

HPRAC

Critical Links: Transforming and Supporting Patient Care

A Report to the Minister of Health
and Long-Term Care on Mechanisms to
Facilitate and Support Interprofessional
Collaboration and a New Framework
for the Prescribing and Use of Drugs
by Non-Physician Regulated
Health Professions



January 2009

Submitted by the
**Health Professions Regulatory
Advisory Council (HPRAC)**





Ontario

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Advisory Council

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January 31, 2009

Honourable David Caplan
Minister of Health and Long-Term Care
10th Floor, Hepburn Block
80 Grosvenor Street
Toronto, ON M7A 2C4

Dear Minister,

When the *Regulated Health Professions Act* was passed in 1991, Ontario was credited with enacting ground-breaking legislation. It created an expectation that regulated health professions would hold themselves to the highest quality standards of practice to serve patients and the public. It has been HPRAC's experience that in the great majority of situations this expectation has been met, even exceeded. Health care professionals - and the colleges that regulate them - have put the provision of high quality patient care at the centre of their objectives and they interact with patients and their families in a way that reflects this commitment.

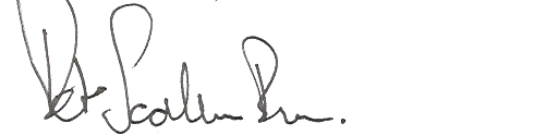
However, demographic, technological and economic factors constantly challenge the health care system. As Minister, you have articulated your government's vision "of a modern, accessible and sustainable health care system that delivers the highest quality care available in the world". Having listened to members of the public and to representatives from the professions and their regulatory colleges, and after examining advances in other jurisdictions, HPRAC recognizes that the status quo will not enable that vision to become a reality. Change is needed. HPRAC has provided advice in this report to help facilitate aspects of that change.

Our advice and recommendations in this report centre on the questions that were posed to HPRAC in June 2007, and we have commented specifically on interprofessional collaboration, non-physician prescribing, as well as on the scopes of practice of specific professions. We have built on the recommendations in *New Directions* and our other reports, addressing the profession-specific issues and also framework issues that we believe will contribute positively towards the systemic changes that are needed.

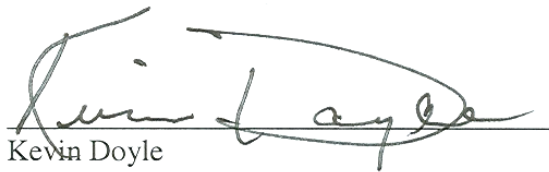
As a Council, HPRAC's work continues to be supported and informed through the generous involvement of members of the public, health professionals, the health colleges and associations, our external advisors, and HPRAC's staff, all of whom contribute their time, energy and knowledge and entrust us to use those resources wisely. We hope we have served them, and you, well with this report.


Yours truly,




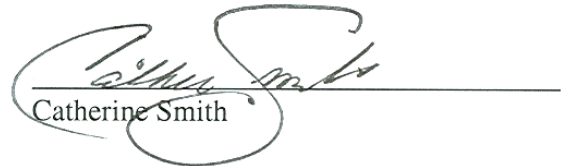
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Transforming and Supporting Patient Care

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CRITICAL LINKS: TRANSFORMING AND SUPPORTING PATIENT CARE

An Introduction

On June 28, 2007, the Minister of Health and Long-Term Care, Hon. George Smitherman, requested that the Health Professions Regulatory Advisory Council (HPRAC) provide advice on a series of eight issues. His request characterized these as “important matters” supporting the government’s commitment to ensure that the health profession regulatory system keeps pace with the health care needs of Ontarians. In this report, HPRAC responds to two of these requests: on the facilitation of interprofessional collaboration between health colleges and their members and on the prescribing and use of drugs by non-physician health professionals.

Why These Issues Matter

HPRAC has undertaken this work at a time when the province’s health care system faces unprecedented challenges. The overriding question for HPRAC is how the regulation of health professions can best be modernized to reflect rapid changes in Ontario society and health care delivery. What is at stake is of vital importance to the people of the province: access to care, the quality of care, and the sustainability of the health care system itself.

Fundamentally, health professions regulation is about people – the people who provide the health care Ontarians need, the way people work together, the opportunity for them to work to the utmost of their knowledge and skills, and the mechanisms that can assist them to work most effectively. It is also about ensuring that the laws, rules, standards and guidelines that health professions must follow are flexible enough to meet dynamic change and thorough enough that people can have confidence that their interests are protected. These matters form the substance of this report.

