22, 2016, from http://www.ispor.org/htaroadmaps/canadamdd.asp

[49] Husereau, D. (2015). Medical device and diagnostic pricing and reimbursement in Canada. In *HTX*. Retrieved March 22, 2016, from http://www.htx.ca/sites/default/files/medical_device_and_diagnostic_pricing_and_reimbursement_in_canada%20(2).pdf

[50] Carbonneil, C., Quentin, F., & Lee-Robin, S. H. (2009). A common policy framework for evidence generation on promising health technologies. *International journal of technology assessment in health care*, *25*(S2), 56-67.

[51] Lehoux, P., Hivon, M., Williams-Jones, B., Miller, F. A., & Urbach, D. R. (2012). How do medical device manufacturers' websites frame the value of health innovation? An empirical ethics analysis of five Canadian innovations. *Medicine, Health Care and Philosophy*, *15*(1), 61-77.

The following chart provides a list of provincial ministries and regional health authorities by province.[Error! Bookmark not defined.]

Province	Ministry	Regional Authority
Alberta	Alberta Health	Alberta Health Service
British Columbia*	Ministry of Health	Fraser Health Interior Health Island Health Northern Health Vancouver Costal Health
Manitoba	Manitoba Health	Interlake-Eastern Regional Health Authority Northern Regional Health Authority Southern Health-Santé Sud Prairie Mountain Health Winnipeg Regional Health Authority
New Brunswick	Ministry of Health	Horizon Health Network Vitalité Health Network
Newfoundland and Labrador	Department of Health and Community Services	Eastern Regional Health Authority Central Regional Health Authority Western Regional Health Authority Labrador-Grenfell Regional Health Authority
Nova Scotia	Department of Health and Wellness	Annapolis Valley Health Authority (District 3) Cape Breton District Health Authority (District 8) Capital Health (District 9) Colchester East Hants Health Authority (District 4) Cumberland Health Authority (District 5) Guysborough Antigonish Strait Health Authority (District 7) IWK Health Centre Pictou County Health Authority (District 6) South Shore Health (District 1) South West Health (District 2)
Nunavut	Department of Health	Health and Social Services
Ontario	Ministry of Health and Long Term Care	Erie St. Clair South West Waterloo Wellington Hamilton Niagara Haldimand Brant Central West Mississauga Halton Toronto Central Central

		Central East Champlain North Simcoe Muskoka North East North West
Prince Edward Island	Department of Health and Wellness	Health PEI
Quebec**	Ministry of Health and Social Services	Bas-Saint-Laurent Saguenay-Lac-Saint-Jean Capitale-Nationale Mauricie et Centre-du-Quebec Estrie Montreal Outaouais

** Coordinated through Provincial Health Services Authority.*
*** Some regions (Centre Intégré de Santé et de Services Sociaux - CISSS) will coordinate.*

The Canada Health Act (CHA) does not require provinces and territories to cover services that occur outside of acute care facilities, including dental care, vision care, physiotherapy, long-term care.[Error! Bookmark not defined.]

Since ministry-led programs do not cover medical technologies related to these services, the reimbursement of these devices will fall on private insurers, who fund about 12% of non-publically-insured-services.[Error! Bookmark not defined.] Third party payers also pay for a similar amount of health services, out-of-pocket.[Error! Bookmark not defined.]

In addition to funding medically necessary acute care services and devices, some provinces run additional reimbursement programs to assist people in paying for licensed medical devices and equipment that is necessary to maintain health and function.[49] These programs fund assistive devices for people with long-term physical disabilities that enable them to increase their independence.

Province	Program	Details
Alberta	Aids to Daily Living Program (AAL)	Financial assistance for the purchase of medical equipment and supplies for people with long-term disability, chronic or terminal illness. Benefits are provided for the following.[52] • Aural rehabilitation • Back and abdominal supports • Bathing and toileting equipment* • Burn garments • Compression stockings and garments • Custom-made footwear • Custom-made ocular prostheses** • Dressing supplies • Hearing aids and FM systems • Homecare beds and accessories* • Incontinence supplies (diapers and catheters) • Injection supplies (not provided for insulin injections) • Laryngectomy equipment and supplies • Breast prostheses** • Orthotic braces (not foot orthotics) ** • Ostomy supplies • Oxygen • Patient lifters* • Pressure reduction overlays • Prosthetic devices** • Respiratory equipment and supplies* • Shoe elevations • Specialized pediatric equipment* • Specialized seating devices • Speech generating communication devices • Therapeutic shoes with custom modifications • Transfer aids • Walkers and walking aids • Wheelchair cushions and accessories • Wheelchairs – manual and power*

