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MEDICAL MALPRACTICE

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Bill 160, *Strengthening Quality and Accountability for Patients Act*, 2017

On October 26, 2017, Bill 160, *Strengthening Quality and Accountability for Patients Act*, 2017 was "carried on division" and referred to the Standing Committee on General Government for consideration. The Bill was introduced by Minister of Health and Long-Term Care, the Honourable E. Hoskins and underwent first reading on September 27, 2017.

If made law, Bill 160 will impact ten pieces of legislation: *Health Sector Payment Transparency Act, 2017; Health Protection and Promotion Act, 1990; Long-Term Care Homes Act, 2007; Retirement Homes Act, 2010; Ambulance Act, 1990; Oversight of Health Facilities and Devices Act, 2017; Medical Radiation and Imaging Technology Act, 2017; Excellent Care for All Act, 2010; Ontario Drug Benefit Act, 1990; and Ontario Mental Health Foundation Act, 1990.*

Of interest to Ontario medical patients is the Bill's creation of the *Oversight of Health Facilities and Devices Act, 2017.*

If enacted, the *Oversight of Health Facilities and Devices Act, 2017* ("OHFDA") would create the legislative framework to designate and regulate what it defines as community health facilities ("CHFs"). The legislation would also create a framework to regulate medical imaging and diagnostic devices, including CT scanners, x-ray machines, ultrasound machines, and MRIs. The legislation defines these types of devices as energy applying and detecting medical devices ("EADMDs"). The legislation sets out a licencing process for CHFs and EADMDs. Oversight authority is given to an Executive Officer, who would be appointed by Cabinet.

Community Health Facilities

A CHF is defined as "(a) a place or collection of places where one or more [health] services prescribed in regulations made by the Minister are provided, and includes any part of such a place, and (b) a place or collection of places prescribed in regulations made the Minister".

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At this point, it is difficult to know how it will be determined which premises fit within the above definition, particularly since the OHFDA provides significant discretion to the Minister to determine which premises it wants covered by the legislation. It is hoped that regulations by the Minister will provide more guidance.

Energy Applying and Detecting Medical Devices

There appears to be an attempt to fully define EADMDs by the OHFDA. The lengthy definition states that EADMDs are defined as a device that "(a) is an instrument, apparatus, contrivance or other similar article, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in, (i) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings, or (ii) restoring, modifying or correcting the body structure of human beings or the functioning of any part of the bodies of human beings, and (b) is used to, (i) apply to the body of a human being acoustic, electromagnetic or particle radiation , or (ii) detect acoustic, electromagnetic, or particle radiation emitted from or applied to the body of a human being pharmaceutically or by other means". This definition would obviously appear to include x-ray machines, CT scanners, ultrasound machines and MRIs, but it remains to be seen whether it will include other medical devices, (e.g. operative instruments).

This proposed regulation of EADMDs should be seen as a welcome step toward furthering patient safety. The government's purpose in including this licence requirement is to "ensure" safety and quality when EADMDs are used on patients.

Inspecting Bodies

The legislation also sets out powers to inspect CHF and use of EADMDs. It is proposed that an Inspecting Body would have broad powers to "request a licensee, prospective licensee or other prescribed person to provide the inspecting body with any information or reports that the inspecting body considers necessary for the purpose of carrying out its functions."

Inspectors would have the power to enter and inspect without a warrant or other order at any reasonable time. The OHFDA enables compliance orders, cessation orders and administrative monetary penalties to be issued. Additionally, every order made by the Executive Officer under the OHFDA in relation to a CHF must be made public. However, similar to the *Regulated Health Professions Act*, 1991, SO 199, c 18, the OHFDA prohibits an inspector or person doing anything authorized by the OHFDA from being a witness in a civil proceeding.

As considerable discretion has been provided to the Minister in creating the regulations under the OHFDA, the full impact of the legislation will not be known until such regulations are published. Hopefully, the publication of Executive Orders will provide greater transparency to patients in relation to the health care facilities that they attend for treatment.

It appears that the Act (*Oversight of Health Facilities and Devices Act, 2017*) will go a long way in ensuring further patient safety for Ontarians by permitting the inspection of CHFs and regulating the use of EADMDs.