

Original Research Article

Navigating Healthcare Regulation in Canada: Ensuring Quality and Accessibility

Abstract:

Healthcare regulation plays a crucial role in ensuring the quality and accessibility of healthcare services in Canada. This article provides an overview of the healthcare regulatory landscape in Canada, focusing on federal and provincial/territorial regulations. The federal level regulations, overseen by Health Canada, encompass drug and medical device regulations, health information privacy and security, and food safety and nutrition regulations. Provincial and territorial regulations, implemented by respective healthcare authorities, address licensing and regulation of healthcare professionals, healthcare facility regulation, and allocation of healthcare resources. The article discusses the importance of health information privacy and security regulations in the digital age and highlights the safeguards and best practices to protect personal health information. By understanding and navigating these healthcare regulations, stakeholders can contribute to a healthcare system that ensures quality and accessibility for all Canadians.

Keywords: Healthcare Regulation, Health Canada, Quality, Accessibility, Federal Regulations, Provincial Regulations, Healthcare Resources.

Introduction:

Navigating the healthcare system in Canada involves understanding and adhering to various regulations put in place to ensure quality, safety, and accessibility of healthcare services. As one of the key regulatory authorities in the country, Health Canada plays a vital role in overseeing healthcare regulation, particularly in the areas of drug and medical device safety, as well as health information privacy and security. This article aims to provide a comprehensive overview of healthcare regulation in Canada, with a focus on the role of Health Canada in safeguarding the well-being of Canadians[1][2].

Health Canada, as the federal regulatory authority for healthcare, is responsible for developing and enforcing regulations that govern the approval, manufacturing, and distribution of drugs and medical devices. These regulations are crucial in ensuring the safety and efficacy of healthcare products available to Canadians. Health Canada's oversight includes rigorous assessment processes for drug approvals, post-market surveillance to monitor adverse events, and ongoing monitoring of manufacturing facilities to maintain quality standards[3].

In addition to its role in drug and medical device regulation, Health Canada also plays a significant part in safeguarding patient information and privacy. With the increasing digitalization of healthcare records and the use of electronic health systems, protecting personal

health information has become a paramount concern. Health Canada collaborates with provincial and territorial authorities to develop and implement regulations that ensure the privacy and security of health information, while also promoting interoperability and efficient information sharing among healthcare providers.

Ensuring accessibility to healthcare services is another crucial aspect of healthcare regulation in Canada. The Canada Health Act, a federal legislation, sets out the principles and criteria for healthcare services, emphasizing the principle of universality, which ensures that all Canadian residents have access to necessary healthcare services. Healthcare regulation at both federal and provincial levels aims to reduce wait times for specialist consultations and surgeries, promote telemedicine and virtual care options, and address healthcare disparities among different populations, including Indigenous communities, rural areas, and marginalized groups.

Understanding and navigating healthcare regulation in Canada is essential for healthcare professionals, policymakers, and patients alike. Compliance with regulations ensures the provision of high-quality care, protects patient safety, and promotes equitable access to healthcare services. By highlighting the role of Health Canada and discussing key aspects of healthcare regulation, this article aims to provide valuable insights into the regulatory framework that underpins the Canadian healthcare system, ultimately contributing to better healthcare outcomes for all Canadians[4][5].

I. Overview of the Canadian Healthcare System:

The Canadian healthcare system is a publicly funded, universal healthcare system that provides essential medical services to all Canadian residents. It is designed to ensure that every individual has access to necessary healthcare services, regardless of their ability to pay. The system is primarily funded through taxes and is governed by a combination of federal, provincial, and territorial regulations.

Under the Canadian healthcare system, medically necessary services are covered by the government, including visits to doctors, hospital care, and diagnostic tests. The system operates on the principle of universality, meaning that all Canadian residents are entitled to receive these services. This principle is enshrined in the Canada Health Act, which outlines the criteria and conditions that provinces and territories must meet in order to receive federal funding for healthcare[6].

