ONTARIO PHYSIOTHERAPY ASSOCIATION

HEALTH QUALITY ONTARIO EXPERT PANEL ON SAFETY AND QUALITY OF ENERGY-APPLYING MEDICAL DEVICES

RESPONSE FROM THE ONTARIO PHYSIOTHERAPY ASSOCIATION

The Ontario Physiotherapy Association (OPA) represents over 5,500 member physiotherapists, physiotherapist assistants and students in Ontario. The OPA is the Ontario Branch of the Canadian Physiotherapy Association. On behalf of our members, the OPA welcomes the opportunity to contribute to this stakeholder consultation on the review of the *Healing Arts Radiation Protection Act* (HARP) and the regulation of energy-applying medical devices (EAMDs).

There are several reasons why the HARP Act is in need of review and why doing so should be a priority for government. The HARP Act came into being in the early 1980s and hasn't been significantly amended since. New medical technologies that didn't exist, were in their infancy or under development in the 1980s are now commonplace, terminology has changed and the education and training of healthcare professions has evolved. Legislation, policies, standards and guidelines internationally in other jurisdictions have evolved beyond the framework established by the HARP Act and other legislation such as the *Occupational Health and Safety Act* and the *Regulated Health Professions Act*.

The physiotherapy profession provides a demonstration of the inability of current legislation to adapt to changes. Studies have demonstrated the importance of medical imaging in assisting physiotherapists to manage patients' disease processes, improve communications about patient care, improve diagnosis, prognosis and interventions for patients and to identify contraindications to examination and interventions.[1]

Starting in 2007, the Ministry of Health and Long-Term Care began to consider authorizing the physiotherapy profession to order x-rays and certain "forms of energy" within the physiotherapy scope of practice as part of a larger scope of practice review for the profession.[2] As a result, amendments to the *Physiotherapy Act, 1991* were tabled in the Legislature in 2009 and were supported by all parties. At the time, the Premier (Mr. McGuinty) and the Minister of Health and Long-Term Care (Mr. Caplan) spoke about the benefits to Ontario's health care system and patients' access to care that would be generated by physiotherapists and other health professionals working up to their full scopes of practice. This included the ability of physiotherapists to order x-rays.[3] The College of Physiotherapists of Ontario standard of professional practice for performing authorized activities was updated in preparation for these changes. The amendments to the *Physiotherapy Act* obtained Royal Assent in December 2009. As of the date of this submission, the profession is still waiting for the authority to order x-rays and other forms of energy to be implemented. A significant barrier remains the implementation of needed regulatory changes to the HARP Act. The physiotherapy profession is not alone in this

predicament. While this may be outside of the mandate of the Expert Panel's work, we want to be clear that while the modernization of the current legislation is necessary, in the interim, we are urging the MOHLTC to address these outstanding scope matters. The MOHLTC must deliver on their commitment to ensure that health care professionals are able to work to their full scope of practice so that Ontarians can access the right care at the right time in the right place.

The OPA is pleased to note the Panel's focus on the safety and quality of "energy-applying medical devices" (EAMDs). In our view, the scope of the *Healing Arts Radiation Protection Act* (HARP) is excessively restrictive in its focus on x-ray equipment that emits radiation with peak energy greater than 5 k. The OPA believes that a modernized and more comprehensive regulatory structure needs to be devised for medical devices and medical imaging technologies that emit ionizing and non-ionizing radiation and other forms of energy that entail a threshold risk of harm to patients, to operators and to the general public.

That being said, in the Expert Panel's terms of reference "therapeutics" is included in the category of EAMDs. Understandably at this point, it is unclear how "therapeutics" is defined or may be defined and specifically whether electrophysical agents (EPA's) are or would be included. "EPAs" is a general term used to describe the collection of devices that use physical energy (electrical, electromagnetic, thermal, light, or sound waves) in a therapeutic manner to reduce impairments or promote recovery of function.[4] We cannot comment on how EPAs are used by members of other professions or how they are regulated by other Colleges. In the case of physiotherapy the appropriate clinical use of the EPAs is taught in all accredited physiotherapy education programs. EPAs are commonly used in physiotherapy practice for the treatment of pain, musculoskeletal and neurological conditions and in some cases, wound care. EPAs are not currently regulated under the HARP Act, nor defined as "forms of energy" pursuant to Regulation 107/96 under the *Regulated Health Professions Act* (RHPA) and never have been. They are regulated by the College of Physiotherapists as part of the practice of physiotherapy in Ontario, as is the case in other jurisdictions to the best of our knowledge. There is no evidence of which we are aware suggesting that the use of EPAs by physiotherapists has not been effectively regulated by the College of Physiotherapists. In meeting the College's standards of professional practice, physiotherapists are required to use their skills, knowledge and judgement in assessing whether the use of an EPA is indicated. Assessment includes being current on the evidence relating to the use of EPAs for a specific condition, the contraindications and precautions and the monitoring of the patient response to treatment. If a patient were harmed during the course of treatment where an EPA is the cause for injury, the Colleges has full and unquestioned jurisdiction to act through the complaints and discipline processes.

The OPA urges the Expert Panel to consult with those professions (both Colleges and professional associations) whose members use EPAs within their respective scopes of practice. The objective is to create a list of EPAs, or a clear definition thereof, that should be included within the "forms of energy" controlled acts (i.e. Regulation 107/96) because their application or administration constitutes a material risk of harm to patients or practitioners

that thereby requires them to be taken out of the public domain and subject to the "controlled acts level" of regulation. EPA's have become ubiquitous in healthcare practice. They have also become a very important component of providing safe and effective care. EPA technologies and applications are constantly changing. Accordingly, and because of a history of safe, appropriate and effective use (at least within the physiotherapy profession) care should be taken to include within the controlled acts regime only those EPAs that cannot be effectively regulated by the RHPA Colleges.