[52] Government of Alberta. (2016). Alberta Aids to Daily Living Benefits. In *Alberta Health*. Retrieved March 22, 2016, from http://www.health.alberta.ca/services/AADL-benefits.html

British Columbia	PharmaCare Prosthetic and Orthotic Program	Provides pre-approved prostheses and orthoses for eligible recipients who require these to maintain function This program covers:[53] • Pre-approved prostheses for eligible patients of any age; • Pre-approved orthoses for eligible patients age 18 or younger; • The lowest cost devices needed to attain or maintain basic functionality or, for orthoses, to prevent further deformity.
Ontario	The Assistive Devices Program (ADP)	ADP covers over 8,000 separate pieces of equipment or supplies in the following categories:[54] • prostheses; • wheelchairs/mobility aids and specialized seating systems; • enteral feeding supplies; • monitors and test strips for insulin-dependent diabetics (through an agreement with the Canadian Diabetes Association); • hearing aids; • insulin pumps and supplies for children; • respiratory equipment; • orthoses (braces, garments and pumps); • visual and communication aids; • oxygen and oxygen delivery equipment, such as concentrators, cylinders, liquid systems and related supplies, such as masks and tubing.
Quebec	Régie de l'assurance maladie du Québec (RAMQ)	Reimburses blood glucose test strips, some wound care products and some assistive devices and equipment, including visual aids, hearing aids, ocular prostheses, external breastforms, appliances for permanent ostomates, accommodation in public facility, accommodation in an intermediate resource, devices that compensate for a physical deficiency and domestic help.[55]

* Equipment might not be new

** All seniors in Alberta who receive prosthetic, orthotic, mastectomy prosthesis and eye prosthesis benefits through the AADL program receive these benefits at no cost. This includes seniors who are currently receiving these benefits as well as those who will be applying for them in the future.

For medical devices that are not reimbursed through any of these programs, some medical expenses are eligible for tax credit.[56] Expenses that can be claimed include the cost of purchased or leased products, equipment or devices that provide relief, assistance or treatment for any illness.[56]

[53] Government of British Columbia. (2016). About PharmaCare. In *British Columbia*. Retrieved March 22, 2016, from http://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/about-pharmacare#ServicesWeCover

[54] Ministry of Health and Long-Term Care. (2014). Assistive Devices Program. In *Ontario Ministry of Health and Long-Term Care*. Retrieved March 22, 2016, from http://www.health.gov.on.ca/en/public/programs/adp/

[55] Gouvernement du Québec. (2015). Citizens - Aid Programs. In *Régie de l'assurance maladie Québec*. Retrieved March 22, 2016, from http://www.ramq.gouv.qc.ca/en/citizens/aid-programs/Pages/aid-programs.aspx

[56] Grant Thornton LLP. (2016). Medical expenses. In *Tax planning guide: 2015-2016*. Retrieved March 22, 2016, from http://www.taxplanningguide.ca/tax-planning-guide/section-2-individuals/medical-expenses/

Additionally, the following programs provide funding and other resources for health technologies, without the requirement of a medical device license[Error! Bookmark not defined.].