The Canadian healthcare system is primarily administered at the provincial and territorial levels, with each province and territory having its own healthcare authority responsible for the delivery of healthcare services. These authorities oversee various aspects of the healthcare system, including licensing and regulation of healthcare professionals, management of hospitals and healthcare facilities, and allocation of healthcare resources.

The federal government, through Health Canada, plays a significant role in healthcare regulation at the national level. Health Canada is responsible for regulating and overseeing drug and medical device safety, ensuring that these products meet stringent standards for quality, efficacy, and safety. The agency also plays a key role in protecting the privacy and security of health information, particularly in the digital age where electronic health records and information sharing are prevalent.

While the Canadian healthcare system is often lauded for its commitment to providing accessible healthcare to all citizens, it is not without its challenges. Wait times for certain procedures and specialist consultations can be lengthy, particularly in high-demand areas. Access to healthcare in rural and remote regions can also be a challenge, with limited healthcare infrastructure and shortages of healthcare professionals.

Efforts are continuously being made to address these challenges and improve the healthcare system. Innovations such as telemedicine and virtual care have been embraced to increase access to healthcare services, particularly for individuals in remote areas. Healthcare regulation plays a crucial role in ensuring quality, safety, and accessibility within the system, while also addressing emerging issues and adapting to evolving healthcare needs.

Overall, the Canadian healthcare system is characterized by its commitment to universality, accessibility, and quality of care. Healthcare regulation, at both the federal and provincial levels, is integral to maintaining and enhancing the healthcare system, ensuring that Canadians receive the care they need when they need it[7][8].

II. Federal Healthcare Regulations:

Federal healthcare regulations in Canada play a significant role in ensuring the safety, quality, and accessibility of healthcare services across the country. These regulations are primarily overseen and implemented by Health Canada, the federal department responsible for promoting and protecting the health of Canadians[9]. Key Federal Healthcare Regulations are mentioned in Table.1.

Table 1: Key Federal Healthcare Regulations

Regulation	Description
Food and Drugs Act	Governs the safety and efficacy of drugs, medical devices, and food products in Canada.
Medical Devices Regulations	Establishes the regulatory framework for the sale and distribution of medical devices in Canada.
Patented Medicine Prices Review	Regulates the prices of patented medicines to ensure

Board (PMPRB) Guidelines	they are not excessive.
Post-Market Surveillance	Monitoring and reporting of adverse events related to drugs and medical devices post-approval.
Biosimilars Initiative	Promotes the use of safe and effective biosimilar drugs as alternatives to costly biologic drugs.

A. Drug and Medical Device Regulations: Health Canada is responsible for regulating the approval, sale, and use of pharmaceutical drugs and medical devices in Canada. The department establishes rigorous standards and processes to ensure the safety, efficacy, and quality of these products.

1. Drug Approval: Health Canada's Therapeutic Products Directorate reviews and approves pharmaceutical drugs before they can be marketed and distributed in Canada. The approval process involves assessing the drug's safety, efficacy, and quality through rigorous scientific evaluations. Health Canada also conducts ongoing monitoring of approved drugs to detect and address any safety concerns or adverse reactions.
2. Medical Device Regulation: Health Canada regulates the sale and use of medical devices to ensure their safety and effectiveness. The department classifies medical devices based on their level of risk and establishes regulatory requirements for each class. Health Canada's Medical Devices Bureau reviews applications for medical device licenses, conducts post-market surveillance, and enforces compliance with regulations[10][11].

B. Health Information Privacy and Security: In the digital age, protecting the privacy and security of health information is of paramount importance. Health Canada, along with provincial and territorial authorities, establishes and enforces regulations to safeguard personal health information[12][13].

1. Personal Information Protection: Health Canada collaborates with provincial and territorial privacy commissioners to develop and enforce privacy legislation and guidelines. These regulations govern the collection, use, and disclosure of personal health information by healthcare providers, ensuring that individuals' privacy rights are respected.
2. Electronic Health Records: Health Canada supports the adoption and implementation of electronic health records (EHRs) to enhance the accessibility and efficiency of healthcare information. The department works with stakeholders to establish interoperability standards and security protocols for EHR systems, ensuring the safe and secure exchange of health information between healthcare providers.

