

Torys on Intellectual Property

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Classifying Patient Management Software in Canada

By [Eileen McMahon](#) and [Jason Gilman](#)

Health Canada has clarified the approach taken by its Medical Devices Bureau to classify patient management software as either a Class I or a Class II medical device.

Classifying Software as a Medical Device

Not all patient management software will fit the definition of a medical device under Canada's *Medical Devices Regulations* (the Regulations), which regulate the sale of these devices. To be designated as a medical device, the software must be intended (as stated on the manufacturer's label) to be used for one of the medical purposes set out in the definition of a device in Canada's *Food and Drugs Act* – for example, for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms.

Classifying Software as a Class I or Class II

Whether patient management software is a Class I or Class II medical device affects its associated regulatory requirements and obligations. Class I medical devices have a lower perceived risk profile and a lower regulatory burden than Class II medical devices. Class I medical devices do not require registration before they are sold, although they are subject to certain other compliance requirements.

The notice that provides the clarification and updates a notice released in August 2009 states that “[a]ny patient management software used only for storing, acquiring, transferring or viewing data or images is considered a Class I medical device.”¹ Software that is used for the purpose of monitoring a physiological condition, state of health, illness or congenital deformity will be classified as a Class II medical device. According to the updated notice, Class II medical device software can include patient management software that is “involved in data manipulation, data analysis, data editing, image generation, determination of measurements, graphing, flagging of results, identifying a region of interest or performing calculations” if the calculations directly affect diagnosis and/or treatment of a patient.

The earlier notice stated that a Class II medical device may be involved in the “transfer of data.” However, this term created uncertainty since most software transfers data in some manner – for example, to a server for back-up storage purposes.

To discuss these issues, please contact the authors.

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¹ A copy of the relevant notice can be found [here](#).

Application of Regulations to Open-Source Software

The updated notice provides that the Regulations also apply to open-source software (which in most cases is available to users at no cost²). The onus is on the user of the open-source software to ensure that the software is properly licensed, and the notice states that “the user will be liable for any unlicensed software.” Health Canada’s approach, as evidenced by this notice, is that it will look to the manufacturer, importer and/or distributor of the patient management software to ensure that any incorporated open-source software complies with the Regulations.

Bringing Your Software into Compliance

Health Canada has suggested that all manufacturers determine the classification of their patient software (i.e., Class I or Class II) by June 15, 2010. It has indicated it will be focusing its compliance efforts on patient management software in early 2011, first focusing on Class I patient management software in early 2011 and then on Class II patient management software in late 2011.

Health Canada is expected to soon publish “Frequently Asked Questions” to provide additional guidance on the classification of patient management software. 

² The definition of “sale” in s. 2 of the *Food and Drugs Act* includes the distribution of a device whether or not the distribution is made for consideration.