Province	Industry Associations and Commercialization Organizations
Nationally	The Canadian Association for Healthcare Reimbursement (CAHR)
	BDC Capital
	Canada Health Infoway
	Department of Foreign Affairs, Trade and Development (DFATD)
	Export Development Canada
	MaRS
	Medical Devices Innovation Institute (MDI^2)
	National Research Council Canada (NRC)
	Techna Institute
	WORLDiscoveries
Alberta	Alberta Health Industry Association Alberta Innovates Technology Futures
British Columbia	LifeSciences British Columbia
Manitoba	LifeScience Association of Manitoba Manitoba Technology Accelerator
New Brunswick	BioNB
Nova Scotia	BioNova
Ontario	Centres of Excellence for Commercialization: - Centre for Imaging Technology Commercialization (London, ON) - Centre for probe development and Commercialization (Hamilton, ON) - Centre for Surgical Invention and Innovation (Hamilton, ON) - MaRS Innovation (Toronto, ON)
	Sunnybrook Research Institute Ontario Regional Innovation Centres Ontario Network of Entrepreneurs (ONE) Ontario Centres of Excellence Ontario Brain Institute Clinical Trials Ontario Resources for Evaluating, Adopting and Capitalizing on Innovative Healthcare Technology (REACH) David Johnston Research and Technology Park (University of Waterloo, ON) Invest Ottawa Life Sciences Cluster
Prince Edward Island	PEI BioScience Cluster
Quebec	Le Campus des Technologies de la Santé (CTS) Montreal InVivo Quebec International Sherbrooke Innopole

Procurement

Once a device has obtained a regulatory license from MDB it is eligible for sale allowing reimbursement decisions to be made. These decisions allow for procurement of the device to take place.[Error! Bookmark not defined.]

The procurement of a device at a provincial and regional level often involves shared delivery or group purchasing arrangements.[Error! Bookmark not defined.] Group purchasing arrangements leverage buying power and are commonly utilized by hospitals, regions, and provinces.[Error! Bookmark not defined.] Shared service organizations (SSOs) are used by health regions to purchase devices in bulk and reduce costs by coordinating the required procurement, information technology and financial functions associated with buying these devices at a regional or provincial level.[Error! Bookmark not defined.] GPOs also consolidate these functions regionally or provincially to reduce costs.[Error! Bookmark not defined.] Three provinces, Alberta, British Columbia, and New Brunswick, have contracts with privately owned GPOs for shared purchasing activities.[Error! Bookmark not defined.] Additionally, Ontario, Quebec, British Columbia, and Alberta have adopted individual purchasing approaches using a shared service approach, as described in the table below.[Error! Bookmark not defined.]

Province	Purchaser Details
Alberta	• Alberta Health Services (AHS) is the major purchaser of medical devices in the province • A guide to doing business with AHS is available here: www.albertahealthservices.ca/org/ahs-orgcpsm-guide-doing-business-with-ahs.pdf
British Columbia	• Health Shared Services BC (HSSBC) is the designated purchaser of medical technologies for the 5 health regions in this province • Medical device manufacturers can access further information on HSSBC here: www.hssbc.ca/Vendors
Ontario	• Medical device procurement largely based on individual hospitals and shared service organizations (SSO) • SSOs in Ontario: o Shared Supports Services South-eastern Ontario (3SO) o Shared Service West (SSW) o Mohawk Shared Service (MSSI) o Plexxus o Champlain Health Supply Services (CHSS) o Health Materials Management Services (HMMS) o Central Ontario Healthcare Procurement Alliance (COHPA) o PROcure Supply Chain Solutions (PROcure) o The Northwest Supply Chain Collaboration (NSC)

Quebec	• Medical devices purchased through hospitals and group purchasing organizations (GPOs, or Groupes d'approvisionnement en commun) • GPOs in Quebec: o Groupe de l'Ouest o Le Groupe d'approvisionnement en commun de l'Est-du-Québec (GACEQ) o Sigma Santé – Montreal • GPOs are owned by the province and managed by the ministry of health, the Ministre de la Santé et des Services Sociaux (MSSS), and currently purchase up to 50% of medical devices for Quebec hospitals, with the aim to increase to 70%

All medical devices procured by regional health authorities are required to comply with the Food and Drugs Act and, if appropriate, have a licence issued by Health Canada. Additionally, each authority may have their own RFP or Purchase Order standards for proving appropriate authorization to manufacture, sell or advertise medical devices.**Error! Bookmark not defined.**

MEDEC and other medical device industry associations have identified procurement issues as a priority concern. The government of Ontario responded with the Ontario Ministry of Finance Open for Business Initiative, providing an alternative to hospital procurement. This method involves additional contracts, including "Alternative Proposals" and "Value Add Incentives", which allow innovative companies to propose their product in lieu of a GPO's requested product, and may add new innovations to a GPO's proposed contracts.**Error! Bookmark not defined.**

Innovators can work in collaboration with research facilities that are aligned with particular government mandates, allowing potential adoption opportunities for smaller medical device innovators. These organizations may consider more niche innovations, receive additional tax breaks, accept alternative licencing (e.g. Investigational Testing) and could lead to wider adoption within the healthcare system.