HPRAC is working toward a regulatory system that enables each of Ontario’s thousands of health professionals to contribute to patient care to the full extent of their training and abilities, to collaborate with each other so that the efforts of all are deployed to produce the best possible results for patients, and to respond with up-to-date skills and a deep sensitivity to the rising expectations of today’s health care consumers.

In the autumn of 2008, Hon. David Caplan, Minister of Health and Long-Term Care, articulated the government’s vision “of a modern, accessible and sustainable health care system that delivers the highest quality care available in the world”.¹ He established two overarching priorities: reducing wait times, especially in emergency rooms, and improving access to family health care. In achieving these priorities, he said the Ministry plans to

¹ Remarks by Hon. David Caplan to Canadian Club, Toronto, November 18, 2008.

focus on three areas: prevention and management of chronic diseases, an eHealth strategy and improving and expanding mental health and addictions services.

HPRAC is convinced that the maximization of health human resources through increased interprofessional collaboration and enhanced roles for a range of health professionals will contribute significantly to achieving the Minister's vision and priorities. Health professionals, working together and performing the right tasks at the right time will drive efficient and effective care in both hospital and community settings.

In an aging society, patients move from one setting to another for health services as their needs change. People may transfer, for example, from home care to long-term care to hospital and back, and be treated by numerous health professionals. Collaboration among professionals can ensure that patient needs are met without interruption and that patients are assured that when they receive care, each professional is aware of what, how and when other health services are being provided and for what reasons. It is vital that health professionals who have the know-how to safely do so can perform health services in a way that will improve care and enhance service and convenience to the patient.

The advice and recommendations in this report centre on the questions that were posed to HPRAC in June 2007. They include comment on interprofessional collaboration among health colleges and health professionals and the prescribing and use of drugs by non-physician health professions. HPRAC is proposing significant changes in the way Ontario's health colleges advance interprofessional collaboration at the regulatory level. Colleges should encourage and promote the delivery of more effective patient care. Health colleges should also have additional flexibility to respond to change.

In HPRAC's view, the proposed reforms will drive continuous improvement in health professions regulation, so Ontarians derive the maximum benefit from those who are charged with protecting their interests. HPRAC is proposing changes that will ensure that health professionals will be able to work to the utmost of their knowledge and skills, to collaborate more closely with others and to adapt more readily to patient expectations. What HPRAC foresees is a dynamic health profession regulatory system for the 21st century – one that will further a modern, accessible and sustainable health care system delivering the best care available in the world.

These changes, as envisaged by HPRAC, will unfold in the context of self-regulation by the health professions. The purpose of self-regulation is to protect the public interest. HPRAC contends that as health professions regulation continues to evolve in Ontario, the public interest must remain paramount. Patients must be at the core, not only as part of a care team, but also as the main impetus for change. As health care roles change,

colleges must be accountable for the competence of their members in providing high quality and safe patient care. We live in an age of accountability. Rising public expectations must be met.

It is also crucial to reduce barriers that inhibit health colleges from carrying out their functions as efficiently as possible. Too often, outdated rules, regulations, and laws limit how health colleges can realize collaboration or effect change. Too often, action must be postponed or cannot proceed because processes and structures are unresponsive when change is required.

HPRAC's recommendations aim to break down the barriers to interprofessional collaboration among health colleges and their members. But the recommendations go beyond removing obstacles to collaboration. They propose a regulatory system that is better aligned with the current and emerging realities of the modern health care system. They propose a regulatory system that has a robust capacity to evolve. They aim to strengthen the accountability of health colleges and how they demonstrate their effectiveness in protecting the public interest.

It is essential to strengthen and adopt a more collaborative approach to self-regulation. To help achieve that goal, HPRAC is recommending that a new independent agency should be introduced to work with the health colleges to modernize the regulatory system, achieve greater transparency and accountability, and facilitate sustained quality improvement in the regulation of health professionals in Ontario.

HPRAC's assessment began with the premise that strengthening collaboration among the health professions should be grounded in the following principles for regulatory reform:²

- Meeting public expectations for improved access to high quality, safe services and patient-centred care;
- Optimizing the contribution of all health professionals;
- Applying rigorous standards for the regulation of health professionals;
- Using resources efficiently;
- Sustaining the health care system, and
- Maintaining self-regulation.

