

NEMA Position Paper

Impacts of the British Columbia Act 73-2004 (an amendment to the Freedom of Information and Protection of Privacy Act) on Medical Device Support in British Columbia

NEMA, the National Electrical Manufacturers Association, is the nation's largest trade association representing the electro-industry. Domestic shipments of electrical products within the NEMA scope exceed \$100 billion.

NEMA's Diagnostic Imaging and Therapy Systems Division represents the majority of diagnostic imaging and therapy device manufacturers and manufacturers of medical image management IT systems.

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1. Purpose and Scope

The purpose of this document is to review the British Columbia Act 73-2004 (the Act) an amendment to the Freedom of Information and Protection of Privacy Act, and to provide guidance to legislators and healthcare providers on the Act's impact on patient safety, patient-care timeliness, and the cost of supporting Medical Information Systems (MedIS¹).

The Act was created with a primary focus on protecting personal financial and medical information by limiting access, viewing, and storage of this data outside of Canadian Borders². The Act significantly alters manufacturers' ability to provide support to their customers from centers of excellence located outside of Canadian borders for MedIS used for clinical care, billing, scheduling, medical record management, etc.

This paper is aimed at assessing the impacts of the Act on MedIS support, patient care, and business costs to the Canadian Healthcare System, resulting from unanticipated changes to MedIS equipment maintenance practices.

2. Summary of the Act

The Act is an amendment to the *Freedom of Information and Protection of Privacy Act, R.S.B.C. 1996, c. 165*, which became law in October 19, 2004. The legislation was responsive to public concerns over disclosure of personally identifiable information (PII) to countries deemed by British Columbia Parliament as implementing less stringent privacy laws. The amendment was passed to ensure PII, and control of PII, remained within Canadian borders. The legislators identified the U.S. Patriot Act, part 215, as a primary concern.³ The Patriot Act allows government access to any data controlled by U.S. corporations without notification to the data owner.

The primary goal of the Act is to restrict access, viewing, and transfer of personal information collected and maintained in British Columbia to only within Canada. Because deploying specialized resources may require the ability to access, transfer, or store data outside Canadian borders, the Act effectively prevents MedIS manufacturers from providing advanced levels of service and support to installed MedIS systems containing PII that are in the custody or control of a public body (i.e., a hospital).

¹ MedIS generally includes all information systems directly employed in delivering health care. Examples include, but are not limited to: HIS (Hospital Information System), PACS (Picture Archiving and Communication Systems), imaging modalities, radiation therapy systems, cardiology information systems, and patient monitoring systems.

² Reference: *Submission of the Office of the Privacy Commissioner of Canada to the Office of the Information Privacy Commissioner for British Columbia*, August 18, 2004.

³ Pub. L. 107-56, *US Patriot Act*, Oct. 26, 2001.

Significant Features of the Act:

- The restrictions on disclosure and use of personal information apply to public body employees, persons who provide services to public bodies, their employees, other individuals and corporations that are service providers as defined in Schedule 1 and Section 4.
- Exceptions for access, transfer, or storage of PII outside of Canada are granted for urgent repair of equipment required for providing critical care only with patient consent.
- All platforms and support applications used for access, transfer, or storage of PII must be located in Canada and be isolated from any connectivity to countries considered to have inadequate privacy laws.
- If a corporation commits an offence⁴ under this section, an officer, director or agent of the corporation who authorizes, permits or acquiesces in the commission of the offence also commits an offence, whether or not the corporation is prosecuted for the offence.
- A person who commits an offence under this section is liable:
 - in the case of an individual, other than an individual who is a service provider, to a fine of up to \$2 000,
 - in the case of a partnership that is or individual who is a service provider, to a fine of up to \$25 000, and
 - in the case of a corporation, to a fine of up to \$500 000.
- Any agreements with public bodies secured prior to October 2004 are exempt from the requirements.

3. Supporting British Columbian Healthcare Initiatives

According to British Columbia's Office of the Ministry of Health Services 2004/2005 Annual Service Plan Report (ASPR), the Ministry has allocated significant resources to improving the quality of health services. The BC ASPR indicates that capital investment in the health sector is used to fund, among other things, imaging modality purchases and information technology tools and systems that support patient care and health system management. "This infrastructure is the foundation that allows the health professionals to provide quality health care and services to British Columbians."⁵

⁴ The Act defines offence as – "unauthorized disclosure of personal information", where disclosure of, production of or the provision of access to personal information, if that disclosure, production or access is not authorized by this Act.

⁵ *Ministry of Health Services Annual Service Plan Report 2004/05*, available at <http://www.bcbudget.gov.bc.ca/annualreports/hs/hs.pdf>, at 83.