C. Food Safety and Nutrition Regulations: Health Canada is responsible for regulating food safety and nutrition standards to protect the health of Canadians. The department establishes regulations and guidelines for food labeling, product safety, and nutritional information to promote consumer awareness and make informed food choices.

1. **Food Safety:** Health Canada establishes regulations to ensure the safety of food products in Canada, including standards for manufacturing, handling, and storage. The department conducts inspections, monitors food recalls, and works collaboratively with provincial and territorial authorities to enforce food safety regulations.
2. **Nutrition Labeling:** Health Canada establishes guidelines for nutrition labeling on packaged food products. These guidelines require food manufacturers to provide accurate and standardized information about the nutritional content of their products, allowing consumers to make informed choices and maintain a healthy diet.

Federal healthcare regulations in Canada are continuously evolving to address emerging issues, technological advancements, and changing healthcare needs. Health Canada plays a vital role in developing and implementing these regulations, working in collaboration with provincial and territorial authorities, healthcare professionals, and other stakeholders. The aim is to ensure the safety, quality, and accessibility of healthcare services, as well as to protect the privacy and well-being of Canadians.

III. Provincial and Territorial Regulation:

Provincial and territorial regulation is a critical component of the Canadian healthcare system, working in conjunction with federal regulations to ensure the delivery of quality healthcare services. Each province and territory in Canada has its own healthcare authority responsible for overseeing and implementing regulations specific to their jurisdiction. These regulations address various aspects of healthcare delivery, licensing and regulation of healthcare professionals, and allocation of healthcare resources[14].

A. **Licensing and Regulation of Healthcare Professionals:** Provincial and territorial regulatory bodies play a crucial role in licensing and regulating healthcare professionals within their jurisdiction. These bodies are responsible for setting standards of practice, establishing licensing requirements, and ensuring that healthcare professionals meet the necessary qualifications and competencies.

1. **Professional Colleges:** Each province and territory has its own professional colleges or regulatory bodies for different healthcare professions such as physicians, nurses, pharmacists, and allied health professionals. These colleges set standards of practice, enforce ethical guidelines, and oversee the licensure and discipline of healthcare professionals to ensure the delivery of safe and competent care.
2. **Scope of Practice:** Provincial and territorial regulatory bodies define the scope of practice for various healthcare professions. This includes outlining the specific activities, procedures, and responsibilities that healthcare professionals are authorized to perform

within their respective disciplines. These regulations ensure that healthcare professionals practice within their areas of expertise and competencies.

B. Healthcare Facility Regulation: Provincial and territorial healthcare authorities also regulate healthcare facilities to ensure compliance with standards of safety, quality, and patient care. These regulations apply to hospitals, long-term care facilities, clinics, and other healthcare settings.

1. **Licensing and Accreditation:** Healthcare facilities must obtain licenses or certifications to operate, which are granted by provincial or territorial authorities. These licenses are contingent upon meeting specific regulatory requirements related to infrastructure, staffing, infection control, and patient safety. Accreditation organizations, such as the Canadian Council on Health Services Accreditation (CCHSA), play a role in assessing and certifying healthcare facilities' adherence to quality standards.
2. **Quality Assurance:** Provincial and territorial healthcare authorities implement quality assurance mechanisms to monitor and evaluate the performance of healthcare facilities. This may involve regular inspections, audits, and assessments to ensure compliance with standards of care, infection control protocols, and patient safety measures. These regulations aim to maintain high-quality healthcare services and patient outcomes.

C. Allocation of Healthcare Resources: Provincial and territorial healthcare authorities are responsible for the allocation and management of healthcare resources within their jurisdictions. This includes healthcare funding, workforce planning, and the provision of services in line with the specific healthcare needs of their populations.

1. **Healthcare Funding:** Each province and territory determines the allocation of healthcare funding based on their budgetary considerations and population needs. These authorities work to ensure the equitable distribution of resources, taking into account factors such as population size, demographics, and healthcare demands.
2. **Healthcare Planning:** Provincial and territorial healthcare authorities engage in strategic planning to address the healthcare needs of their populations effectively. This includes workforce planning to ensure an adequate supply of healthcare professionals, as well as infrastructure development and service delivery models that align with the specific healthcare demands within each jurisdiction.