All of these principles are reflected in HPRAC's recommendations on the regulatory system in general. They are also critical in establishing a new framework for approvals for the prescribing and use of drugs by health professionals, so health professionals can work to their full competencies. These recommendations will maintain the obligations of the government oversight through the regulation-making and approvals processes, while ensuring a more effective and efficient regulation-making and approvals process. HPRAC is convinced that both rigour and efficiency are key components in ensuring the commitment to patient-centred collaborative care.

² HPRAC (2008). *An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals: Phase II, Part I*: 8.

In short, the recommendations presented in this report reflect HPRAC's view that excellence in health professions regulation will lead to excellence in health care.

The Minister's Requests

Interprofessional Collaboration

In his June 2007 letter, the Minister asked HPRAC to:

Recommend mechanisms to facilitate and support interprofessional collaboration between health Colleges, beginning with the development of standards of practice and professional practice guidelines where regulated professions share the same or similar controlled acts, acknowledging that individual health Colleges independently govern their professions and establish the competencies for their profession.

He also asked HPRAC, in its analysis, to:

take into account, when controlled acts are shared, of public expectations for high quality services, no matter which health profession is responsible for delivering care or treatment.

Non-Physician Prescribing

In a further request, the Minister requested HPRAC to:

Examine the authority given to non-physician health professions to prescribe and/or use drugs in the course of their practice under the *Regulated Health Professions Act, 1991 (RHPA)* and the health profession Acts.

He also asked HPRAC to:

provide advice specific to each of these professions respecting whether lists, categories or classes of drugs should be prescribed by regulation for the profession, or whether restrictions on prescribing of drugs should be placed in regulation under the respective health profession Act.

and to:

provide advice on a framework and process for the ongoing evaluation of requests by Colleges for changes to regulations in this regard to ensure that such regulations reflect efficiency, best practices of the profession and provide maximum public protection.

This document contains HPRAC's third report to the Minister on interprofessional collaboration between health colleges and health

professionals, as well as its report conveying analysis and advice regarding a framework for approvals of drug regulations and specific recommendations for a number of professions who prescribe or use drugs in the course of their practice.

About HPRAC

HPRAC is an independent agency of the Government of Ontario created in 1993 under the *Regulated Health Professions Act, 1991 (RHPA)* to provide advice to the Minister of Health and Long-Term Care on matters related to the regulation of health professions in Ontario. Its mandate includes providing advice on:

- Whether unregulated health professions should be regulated;
- Whether regulated health professions should no longer be regulated;
- Amendments to the *RHPA* and related Acts, and their regulations;
- Matters concerning the quality assurance programs of the colleges;
- Any matter related to the regulation of health professionals, referred to HPRAC by the Minister, and
- The effectiveness of each college's patient relations program.

The Minister relies on recommendations from HPRAC as an objective source of information, analysis and advice in the formulation of public policy. In providing its advice and conducting its affairs, HPRAC is independent of the Minister, the Ministry of Health and Long-Term Care, the colleges, health care associations and others with an interest in issues on which advice is provided.

Primacy of the Public Interest

The purpose of health professions regulation is the advancement of the public interest, and this is the first principle or fundamental ground upon which everything else is founded. It is a basic moral precept that has become enshrined in the ethical codes of the health professions, and is enforced by professional regulation. HPRAC keeps this principle foremost in mind throughout its deliberations.

The Forces Driving Change

Heading the list of challenges facing the health care system is the changing demographic make-up of the province. Ontario is growing, aging and becoming more urbanized and more diverse – creating new and more complex needs.³

The population of the province is expected to increase by 3.1 million by 2025, with growth coming mainly from immigration and centred largely in the Greater Toronto Area (GTA). While the GTA's population is expected to grow by one third, the central, eastern and southwestern regions will likely

³ See Ontario Ministry of Finance, *Toward 2025: Assessing Ontario's Long-Term Outlook* and Statistics Canada, Census Data, 2001.

record slower increases and both northeastern and northwestern Ontario will probably experience population declines. According to the 2001 census, nearly a quarter of Ontario's population speaks one of more than 100 languages other than English.