The HARP Act itself specifying those professions that may order x-rays or operate x-ray equipment has made it difficult to amend in order to enable members of additional professions to order or take x-rays as part of their legislated scope of practice in response to a combination of enhanced competencies and health care system demands. This situation has resulted in unacceptable delays for professions that have acquired the competencies to order x-rays safely and effectively, to facilitate timely and effective diagnosis, to enhance efficiency in healthcare delivery and to improve the patient experience.

We are, therefore, recommending a much more flexible regulatory framework wherein the foundational statute provides an enabling framework that specifies the reach of the regulatory system, as well as its objectives and establishes whatever agencies of government that may be deemed necessary for regulatory purposes. Beyond that, as much as possible of the regulatory system should rely on regulations (where legal enforceability is required), policies, standards of practice and guidelines that can be relatively easily amended to respond to changing circumstances and requirements. This overarching framework would ensure protection of the practitioner, patient and public safety, but should also promote the adoption of safe and effective EAMDs to the benefit of Ontario's healthcare delivery system.

It is also our view that the regulation of practitioners who operate EAMDs or who order imaging or tests generated by EAMDs, should be incorporated into the controlled acts regime of the *Regulated Health Professions Act* (RHPA) specifically within the controlled act of "applying or ordering the application of a form of energy prescribed by the regulations under this Act" (subsection 27. (2) 7.). This consolidation would promote regulatory efficiency and consistency. Under this approach, the Colleges would be responsible for the regulation, standards and competencies required of regulated professionals who perform these acts.

In that regard, we propose a different approach to the identification of practitioners authorized to operate EAMDs and/or order tests or therapies by EAMDs. In the approach we propose, "core" or "minimum" competencies would be specified by regulation under the foundational statute and would be adapted and implemented on a profession-specific basis by individual RHPA Colleges for which the controlled act, or portions thereof, have been authorized.

We also propose the establishment of a standing Expert Panel that consists of individuals who have relevant expertise from the federal and Ontario governments and from non-

government bodies. Members of the panel would be appointed by the Lieutenant-Governor-in-Council. Its role would be to continuously review the regulatory system, including the relevant statute(s), regulations, policies, standards and guidelines to recommend appropriate updates and other changes and to receive advice from stakeholders. The Expert Panel should also monitor and ensure compliance with the RHPA Colleges' regulations, policies, standards of practice and guidelines insofar as they apply to the regulation of practitioners authorized to order EAMD tests or therapies, or practitioners who are authorized to operate EAMDs.

The Radiation Protection Officer (RPO) function needs to be given more prominence within the regulatory framework and its role (and title) expanded to include all EAMDs included within the regulatory ambit. The competencies required for the "RPO" function and their accountabilities need to be clearly specified and also need to be distinct from those required to order the application of EAMDs or operate EAMDs. Someone who has the competencies to order the application of an EAMD doesn't necessarily have the competencies to be an "RPO". In our view, the successors to RPOs need not necessarily be members of an RHPA profession (e.g. diagnostic sonographers, certified medical physicists), but must demonstrably have acquired the specialized competencies necessary to provide effective technical oversight.

The Ontario government should regulate facilities in which defined EAMDs are located to serve and protect the public. There needs to be legislative and regulatory integration between the new EAMDs regulatory framework and other legislation, such as Ontario's *Occupational Health and Safety Act*. We also urge the Government of Ontario to require and verify Quality Assurance Programs in each EAMD facility. The Government of Canada (one presumes through the Health Devices Directorate of Health Canada) and the Canadian Standards Association should continue to regulate EAMDs themselves from the perspective of safety and effectiveness

In conclusion, the OPA recommends an enabling legislative framework that achieves public, practitioner and patient protection, is adaptive to new and evolving technologies and sets out the competencies for the defined roles within the framework. Legislation achieving these objectives will enable, and not act as an unintentional barrier to, health professionals working to their full scopes of practice. For regulatory efficiency and consistency, we also think that integration of the regulation of all EAMDs whose application entails a risk of harm to patients, operators or the public (including the application of ionizing and non-ionizing radiation) is essential. The OPA expects that activities currently underway by government to ensure the outstanding authorized activities are implemented continue during this review exercise and we would be pleased to continue to work with government to support their work in this area and in the concurrent development of a new legislative and regulatory framework for the HARP Act.

ONTARIO PHYSIOTHERAPY ASSOCIATION

Sincerely,

Dorianne Sauvé,
Chief Executive Officer

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[2] Ontario Physiotherapy Association and College of Physiotherapists of Ontario. (2008) Physiotherapy Scope of Practice Review 2008: submission to the Health Professionals Regulatory Council. Available at: http://www.opa.on.ca/pdfs/HPRAC_Scope062708.pdf

[3] The Ministry of health and Long Term Care. Minister Considering Seeking Approval of Certain Regulation Proposals to Improve Access to Care for Ontarians. Health Bulletins. 29 June 2012. Accessed at: http://www.health.gov.on.ca/en/news/bulletin/2009/regulation_accesstocare.aspx

[4] Houghton PE, Nussbaum EL, Hoens AH. (2010). ELECTROPHYSICAL AGENTS - Contraindications and Precautions: An Evidence-Based Approach to Clinical Decision Making in Physical Therapy. Physiother Can. Fall 62(5):1-80