Impacts of Act 73-2004 Amendment to Freedom of Information and Protection of Privacy Act

August 2005

The Ministry effort to “[e]ncourage innovation, integrating services and applying proven best practices in the treatment of health conditions”⁶ spans a broad spectrum of activities, including:

- Investment in leading-edge medical equipment, such as **a new PET unit** to be located at the Vancouver Cancer Centre; **new CT scanners** for Royal Columbian Hospital, Royal Jubilee Hospital, Vancouver General Hospital, Lion’s Gate Hospital and Kelowna General Hospital, and **a new MRI scanner** at Children’s and Women’s Hospital, **a mobile MRI scanner** for the Kootenays and South Okanagan, and an upgraded MRI scanner at UBC hospital.
- Established an **Electronic Health Steering Committee** to accelerate the development and implementation of eHealth for British Columbia.
- Construction of new **300-bed Abbotsford Regional Hospital and Cancer Centre**, estimated completion—2008.
- Redevelopment of Prince George Regional Hospital, including **new patient care building** with new medical/surgical beds, **improved critical care services** and **new emergency department**.
- Redevelopment of the Royal Inland Hospital, Kamloops, with a new emergency department and a **new medical imaging department** scheduled to be opened—Summer 2005.
- Construction of **Nanaimo Regional General Hospital**.
- Construction of the 19-story Jim Pattison Pavilion at Vancouver General Hospital, with 459 new beds and **modern equipment and care facilities**.
- Fraser Valley Cancer Centre in Surrey, and Vancouver Cancer Centre to acquire and accommodate **eight new and replacement linear accelerators**.⁷

In 2003, the First Ministers’ Accord on Health Care Renewal allocated \$1.5 billion for a national diagnostic and medical equipment fund.⁸ B.C. alone, received \$200.1 million for spending through 2005/06. In September of 2004, the First Ministers’ Agreement then added to this allocation an additional \$66 million in Medical Equipment funding for British Columbia.

According to data provided by the Canadian Institute for Health Information (CIHI)⁹, for example, the number of CT scanners installed in the British Columbia region has doubled in the last 13 years. MRI scanner installations have increased by more than 600% since

⁶ *Id.* at 3.

⁷ *See id.* at 14.

⁸ *See id.* at 85.

⁹ Canadian Institute of Health Information, available at <http://secure.cihi.ca/cihiweb>.

1991. The increase in installations of Medical Imaging Devices is reflective of the increase in need for these services (population growth, disease management, quality healthcare delivery) and medical-technological progress, yet falls short of projecting the upcoming surge of installations promised by the Ministry's current initiatives. The increase in imaging device installations and utilization of associated technologies and services will likely continue to rise, if the Ministry adheres to its objectives.

4. Impacted MedIS Support Practices

MedIS manufacturers currently leverage global support applications, infrastructure and expert resources from all regions of the world to provide elevated uptime and deliver superior customer care. This involves sharing knowledge and data among support team members to deliver more rapid and effective customer support. Enforcing the Act as it currently stands will prevent MedIS from using support resources outside of Canada; increase the cost to providers; and ultimately increasing the cost to Canadian Healthcare. The increased cost will likely impact the Ministry's priority strategy (*Priority Strategy 13*) to "manage the delivery of services within budget."¹⁰ Given the Ministry's considerable resource allocation to the various projects for improving and developing healthcare facilities and services, the need for MedIS support will undoubtedly increase.

The following are examples of the quality service features which are relied upon by MedIS manufacturers, Healthcare providers, and patients:

- Supporting over-the-shoulder consultative expertise from service and clinical luminaries.
- Leveraging diagnostic clinical services outside of Canada for peak and off peak care volumes.
- Providing medical records for Canadian residents traveling outside of Canada.
- Using follow-the-sun support models to provide awake and alert 24x7x365 service coverage.
- Accessing system experts throughout the organization to provide deeper technical support.
- Using files/data from customer systems to recreate issues in development labs for rapid remote resolution of application and hardware issues.
- Retrieving data from the equipment to identify problems and parts needing replacement and ship them to the site prior to the arrival of the field service engineer.
- Rapid distribution MedIS-approved security patches.
- Global support flexibility based on redundant remote support centers.

¹⁰ Ministry of Health Services Annual Service Plan Report 2004/05, available at <http://www.bcbudget.gov.bc.ca/annualreports/hs/hs.pdf>, at 58.