The proportion of seniors in the Ontario population is forecast to rise sharply from 12.9 percent in 2005 to 19.4 percent in 2025, as the baby boom generation ages and life expectancies continue to rise. The expanding senior population brings a higher rate of chronic diseases, an increased need to care for patients with multiple complex conditions and more emphasis on resources to help seniors remain in their own homes.

As Ontario's population ages, so does its health care workforce. For example, 19 percent of practicing physicians are over the age of 60, and 11 percent are over 65.⁴ In the nursing profession, 2007 statistics show that one quarter of registered nurses in the general class are 55 years or older and 11 percent are 60 or older.⁵

Attracting and retaining physicians, nurses, technologists and other health professionals is already a challenge, not only in northern, rural and remote areas but increasingly in urban centres. This challenge will intensify as the health care workforce ages, with shortages of health professionals forecast to continue for at least the next two decades. During this period, Ontario's growing and aging population will rely on a constrained supply of professionals to provide necessary care.

Further pressure for change comes from progress in medical technology – both new equipment and new knowledge. Advanced technologies – from magnetic resonance imaging to image-guided surgery – enable earlier diagnosis or more effective treatment or both. In the longer run, genomics and new medical applications, such as robotics and nanotechnology, are expected to bring exponential changes to the delivery of health care.

At the same time, clinical practice has been reshaped by less invasive surgeries, more day surgery, more ambulatory care and the substitution of drug therapies for surgery. Innovations in pharmacotherapy have revolutionized treatment of diseases such as HIV/AIDS, cancer, mental illness and cardiac care. As a result, health services that were previously provided in hospital can now be delivered safely in the community or provided on an outpatient basis. As patients move between settings – for example, from hospitals to their own homes or long-term care facilities – continuity of care is a priority to keep the focus on patient needs.

In the digital age, the Internet has empowered consumers to become more informed participants in their own care and telemedicine has improved access to specialized diagnosis and treatment. Eventually, all Ontarians will have an electronic health record, giving patients and providers the ability to access, share and use health information.

⁴ Ontario Medical Association. *Doctors: Physician Resource Crisis Continues to Deepen in Ontario*, November 21, 2005 (<http://www.oma.org/Media/News/pr051121.asp>).

⁵ College of Nurses of Ontario, *Membership Statistics Report 2007*. 8, 24.

These rapid changes in population needs, coupled with advances in technology and clinical practice place enormous demands on professionals to keep pace – demands that must be met not only by working to the maximum extent of their capabilities, but also by developing new competencies.

Focus on Health Human Resources

All in all, these firmly established trends have combined to put a new focus on health human resources. It is clear that innovation in their use, development and management is essential.

This is why, in May 2006, the Ministry of Health and Long-Term Care announced the creation of HealthForceOntario – a multi-year strategy to give Ontario the right number and mix of health care providers. The strategy includes initiatives to predict Ontario's health human resource requirements, develop new provider roles to meet changing needs, reshape educational programs to develop people with the right knowledge, skills and attitudes, and recruit and retain health professionals by competing effectively with other jurisdictions.⁶

One of the most significant measures is the development of new models to forecast the number of physicians and nurses that will be needed in the future, based on projections of patient needs rather than on population growth alone. As well, an allied health database is being created to collect education, employment and demographic data on other health professions, to help plan the right combination of health human resources for the future.

Making the most of valuable health human resources is the underlying purpose behind HPRAC's work on both interprofessional collaboration and the authorities of non-physicians in prescribing and use of drugs in the course of their practice. HPRAC's efforts not only support the goals of HealthForceOntario, but speak to critical initiatives that will attract and retain health professionals in Ontario by recognizing skills and knowledge that are based on team approaches rather than hierarchical systems.

Increased Emphasis on Interprofessional Care

A key priority in HealthForceOntario is to place more emphasis on interprofessional, collaborative care to make better use of vital health human resources. In July 2007, the Interprofessional Care Steering Committee submitted a report, *Interprofessional Care: A Blueprint for Action in Ontario*. It defines interprofessional care as “the provision of comprehensive health services to patients by multiple health caregivers who work collaboratively to deliver quality care within and across settings”.⁷

As the report observes:

The health care system is gradually being transformed to ensure that the patient is at the centre, delivery is timely, care is safe, continuity

⁶ HealthForceOntario, May 3, 2006 (<http://www.healthforceontario.ca/WhatIsHFHO.aspx>).