Provincial and territorial regulations complement federal healthcare regulations in Canada, allowing for tailored approaches to healthcare delivery while upholding consistent standards of quality, safety, and accessibility. The collaborative efforts between federal, provincial, and territorial authorities ensure that healthcare regulation is comprehensive and responsive to the specific needs of Canadians across the country[15].

IV. Health Information Privacy and Security:

In an era of increasing digitalization and interconnected healthcare systems, health information privacy and security have become critical considerations in healthcare regulation. Protecting the confidentiality and integrity of personal health information is essential to maintain patient trust and ensure compliance with legal and ethical standards. In Canada, health information privacy and security regulations are established at both the federal and provincial/territorial levels.

A. Federal Regulations: At the federal level, the Personal Information Protection and Electronic Documents Act (PIPEDA) governs the collection, use, and disclosure of personal health information in the private sector. PIPEDA sets out rules and principles for the protection of personal information, including health information, by private organizations engaged in commercial activities.

Under PIPEDA, organizations are required to obtain informed consent for the collection, use, and disclosure of personal health information. They must also ensure that appropriate security safeguards are in place to protect the information against unauthorized access, loss, or theft. In cases where a privacy breach occurs, organizations are obligated to notify affected individuals and the Office of the Privacy Commissioner of Canada.

B. Provincial and Territorial Regulations: Provincial and territorial authorities also play a significant role in health information privacy and security regulations. Each province and territory has its own legislation or regulations that govern the protection of health information within their jurisdiction.

1. Personal Health Information Acts (PHIAs): Several provinces and territories have enacted Personal Health Information Acts (PHIAs) that specifically address the protection of health information in the healthcare sector. These acts outline the rights and responsibilities of healthcare providers and organizations, the conditions for collecting and using health information, and the mechanisms for individuals to access and correct their personal health information.
2. Health Information Custodians: Provincial and territorial legislation designates certain entities or individuals as "health information custodians" who are responsible for the collection, use, and disclosure of health information within the healthcare system. These custodians are required to adhere to privacy and security standards, implement policies and procedures for the protection of health information, and ensure appropriate access controls and safeguards are in place.

C. Safeguards and Best Practices: To ensure compliance with health information privacy and security regulations, healthcare organizations and providers are encouraged to adopt best practices and implement safeguards. These may include:

1. Privacy Policies and Procedures: Healthcare organizations should develop and implement comprehensive privacy policies and procedures that align with legislative requirements. These policies should address how personal health information is collected, used, disclosed, and retained, as well as the measures in place to protect against unauthorized access and breaches[16][1][2].

2. **Access Controls and Authentication:** Implementing robust access controls, such as unique user IDs, strong passwords, and role-based access, helps ensure that only authorized individuals have access to personal health information. Multi-factor authentication can provide an additional layer of security to protect against unauthorized access.
3. **Encryption and Data Security:** Encryption technologies should be employed to secure personal health information when it is transmitted or stored electronically. This helps to safeguard the information in the event of unauthorized interception or theft.
4. **Staff Training and Awareness:** Healthcare organizations should provide regular training and awareness programs to staff members regarding privacy and security practices. This includes educating employees on their responsibilities in handling personal health information and raising awareness about potential risks and threats.
5. **Privacy Impact Assessments:** Conducting privacy impact assessments (PIAs) when implementing new systems or processes can help identify and address potential privacy risks and ensure compliance with privacy regulations. PIAs assess the potential impact of new initiatives on the privacy and security of personal health information.

By implementing robust privacy and security measures, healthcare organizations and providers can effectively protect personal health information and uphold individuals' privacy rights. Compliance with federal and provincial/territorial regulations is essential to maintain patient trust, promote information sharing, and ensure the safe and secure exchange of health information within

V. Access to Care and Wait Times

A. **The Canada Health Act and the principle of universality:** The Canada Health Act, enacted in 1984, is a federal legislation that sets out the principles and criteria for healthcare services in Canada. One of the key principles is universality, which ensures that all Canadian residents have access to necessary healthcare services regardless of their ability to pay. This principle guides healthcare regulation in Canada, emphasizing the importance of equitable access to care for all citizens.