When the medical device innovation has the potential to improve patient care and quality of life, marketing the device to providers can lead to better adoption. GPO's are primarily cost-driven, but physicians and hospitals consider the innovation's ability to improve patient care and often push for the adoption of these devices by requesting an HTA and presenting options for reimbursement.**Error! Bookmark not defined.**

As explained by the Institute for Health Economics (IHE) "Any procurement over $100,000 needs to follow an open competitive bid process that meets requirements of national legislation called the Agreement on Internal Trade (AIT), which dictates procurement must be open, fair, and transparent. Western provinces (British Columbia, Alberta, and Saskatchewan) must also comply with the New West Partnership Trade Agreement. There are three approaches to open competitive bidding: Request for Information (RFI), Request for Proposal (RFP), and Request for Quotation (RFQ/Tender)."**Error! Bookmark not defined.**

The process of procurement for new innovations can be difficult to define. Ontario has launched a new approach to innovation procurement to address these difficulties.[Error! Bookmark not defined.] The approach focuses on outcome-based specifications (OBS) instead of the usual product specific specifications.[Error! Bookmark not defined.] The new OBS guidelines for innovation procurement:[Error! Bookmark not defined.]

- specify that procurement be outcome-based without describing how proponents should meet the desired outcomes;
- outline RFP bid requirements that specify how outcomes should be appropriate to the size and complexity of the innovative solution, and be accurately specified;
- clearly define all elements included in the evaluation criteria; and
- specify standards as needed.

The OBS procurement approach can be applied to new and old innovation procurement and can be used to consider alternative proposals in a routine procurement process.[Error! Bookmark not defined.]

APPENDIX A: Standards

Electrical Safety Standards – Canadian Electrical Code

If the device uses line-powered electrical equipment, it falls under the electrical safety regulations of each individual province or territory. Electrical products must meet the standards within the Canadian Electrical Code, and must bear a mark from an accredited agency showing compliance, such as the Canadian Standards Association (CSA).[57]

Quality Management System (QMS) Standard – ISO 13483

If the medical device falls within risk classes II, III, or IV (and therefore you need a Health Canada Medical Device Licence), you are required under the Medical Device Regulations to implement a quality system compliant with ISO 13485:2003.[58] There are no regulatory quality system requirements for Class I medical devices.

In order to show compliance, the manufacturer of a medical device must submit a valid certificate issued by a Health Canada recognized Registrar.[59] The essential information that Health Canada requires to be displayed on ISO 13485:2003 quality management system (QMS) certificates can be found at this Guidance Document.[60] Health Canada's website provides you with the most recent list of accredited certificate registrars recognized by Health Canada (as of December 2014). An accredited registrar should be contacted prior to completing your application, to ensure that you have all the appropriate documents.

To demonstrate conformance with the safety and effectiveness requirements or the labeling requirements by using one or more recognized standards (including ISO 13485), a "Declaration of Conformity" must be submitted. The form for making a "Declaration of Conformity" is posted on Health Canada's Form Index page. A "Declaration of Conformity" will be necessary in order to obtain a new or amended MDL for Classes II-IV, authorization for Special Access, or authorization to sell/import Class III or IV custom-made devices, and investigational testing for Classes II-IV devices.[61] A certificate issued by a recognized registrar for a quality management system is an "attestation of conformity" to the specified requirements. A copy of the new or amended certificate should be sent with your application to the Medical Devices Bureau. Form

[57] CSA Group. (2016). *The Canadian Electrical Code.* Retrieved October 14, 2016, from http://www.csagroup.org/global/en/services/codes-and-standards/installation-codes/canadian-electrical-code

[58] Health Canada. (2016). Quality Systems ISO 13485. Retrieved October 14, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/index-eng.php

[59] Health Canada (2011). *Study Guide GD211: Guidance on the content of quality management system audit reports.* Retrieved October 14, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/md_im_stu_gui_etude_gd211-eng.php