⁷ *Interprofessional Care: A Blueprint for Action in Ontario*: 7.

is maintained and access is guaranteed. Improved collaboration and teamwork are expected to help caregivers manage increasing workloads, reduce wait times and reduce the likelihood of adverse reactions to care.⁸

It calls for the incorporation of interprofessional care into existing legislation, systems and infrastructure and notes that recent initiatives such as family health teams, wait-times management and Local Health Integration Networks (LHINs) all depend on a model of interprofessional care.

The Interprofessional Care Strategic Implementation Committee was established to act on key elements of the *Blueprint* report. The Committee's mandate is to:

- Provide guidance to government in managing the implementation of interprofessional care at the system, organizational, education, practice and policy levels;
- Serve as a key resource for interprofessional care implementation by establishing partnerships, facilitating dialogue and promoting best practices of IPC models and concepts; and
- Establish and direct working groups to address technical structures and processes that will provide the tools to support and facilitate interprofessional care, such as approaches to knowledge transfer and evaluation.⁹

The Committee's work will help foster a culture of collaborative, patient-focused care in the province. HPRAC activities in the regulation of health professionals will complement and inform the committee's work.

Distinction between Interprofessional Care and Interprofessional Collaboration

Interprofessional collaboration – the subject of the Minister's request to HPRAC – is a broader concept than interprofessional care.

Interprofessional care takes place at the clinical level. It is about teamwork among health professionals from different disciplines to provide comprehensive, quality care to patients, whether in hospitals, or in the community. Interprofessional collaboration refers to cooperation, not only among practitioners, but also among the health profession colleges of which they are members. Interprofessional collaboration takes place at the regulatory level, as well as at the clinical level. One objective of regulatory collaboration is to foster interprofessional care. Another is to ensure that the standards of practice set by one college are workable for, and understood by, members of other colleges. Other reasons for colleges to collaborate include improving the overall operation of the regulatory system, increasing access to health services and making optimal use of professional skills and competencies.

⁸ Ibid: 11.

⁹ See

<http://www.healthforceontario.ca/WhatIsHFO/AboutInterprofessionalCare/StrategicImplementationCommittee.asp>.

Through extensive consultations in developing recent reports, HPRAC has found that interprofessional care is already happening in hospitals, long-term care homes and other settings across Ontario. An interprofessional approach is also thriving in the education sector as illustrated by Ottawa's Academic Health Council (AHC), recently launched to forge links between the educational institutions that train health professionals. The AHC is a partnership comprised of a number of key educational institutions and was created to respond to the challenges of preparing a skilled workforce able to integrate a collaborative approach in the health care sector.¹⁰ The challenge now is to sustain the momentum at the clinical and educational levels and promote broader collaboration among professional colleges at the regulatory level.

Trends in Non-Physician Prescribing

In Ontario and in numerous other jurisdictions, the abilities of several professions to respond to patient needs have advanced significantly in recent years. Historically physicians, and possibly dentists, were seen to be experts in drug therapy; today, many professions are trained, at the beginning of their careers, to prescribe, dispense, sell, compound, administer or use drugs in the course of their practice. They are skilled in the foundations of medication management and their knowledge is fundamental to the work they do within the boundaries of their professional work. Pharmacists, in today's world of health care, are considered to be the most knowledgeable in drug therapy and are relied upon by other professions and patients for advice.

The recognition of the proficiency of many health professions in numerous aspects of drug therapy is a growing trend. Whether it is a respiratory therapist administering oxygen, or a midwife or chiropractist prescribing drugs for pain control, or a dietitian participating as part of a team in providing parenteral therapy, or a pharmacist providing advice to patients or other health professionals, the knowledge of drugs and their application is a fundamental skill in the work of many health professions. The authority to prescribe or use drugs is based on the knowledge, skills and judgment of the profession and the scope of the services they are qualified to provide to patients.

In recent years, there has been an increasing recognition that limitations on the authority to use this knowledge can be counter-productive. It is frustrating for qualified health professionals, and their patients, when outdated regulations and laws limit their ability to provide timely and appropriate care within their scope of practice. It is equally a problem when members of a profession must provide direction and be accountable for decisions that they are confident members of another profession can provide safely.