B. **Challenges in ensuring timely access to care:** Despite the commitment to universality, Canada faces challenges in providing timely access to care. Wait times for specialist consultations and surgeries have been a persistent concern. Factors contributing to these wait times include a shortage of healthcare professionals, limited healthcare infrastructure, and increasing demand for services.

Efforts to reduce wait times: To address these challenges, various strategies have been implemented across the country to reduce wait times and improve access to care. These initiatives include:

1. **Wait Time Guarantees:** Some provinces have introduced wait time guarantees for certain procedures, setting maximum acceptable wait times for specific services. This approach aims to provide patients with timely access to care and ensures accountability within the healthcare system[3].
2. **Centralized Referral Systems:** Several provinces have implemented centralized referral systems to streamline the process of accessing specialist care. These systems help prioritize patients based on the urgency of their condition and ensure a more efficient referral process.
3. **Improved Surgical Efficiency:** Efforts have been made to improve the efficiency of surgical services, including implementing standardized operating room protocols, optimizing scheduling and coordination, and adopting innovative surgical techniques. These measures aim to maximize the utilization of surgical resources and reduce wait times for elective procedures.

C. Impact of healthcare regulation on access to care:

1. **Telemedicine and virtual care:** The COVID-19 pandemic has accelerated the adoption of telemedicine and virtual care services in Canada. Healthcare regulation has played a crucial role in facilitating the expansion of these services by providing guidelines and standards for their implementation. Telemedicine has the potential to improve access to care, particularly for individuals in remote or underserved areas, by allowing patients to consult with healthcare professionals remotely.
2. **Regulation of private healthcare services:** The regulation of private healthcare services in Canada is a complex issue. While the public healthcare system aims to provide equitable access to care, some Canadians seek private healthcare options to bypass wait times. Healthcare regulation plays a role in ensuring that private healthcare services adhere to quality and safety standards while maintaining the principles of universality and accessibility[17].

VI. Health Professions Regulation and Scope of Practice

A. **Regulation of healthcare professionals' education and training:** Healthcare professionals in Canada are subject to stringent regulations governing their education and training. Regulatory bodies, such as the College of Physicians and Surgeons, College of Nurses, and College of Pharmacists, ensure that healthcare professionals meet the required standards of competence and ethics. These regulatory bodies establish licensing requirements, develop and enforce professional codes of conduct, and oversee continuing education programs to ensure ongoing professional development.

B. Ensuring professional competence and ongoing learning: Healthcare regulation in Canada emphasizes the importance of professional competence and ongoing learning to maintain high standards of care. Healthcare professionals are required to engage in continuing education and professional development activities to stay updated with the latest advancements in their respective fields. Regulatory bodies monitor compliance with these requirements and may conduct periodic assessments or audits to assess competence.

C. Interprofessional collaboration and scope of practice:

1. Nurse practitioners and expanded roles: Nurse practitioners (NPs) play a vital role in the Canadian healthcare system, particularly in primary care settings. Healthcare regulation has recognized the expanded scope of practice for NPs, allowing them to perform certain functions traditionally reserved for physicians, such as prescribing medications and ordering diagnostic tests. This expanded role enhances access to care, particularly in underserved areas, and promotes interprofessional collaboration.
2. Collaborative practice models: Healthcare regulation encourages collaborative practice models where healthcare professionals from different disciplines work together to provide comprehensive care. These models facilitate coordinated and integrated care delivery, ensuring that patients receive the right care from the right professionals at the right time. Regulatory bodies establish guidelines and frameworks for interprofessional collaboration, emphasizing the importance of effective communication, shared decision-making, and respect for professional boundaries[18].