**Impacts of Act 73-2004 Amendment to Freedom of Information and
Protection of Privacy Act** **August 2005**

The exposure of Canadian personal information as a result of these activities comprises the “incidental access” as discussed in the Information Technology Association of Canada (ITAC) Position Paper “The USA Patriot Act and the Privacy of Canadians.”¹¹ Impeding these practices will adversely affect system uptime, patient care and safety, system effectiveness, and system functionality, resulting in decreased delivery of high-level, cost-effective service and support. In addition, the Act is likely to reduce the number of MedIS manufacturers able or willing to respond to provincial RFPs and direct sale proposals for the “Canada Health Infoway.”¹²

In effect, the Act will seriously hinder the program mission:

to foster and accelerate the development and adoption of electronic health information systems with compatible standards and communications technologies on a pan-Canadian basis with tangible benefits to Canadians,¹³

as well as the Ministry’s vision:

to provide a high-quality, sustainable and effective Canadian healthcare system supported by an info-structure that provides Canadians and their healthcare providers timely, appropriate and secure access to the right information when and where they enter into the healthcare system.¹⁴

The following table provides a summary of impacts to healthcare providers and their patients.

¹¹ ITAC Position Paper, *The USA Patriot Act and the Privacy of Canadians*, July 2005 –available at <http://www.itac.ca/Library/PositionStatements/05July4ITACUSAPatriotAct.pdf>.

¹² *Canadian Health Infoway*, available at <http://www.infoway.ca/aboutinfoway/vision.php?lang=en>.

¹³ *Id.* at <http://www.infoway-inforoute.ca/news-events/index.php?loc=20020626b&lang=en>.

¹⁴ *Id.*

**Impacts of Act 73-2004 Amendment to Freedom of Information and
Protection of Privacy Act** **August 2005**

Legislative Requirement	Manufacturer Response Options	Financial & Functional Implications	Healthcare Implications & Policy Concerns
Access to PII only within Canada	Expand, develop or build MedIS support capabilities in Canada.	<p>Increase in manufacturer cost to provide services.</p> <p>Potential to pass along increased costs to the customer.</p>	<p>General reduction in quality of care.</p> <p>B.C. Ministry of Health Services Goals to increase and improve clinical care rendered unattainable and ineffective due to heightened MedIS costs.</p> <p>Enforcement directly conflicts with Ministry of Health Services Goals:</p> <ul style="list-style-type: none"> • Increasing Access • Improving Quality • Future Sustainability <p>Reduction of patient access to certain types of care (inefficient patient-flow through system due to service- related events).</p> <p>Reduction in national productivity, due to decline in health.</p>
	Limit services to accommodate Act's requirements.	<p>Decreased efficiency based on impacts to operational workflow and diminished servicing resources.</p> <p>Limits support by system specialists, resulting increase response time, increased risk to patient safety and access to clinical specialists</p>	
	Limit products / market withdrawal.	Decreased efficiency based on reduction of access to technology advancements.	

**Impacts of Act 73-2004 Amendment to Freedom of Information and
Protection of Privacy Act**

August 2005

Legislative Requirement	Manufacturer Response Options	Financial & Functional Implications	Healthcare Implications & Policy Concerns
<p>Transfer of PII only within Canada</p>	<p>Stop file/study transfers to global support and development centers.</p> <p>Increase staff or increase response time.</p>	<p>Increase in manufacturer cost to provide products and services.</p> <p>Potential to pass along increased costs to the customer.</p> <p>Decreased efficiency based on operational workflow and diminished servicing resources.</p> <p>Limits support by system specialists, resulting increased response time, increased risk to patient safety and access to clinical specialists.</p>	<p>General reduction in quality of care.</p> <p>B.C. Ministry of Health Services Goals to increase and improve Medical IT rendered unattainable and ineffective due to heightened costs.</p> <p>Enforcement directly conflicts with Ministry of Health Services Goals:</p> <ul style="list-style-type: none"> • Increasing Access • Improving Quality • Future Sustainability <p>Reduction of patient access to certain types of care (inefficient patient-flow through system due to service-related events).</p> <p>Reduction in national productivity, due to decline in health.</p>
	<p>Limit products / market withdrawal.</p>	<p>Decreased efficiency based on operational workflow and diminished servicing resources.</p>	

**Impacts of Act 73-2004 Amendment to Freedom of Information and
Protection of Privacy Act** **August 2005**

Legislative Requirement	Manufacturer Response Options	Financial & Functional Implications	Healthcare Implications & Policy Concerns
Canadian isolation of support networks and systems	Expand, develop or build MedIS support capabilities in Canada and hire additional staff	<p>Increase in manufacturer cost to provide services.</p> <p>Potential increase in cost to customer.</p> <p>Decreased efficiency based on operational workflow and diminished servicing resources.</p> <p>Loss of access to system specialists, clinical experts online escalations, software upgrades and diagnostic applications.</p>	<p>General reduction in quality of care.</p> <p>B.C. Ministry of Health Services Goals to increase and improve clinical care rendered unattainable and ineffective due to heightened MedIS costs.</p> <p>Enforcement directly conflicts with Ministry of Health Services Goals:</p> <ul style="list-style-type: none"> • Increasing Access • Improving Quality • Future Sustainability
	Limit products / market withdrawal.	<p>Decreased efficiency based on reduction of access to technology advancements.</p> <p>Loss of access to system specialists, clinical experts online escalations, software upgrades and diagnostic applications.</p>	<p>Reduction of patient access to certain types of care (inefficient patient-flow through system due to service- related events).</p> <p>Reduction in national productivity, due to decline in health.</p>