Governments and health professions in many jurisdictions have recognized both the advantages of expanded training and the shortcomings of current

¹⁰ See http://www.media.uottawa.ca/mediaroom/news-details_1584.html.

rules, and are judiciously expanding the authorities of non-physician health professionals to provide drug therapy in patient care. Not all professions should have equal authority to prescribe, administer or use drugs and their competency to perform these functions, within their scope of practice, needs to be fully assessed. This is more fully discussed in Chapter three of this report and in other chapters that relate specifically to health professions.

An Evolving Legislative Framework

HPRAC's work on both interprofessional collaboration and non-physician prescribing and use of drugs takes place within the context of a complex and evolving legislative framework for the regulation of health professions. This section presents an overview of the framework and its recent evolution.

Groundbreaking Legislation

The legislative framework for the health professions comprises an umbrella statute, the *Regulated Health Professions Act, 1991 (RHPA)* and a series of profession-specific Acts. Considered groundbreaking legislation when enacted, the *RHPA* replaced a series of professional monopolies, based on exclusive scopes of practice, with a model of regulation based on controlled acts, most of which are authorized to more than one profession. The *RHPA* also contains a Procedural Code that governs the functioning of the health profession colleges, including such matters as the registration of health professionals, complaints, discipline, quality assurance and patient relations.

The *RHPA* addressed issues of public protection by:

- restricting who may perform hazardous acts and procedures;
- prohibiting unregulated practitioners from providing treatment or advice when physical harm to the patient or client may result;¹¹
- restricting the use of professional titles and designations;
- providing complaints, discipline and fitness to practise processes, and
- requiring reporting of incompetence, incapacity or professional misconduct.

The Procedural Code under the *RHPA* set out eight general objects for each college:¹²

1. regulating the practice of the profession and governing the members;
2. developing and maintaining standards of qualification for entry into the profession;

¹¹ Effective June 4, 2009 or on an earlier day to be established by proclamation, s. 30 of the *RHPA* will be amended by striking out “physical” and substituting “bodily”. See *Health System Improvements Act*, 2007, S.O. 2007, c. 10, Sched. M, ss. 6 and 75 (1).

¹² *RHPA* Procedural Code, S. 3(1).

3. developing and maintaining programs and standards for quality assurance;
4. developing and maintaining standards for continuing competence;
5. developing and maintaining standards of professional ethics;
6. assisting individuals to exercise their rights under the legislation;
7. administering the legislation, and
8. fulfilling any other objects relating to human health care and that the college council considers desirable.¹³

Under the Code, in carrying out its objects, each college has an overriding duty to serve and protect the public interest.¹⁴

Overlapping Scopes of Practice and Shared Controlled Acts

Since the *RHPA* allows overlapping scopes of practice, more than one profession is authorized to perform some of the same or similar controlled acts and to set standards for the performance of those acts. For example, the controlled act of prescribing drugs is authorized to physicians and a number of other health professions, with various restrictions. All professions sharing the same or similar controlled acts are expected to provide the highest quality of patient care in performing those acts.

The *RHPA* model of overlapping scopes of practice and specific authorized acts is often heralded as an historic attempt at promoting interprofessional collaboration.¹⁵ By making it possible for a number of health professions to initiate and perform some of the same activities, overlapping scopes can enable the creation and operation of interprofessional teams to deliver patient-centred care.

On the other hand, overlapping scopes or the sharing of controlled acts can also pose barriers to collaboration. This occurs because different interpretations of the same or similar controlled acts, and different standards and guidelines adopted by professions that perform them, can create friction and obstacles to working together. HPRAC has been challenged to address these barriers by the Minister's request for advice on the development of standards of practice and professional practice guidelines where health professions share the same or similar controlled acts. HPRAC's work on non-physician prescribing and use of drugs centres on one specific controlled act and how the authority should be shared by professions in a way that optimizes efficiency, effectiveness and patient safety.

New Regulatory Directions Implemented

The regulation of health professions is an ongoing, evolving process. In April 2006, HPRAC provided extensive advice to the Minister through its

¹³ Ibid. S. 3(1).

¹⁴ Ibid. S. 3 (2).