[60] Health Canada. (2015). Guidance Document GD207: Guidance on the Content of ISO 13485 Quality Management System Certificates Issued by Health Canada Recognized Registrars. Retrieved October 14, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas_scecim_accep_cert13485_gd207-eng.php

[61] Health Canada. (2009). Guidance Document: Recognition and Use of Standards under the Medical Devices Regulations. Retrieved October 14, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_standards_im_ld_normes-eng.php

F202 can be used if you are sending the certificate information separate from an application, for example, if you need to send an updated certificate to the Medical Devices Bureau.[62]

All records, including the actual test data or information relating to a manufacturer's compliance or "Declaration of Conformity" with standards, should be maintained for a period of two years after a licence or authorization has been obtained for the device, or for the expected design life of the device, whichever is longer. If Health Canada ceases to recognize a standard, licences and authorizations issued under the old standard will continue to be valid, but conformance with it will no longer be acceptable for obtaining a new device licence or an authorization.

Note that if a recognized standard describes a test method, but does not specify a unique pass and/or fail criterion, the supporting evidence must be submitted. Remember to keep all evidence for a period of at least 2 years, or the life of the device if longer, after authorization is obtained. Also note that there may be other standards with which to conform to depending on your particular innovation: see guidance from Health Canada on medical devices standards for more information.[63] The current list of Health Canada recognized standards is posted on the Health Canada web site – please ensure that you consult this list before submitting your application.

Information Security Standards – ISO 27001; ISO 27002; ISO 17788; ISO 17789; ISO 27017

When considering the use of cloud computing for your IT services, it is recommended that international standards be applied. In particular, ISO/IEC 27001:2013 Information Technology Security Techniques – Information Security Management Systems Requirements[64] is recommended for any outsourced IT services. Its companion standard ISO/IEC 27002:2013 Code of Practice for Information Security Management[65] is particularly useful for medical device innovators, as it includes requirements for a comprehensive set of information security safeguards for commercial services. This standard recommends information security controls for preventing or mitigating risks to confidentiality, integrity, and availability of information. This includes having information security continuity, sufficient redundancy and appropriate backups, secured networks, security requirements for information systems (including web applications and transactions), compliance with legal requirements, and information security reviews.

A health service or hospital wishing to use your medical device may ask you for full disclosure of ISO 27001 or ISO 27002 certification documents. Critics of these standards have noted their broad nature and a lack of reference to two extremely pressing information security issues:

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[62] Health Canada (2013). Form F202 – Submission of a New or Modified Quality Management System Certificate. Retrieved October 14, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/md_im_f202-eng.php

[63] Health Canada. (2013). Guidance Document: Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers. Retrieved October 14, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_suppliers_im_ld_fournisseurs-ghtf-eng.php

[64] The ISO 27000 Directory. (2013). An Introduction to ISO 27001 (ISO26001), Retrieved October 14, 2016, from http://www.27000.org/iso-27001.htm

[65] The ISO 27000 Directory. (2013). An Introduction to ISO 27002 (ISO26002), Retrieved October 14, 2016, from http://www.27000.org/iso-27002.htm

BYOD (bring your own device) and cloud computing. ISO subsequently released two new standards for cloud computing: ISO/IEC 17788 and ISO/IEC 17789. By the end of 2015, ISO/IEC 27017 was published to close some of the gaps related to cloud computing within the existing standards. Nonetheless, the safeguards outlined in these standards may need to be supplemented when outsourcing to a cloud computing service and when dealing with particularly sensitive health information.

Privacy Standards – CSA Model Code

The CSA *Model Code for the Protection of Personal Information,* based on OECD Guidelines and forming an important component of Canada's *Personal Information Protection and Electronic Documents Act* (PIPEDA), is based on the following 10 principles:

1. Accountability
2. Identifying purposes
3. Consent
4. Limiting collection
5. Limiting use, disclosure, and retention
6. Accuracy
7. Safeguards
8. Openness
9. Individual access
10. Challenging compliance

When handling sensitive health information, it is particularly crucial to ensure that cryptography is properly implemented and the keys securely managed in line with approved and appropriate encryption standards. While the CSA Model Code is a voluntary standard, it is supported and endorsed as a national standard on privacy protection.[66]

Procedure regarding alternative methods of compliance with standards

Conformance with recognized standards is *voluntary*. A manufacturer applying to Health Canada for a medical device licence may choose to demonstrate conformance with a recognized standard, but also has the option to address the relevant issues in another manner.