VII. Addressing Healthcare Disparities

A. The impact of social determinants of health: Healthcare disparities in Canada are influenced by social determinants of health, such as income, education, employment, and access to housing and healthy food. These factors contribute to inequities in health outcomes, with certain populations experiencing higher rates of illness and reduced access to healthcare services. Recognizing the impact of social determinants of health is essential for developing effective regulatory initiatives to address healthcare disparities as mentioned in Table.2.

Table 2: Regulatory Initiatives to Address Healthcare Disparities

Initiative	Description
Indigenous Cultural Safety Training	Cultural safety programs to enhance healthcare providers' understanding of Indigenous cultures and improve healthcare delivery to Indigenous communities.
Mental Health Outreach Programs	Community-based programs and services to improve access to mental health support and reduce disparities in mental healthcare.

Rural and Remote Healthcare Hubs	Establishing healthcare hubs in rural and remote areas to centralize services, ensuring access to comprehensive care.
Language Interpretation Services	Providing language interpretation services in healthcare settings to address language barriers and improve access to care for diverse populations.

B. Regulatory initiatives to address health disparities:

1. Indigenous healthcare and cultural safety: Canada has made efforts to address the healthcare disparities faced by Indigenous communities. Regulatory bodies and healthcare organizations are implementing cultural safety training programs to enhance healthcare providers' understanding of Indigenous cultures, histories, and experiences. These initiatives aim to improve access to culturally appropriate care and address historical injustices in the healthcare system.
2. Mental health and addiction services: Healthcare regulation in Canada recognizes the importance of mental health and addiction services in achieving overall health and well-being. Efforts are underway to improve access to mental health services, increase funding for community-based programs, and enhance coordination between primary care providers and mental health specialists. Regulatory bodies also play a role in developing guidelines for the appropriate prescribing and monitoring of psychotropic medications.
3. Rural and remote healthcare challenges: Healthcare regulation acknowledges the unique challenges faced by individuals in rural and remote areas in accessing healthcare services. Initiatives have been implemented to improve access, such as the deployment of telemedicine and mobile healthcare clinics, financial incentives for healthcare professionals to work in underserved areas, and the establishment of healthcare hubs to centralize services. Regulatory bodies collaborate with regional health authorities to address these challenges and ensure equitable access to care across the country.

VII. Addressing Healthcare Disparities

C. Regulatory initiatives to address health disparities :

4. Culturally competent care for diverse populations: Canada is a multicultural and diverse country, and healthcare regulation recognizes the importance of providing culturally competent care to diverse populations. Regulatory bodies promote cultural competence training for healthcare professionals to enhance their understanding of the cultural, linguistic, and religious backgrounds of patients. This approach helps ensure that

healthcare services are delivered in a respectful and inclusive manner, addressing disparities related to language barriers, cultural norms, and beliefs.

5. Health equity and social determinants of health: Recognizing the impact of social determinants of health on healthcare disparities, regulatory initiatives are focusing on addressing broader social factors that influence health outcomes. This includes collaborations with other sectors such as education, housing, and employment to create policies and programs that tackle social determinants of health. By addressing social inequities and structural barriers, healthcare regulation aims to improve health equity and reduce disparities across different populations[1][2].

Conclusion:

Healthcare regulation in Canada is a complex and multifaceted system that plays a crucial role in ensuring quality, safety, and accessibility of healthcare services. The regulatory framework spans federal, provincial, and territorial levels, with each level addressing specific aspects of healthcare delivery. Through regulations, policies, and initiatives, Canada strives to provide equitable access to care, reduce healthcare disparities, and promote patient safety.

However, healthcare regulation is an evolving field, and ongoing efforts are necessary to adapt to changing healthcare needs, technological advancements, and societal challenges. Collaboration among policymakers, healthcare professionals, regulatory bodies, and stakeholders is essential to drive continuous improvement and address emerging issues.

By maintaining a strong regulatory framework, promoting innovation, investing in healthcare infrastructure, and addressing healthcare disparities, Canada can enhance its healthcare system and ensure that all Canadians have access to high-quality care when they need it. Ultimately, a well-regulated healthcare system is essential for safeguarding the health and well-being of the Canadian population.

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