¹⁵ This was a common theme emerging from the responses to HPRAC's discussion guide on interprofessional collaboration, distributed in early 2008.

report, *Regulation of Health Professions in Ontario: New Directions*. At that time HPRAC commented:

Significant changes have occurred since the RHPA was first introduced in Ontario in 1993, including a shift to multi-disciplinary and collaborative care. Facilitating this trend, through provisions in health professions regulation is essential. It is also vital that our professionals have the flexibility to provide treatment and patient care to the fullest extent of their qualifications and training, and that they are able to respond effectively to changes in technologies and to new methodologies. Further, colleges need the appropriate tools and flexibility to fulfil their responsibilities while also building public confidence in self-regulation.¹⁶

In *New Directions*, HPRAC recommended that the *RHPA* be amended to include new objects for the regulatory colleges that related specifically to collaboration among the colleges. Following HPRAC's report, the *Health System Improvements Act, 2007* added three new objects to the *RHPA*'s Procedural Code. New mandates were enacted for each health regulatory college to:

- promote and enhance relations between the college and its members, other health profession colleges, key stakeholders and the public;
- promote interprofessional collaboration with other health profession colleges, and
- develop, establish and maintain standards and programs to promote the ability of members to respond to changes in practice environments, advances in technology and other emerging issues.

With these new objects, interprofessional collaboration is now firmly embedded in the legislative framework for health professions regulation.

While these objects stem from *HPRAC*'s recommendations to enhance interprofessional collaboration, they go further by obligating the colleges to enhance their relations with the public and key stakeholders. Moreover, the third object places a proactive requirement on the colleges to ensure that they regulate their members in the context of the changing health care environment. HPRAC's work on non-physician prescribing supports this object, as one of the key goals is to enable health colleges and their members to respond to changes in medication therapies that play an ever-increasing role in patient care.

The *Health System Improvements Act, 2007* also implemented HPRAC's recommendations in *New Directions* to regulate four new health professions: kinesiology, homeopathy, naturopathy and psychotherapy, and to include pharmacy technicians as a regulated profession under the *Pharmacy Act, 1991*. This step, coupled with the regulation of traditional Chinese medicine under legislation passed in late 2006 and recommended

¹⁶ HPRAC (April 2006). *Regulation of Health Professions in Ontario: New Directions* (available at <http://www.hprac.org/>): 7.

earlier by HPRAC, will give Ontario a total of 26 regulated health professions.

Recent Legislative Measures

A recent enhancement to the regulatory framework is the *Increasing Access to Qualified Health Professionals for Ontarians Act, 2008*. The measure places a duty on the colleges to work in consultation with the Minister to ensure, as a matter of public interest, that the people of Ontario have access to adequate numbers of qualified, skilled and competent regulated health professionals. The purpose of this legislation is to ease the way for internationally trained health care professionals to practise in Ontario.

In October 2008, the government introduced Bill 108, the *Apology Act, 2008*. If passed, the Bill would provide that an apology made in relation to a civil dispute does not constitute an admission or acknowledgement of fault or liability. This provision would allow individual health professionals and organizations such as hospitals to apologize for a mistake or wrongdoing, without this being used as evidence of liability in a civil court case. As a result, they would be better able to deal openly and honestly with patients and their families. For professionals working in interprofessional care teams, the ability to apologize to one another or to the patient, without fear of legal repercussions, could help avoid a culture of blame and build mutual trust. This is an essential function in the successful advancement of patient safety programs, and reflects other recent changes under the *Public Hospitals Act* regulations that require hospital boards to ensure reporting of critical incidents to patients.

In December 2008, the Minister introduced a Bill that, if passed, would give health regulatory colleges new powers to conduct comprehensive inspections in unregulated settings (e.g., outside hospitals or independent health facilities). Bill 141, the *Regulated Health Professions Amendment Act, 2008* would allow a college to directly observe a health professional's practice and watch a procedure being performed. The government's objective is to improve patient safety and the quality of care in the province, and the progress of the Bill through the legislative process will likely be watched with interest and involvement by health colleges and their members as it establishes new accountabilities for both.

The considerable changes that have been made to date to the *RHPA* and to associated statutes in recent months, and those that are in process, affect the way health colleges in Ontario exercise their responsibilities to protect the public interest. They also support a culture of continuous improvement and patient safety, and demand new accountabilities from health colleges.