If a standard is recognized by Health Canada, a manufacturer applying for a licence for a device to which that standard applies must either:

a. meet the standard; or
b. meet an equivalent or better standard; or
c. provide alternate evidence of safety or efficacy

If the manufacturer chooses option (b) or (c), detailed information must be submitted with the device licence application. If the manufacturer does none of the above, a licence will not be issued.

[66] Brook, J. C. (2016). CSA Model Code. Retrieves October 14, 2016, from https://www.cippguide.org/2010/06/29/csa-model-code/

APPENDIX B: Risk-based Classification system for non-In Vitro Diagnostic Devices

The following is the rule-based classification process, as specifically described in the Appendices of the Health Canada Guidance Document - Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs) (updated June 12, 2015). These descriptions, together with the MDRS and other Health Canada guidance documents, were used to inform the classification information in this document.

Rules for non-IVDD medical devices[67]

1. **Invasive Devices (Rules 1 - 3)**
2. **Non-invasive Devices (Rules 4 - 7)**
3. **Active Devices (Rules 8 - 12)**
4. **Special Rules (Rules 13 - 16)**

Invasive Devices

Rule 1: all surgically invasive device, II, unless intended to diagnose, monitor, control or correct a defect of the CVS/CNS or fetus in utero, IV, unless intended to be absorbed by the body, III, unless long term (≥ 30 days) surgically invasive, III.

Rule 2: All devices invasive via a body orifice or that come into contact with the surface of the eye; II, unless placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum, I, unless long term (≥ 30 days) invasive, III, unless intended to prevent transmission of infectious agents during sexual activities or reducing the risk thereof, III.

Rule 3: despite rules 1 and 2, all denture materials and orthodontic appliances, and their accessories, II, all surgical or dental instruments, I, all latex condoms, II.

Non-invasive Devices

Rule 4, Come into contact with injured skin, II, unless intended to be used as a mechanical barrier, for compression or for absorption of exudations, I.

Rule 5, channel or store gases, liquids, tissues or body fluids for eventual administration into the body, II.

[67] Health Canada (2015). *Guidance Document – Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs).* Retrieved October 14, 2016, from http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/gd_rbc_non_ivdd_lg_scr_autres_idiv-eng.php

Rule 6, modify the biological or chemical composition of body fluids or liquids for eventual administration into the body, III, unless, modification may introduce a foreign substance that is potentially hazardous, IV. Unless, modification accomplished through centrifugation, filtration or the exchange of heat or gas, II.

Rule 7, all others, I, unless, connected to a Class II, III, or IV active device, II. Unless, act as calibrator, tester or quality control support, II.

Active Devices

Rule 8, Emit ionizing radiation, including any device intended to control, monitor or influence such a device, III, unless intended to be used in radiographic mode, II, unless, intended to be used for mammographies, III.

Rule 9, active therapeutic device (and dedicated software) intended to administer or withdraw energy to or from the body, II, unless, administration or withdrawal is potentially hazardous, III, unless, control treatment of patient's condition through a closed loop system, IV.

Rule 10, active diagnostic device (& dedicated software) intended to image or monitor physiological processes, II, unless, erroneous readings could result in immediate danger, III.

Rule 11, administer or withdraw drugs, body fluids or other substances to or from the body, II, unless, administration or withdrawal is potentially hazardous, III, unless, control treatment of patient's condition through a closed loop system, IV.

Rule 12, all others, I.

Special Rules

Rule 13, Intended to be used to: Disinfect or sterilize blood, tissues or organs that are intended for transfusion or transplantation, IV, unless, disinfect or sterilize a medical device, II.

Rule 14, manufactured using animal or human cells or tissues or their derivatives or produced through the use of recombinant DNA technology, IV, unless, intended to only come into contact with intact skin, I.

Rule 15, a material sold to a health care professional or dispenser for configuration or arrangement into a mould or shape to meet an individual's needs is the same class as the class of the finished medical device.

Rule 16, despite rules 1 to 15, breast implants, IV, tissue expanders for breast reconstruction and augmentation, IV.