

HEALTH INFORMATICS

On August 31 2009, Health Canada issued a notice that patient management software is subject to the *Medical Devices Regulations* under Canada's Food and Drug Act. This notice affects manufacturers, importers, distributors and users of patient management software. This Bulletin provides an overview of the impact of Health Canada's decision on the procurement, implementation and management of electronic record keeping systems used by health care providers to create, maintain and transfer personal health information.

August 31 2009 Notice

The notice provides that:

Any patient management software used only for archiving or viewing information or images and not involved in the primary acquisition, manipulation and transfer of data, is considered a Class I medical device.

Any patient management software with capabilities beyond basic data visualization is considered a Class II medical device, including any dedicated software that supplies energy for the purpose of imaging or monitoring physiological processes.

Patient management software for data manipulation, data analysis, data editing and recording of measurements is also classified as an active diagnostic device.

In general:

- Organizations that import, sell or otherwise distribute Class I or Class II patient management software must have an **establishment license**;
- Organizations that manufacture Class II patient management software for sale or distribution must have a **medical device license** for each patient management software product sold;
- Manufacturers of medical devices must hold a **quality management system certificate** demonstrating compliance with ISO 13485: 2003 *Medical devices – Quality management systems – requirements for regulatory purposes*.



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HEALTH INFORMATICS

- Certain post-market responsibilities, including maintaining records of complaints and their management, problem reporting and recalls will be imposed.

Guidance Letter to Hospital Administrators

In a letter addressed to hospital administrators, Health Canada underlined the requirement for health care providers to comply with the Canadian *Medical Devices Regulations* including those relating to medical device licensing. It was *explicitly* noted that *facilities who import and purchase unlicensed devices may place the health and safety of their staff and patients at risk* – and as a result, *Health Canada advises that medical devices that are not licensed for sale in Canada should not be purchased by health care facilities.*

Issues

Although Class I and Class II medical devices are described in the notice, the details surrounding the licensing requirements for patient management software remain unclear. The ambiguities include how the medical device licensing regulations apply to: a) software that connects separate applications for interoperability (referred to as “middleware”), interfaces enabling online access, and the core software underlying (“driving”) an application (referred to as “engines”); b) application service providers (that provide information technology services to health care providers over a network); c) the configuration and integration of commercial off-the-shelf software; and d) legacy systems (as many patient management software providers do not currently have establishment licenses or medical device licenses for their products).

In response to a request for clarification submitted by the Information Technology Association of Canada (ITAC), Health Canada notified ITAC on about May 17, 2010 that the deadline for obtaining establishment licenses for the sale of Class I Devices will be February 1, 2011 and the deadline for obtaining medical device licenses for Class II Devices will be September 1, 2011.

Given the size of the Canadian health care market and the reality that many vendors of patient management software are not Canadian companies, the question arises as to what health care providers are to do if the vendor of software they are using refuses to obtain the required licenses. There are also questions around the responsibilities for licensure where patient management software is being developed. For example, there is no clear guidance on who bears the responsibility to obtain the required licenses where a health care provider, Ministry of Health or government agency retains a company to develop software and the intellectual property and distribution rights belong to the provider, Ministry or agency rather than the developer.

Yet another issue involves how quickly Health Canada will be able to process applications for the required licenses given the windows often placed around funding provided for information technology projects in the health care sector.

HEALTH INFORMATICS

Summary

As a result of Health Canada's inclusion of patient management software in the definition of a medical device, hospitals and other health care providers should in the short term:

- take an (or update their) inventory of the patient management software they are using;
- request a representation from their patient management software vendors/licensors that they will be in compliance with the medical device regulatory scheme in Canada on the applicable dates;
- revise their procurement materials and processes and their agreements for patient management software and related services to include the mandatory requirements for patient management software;
- ensure that any patient management software that was or is developed by the organization will be compliant with the requirements.

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