5. Recommendations

MedIS manufacturers understand and support the importance of the right to privacy and our objective does not diminish our stance on privacy of patient information. Medical information privacy legislation, however, has elucidated the potential for conflict between principles of information privacy and those of patient care. This group strongly recommends careful consideration of these issues with a bias in favor of patient safety. Further, we agree with and strongly encourage the context-specific, risk-based, non-

Impacts of Act 73-2004 Amendment to Freedom of Information and Protection of Privacy Act

August 2005

legislative approach for managing cross-border data flow put forth by the ITAC Position Paper¹⁵ and its adoption.

The Ministry's Priority Strategy 5 of the ASPR: *Build the Foundation for Integrated Care Networks*, "focuses on integrating and providing care in the most coordinated and seamless manner possible to the benefit of patients and health care providers. The first part of the strategy concerns adapting business process and using technology to allow care providers and facilities such as laboratories and hospitals to share information and provide coordinated care."¹⁶

MedIS manufacturers have developed and implemented privacy policies and security practices to ensure that PII is properly handled as required by multiple pieces of global privacy and security legislation. These policies and practices were developed to provide the highest level of support, while simultaneously protecting patient privacy.

Recommendations include:

- Require MedIS manufacturers to authenticate users connecting to the system from outside Canada.
- Require accountability trails and provide quarterly reports to healthcare providers.
- Develop materials and educate patients and government officials on:
 - PII content that MedIS manufacturers may need or have access to during support activities.
 - The limited timeframe that PII is maintained by MedIS manufacturers.
- Amend The Act to allow access by MedIS manufacturers in order to provide remote support.

These recommendations should be reviewed at a meeting with the office of the British Columbia Privacy Commissioner, healthcare providers, and NEMA member manufacturers.

6. Conclusion

The Act was enacted to limit the disclosure of personal financial information outside of Canada, and to reduce the risk of Information Technology outsourcing and disclosures by domestic or foreign law enforcement agencies.

This group strongly believes that the legislative effects of the Act, which effectively prevent MedIS services from accessing information necessary to perform the highest

¹⁵ ITAC Position Paper *The USA Patriot Act and the Privacy of Canadians*, July 2005 - <http://www.itac.ca/Library/PositionStatements/05July4ITACUSAPatriotAct.pdf>.

¹⁶ *Ministry of Health Services Annual Service Plan Report 2004/05*, available at <http://www.bcbudget.gov.bc.ca/annualreports/hs/hs.pdf>, at 38.

quality of service, are counter to the Ministry's initiatives and will significantly impair the Ministry's ability to adhere to its own stated priorities.

Without the ability to obtain the best possible services for the newly-funded systems and devices in the most cost-effective and efficient manner, the quality and quantity of health services will likely suffer. The assumption that the costs associated with enforcement of the Act would be borne by the manufacturers, and thus are of lesser concern to the overall healthcare system is unrealistic. The reality is that the cost distribution will be experienced by all customers, most notably, the increasing population in need of these services. "An aging population with a rising burden of chronic illness resulting in the continuing rise in demand for increasingly complex and expensive health care services," will be impacted by the imposition of the Act.¹⁷ By allowing an exception, or providing a clarification enabling high-quality, timely, and appropriate services to be performed by manufacturers with Canadian (specifically British Columbian) installations, the Ministry's spending initiatives will be more effective in increasing imaging and other health services. Furthermore, precedent for an exception to the restrictions, or legislative accommodation, may assist in effectuating change throughout Canada and internationally, where other regions may initiate similar legislative efforts.

In order to continue providing high-quality products and services to existing installations, as well as increase service-levels to accommodate these proposed future developments, product manufacturers outside Canadian borders, and those providing services from outside Canadian borders (i.e., remotely), must find a suitable avenue allowing access to necessary systems and information.

Discussions between the British Columbia Privacy Commissioner and MedIS manufacturers, with an objective to develop a balanced approach, are necessary to produce a clarification paper, or proposed amendment, addressing patient privacy concerns and simultaneously supporting the highest levels of safe, quality, cost-effective patient care.

¹⁷ See *id.* at 10.