HPRAC's Approach to the Minister's Questions

Interprofessional Collaboration

In March 2008, HPRAC submitted an interim report to the Minister on interprofessional collaboration, highlighting its activities on this subject to

date.¹⁷ To briefly recap, HPRAC completed the following tasks in the first phase of the interprofessional collaboration project:

- sponsored two workshops in October 2007 with representatives from health colleges and associations representing health care professionals, facilities and providers to assess interprofessional issues and identify barriers to collaboration;
- conducted and published a literature review to gather information on the current evidence about interprofessional collaboration;
- conducted and published a jurisdictional review to learn about the steps other jurisdictions are taking and mechanisms that Ontario could consider to advance interprofessional collaboration;
- prepared and published a discussion guide for members of the public, health care professionals, regulatory bodies, educators, health care providers, associations and others;
- reviewed options for specific professions, including the new professions of traditional Chinese medicine and psychotherapy, where collaboration in the development of standards of practice is expected, and
- considered concerns about professions providing eye care.

In its interim advice, HPRAC recommended specific mechanisms for improving collaboration among the professions that practice acupuncture and psychotherapy. As well, HPRAC provided an initial overview of matters that affect people served by eye care professionals in Ontario.

In addition, the interim report described the next steps in the project, including analysis of responses to the discussion guide on interprofessional collaboration and reviews of the scope of practice of professions whose work fundamentally demands interprofessional relationships.

A second interim report (Phase II, Part I) was submitted to the Minister in September 2008. It presented the results of four scope of practice reviews, specifically for:

- dietitians,
- midwives,
- pharmacists and
- physiotherapists.¹⁸

This report is HPRAC's third report on interprofessional collaboration among health colleges and their members. It includes scope of practice reviews for the professions of medical radiation technology and medical laboratory technology.

It presents HPRAC's overall conclusions and recommendations for encouraging interprofessional collaboration among professions in Ontario's health care system. It articulates HPRAC's conclusions about new

¹⁷ HPRAC. *An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals*, March 2008.

¹⁸ Ibid.

paradigms for the delivery of efficient and effective patient-centred care in Ontario, and explains how organizational structures and processes can be shaped to facilitate collaboration among regulatory bodies and closer working relationships among professionals who provide clinical care. Finally, it proposes a new framework for oversight of Ontario's health regulatory colleges by integrating HPRAC's current roles into a new agency with additional responsibilities. Moreover, HPRAC's advice on interprofessional collaboration provides a foundation for its recommendations on non-physician prescribing and use of drugs in professional practice.

Non-physician prescribing and use of drugs in professional practice

HPRAC was asked by the Minister to consider the ongoing evaluation of requests by Ontario's health colleges for changes to regulations made under health professions legislation to ensure that they reflect efficiency, best practices of the profession and provide maximum public protection. This question was posed in the context of advice on a framework and process for approvals of designated drugs in the future. To develop its response, HPRAC reviewed requests for changes to current authorities made under regulations for the professions of medical laboratory technology, medical radiation technology, chiropody and podiatry, dental hygiene, dentistry, midwifery, naturopathy, nursing, optometry, pharmacy, physiotherapy, and respiratory therapy. The controlled act of administration of a substance by injection and inhalation, a controlled act authorized to some professions, was considered, as was the authority to use drugs, which is specified in regulations for certain professions.

HPRAC drew heavily on submissions from health colleges, professional associations and experts in pharmacotherapeutics in the information-gathering process. It also incorporated work conducted as part of the recent scope of practice reviews of nurse practitioners, pharmacy, physiotherapy, midwifery, medical laboratory technology and medical radiation technology. As well, HPRAC has referred to work undertaken as part of its *New Directions* report in April 2006.

To gain a more complete understanding of issues to be addressed and how they were being met, HPRAC conducted literature, jurisdictional and jurisprudence reviews. The literature review focused on identifying key documents in the scholarly and grey literature as well as publicly available reports and websites, presenting relevant current information about the rationale, history and background of non-physician prescribing and drug administration.

In addition, health colleges that were part of the review were asked to respond to a questionnaire highlighting key issues relating to prescribing and use of drugs in their profession and to the drug approvals framework in Ontario. Responses are posted on the HPRAC website.

This work was supplemented by extensive intelligence and valuable insights gathered from interviews with key informants including the colleges, health

professionals, professional associations, representatives from hospitals, the community sector, patient safety organizations, and experts from other jurisdictions. A pharmacology expert was engaged to assist in providing specialized knowledge in framing questions and analyzing responses. Changes in federal regulations were considered at some length, following extensive interviews and discussions concerning the treatment of natural health products in the context of provincial drug regulations.

The Balance of This Report

HPRAC views interprofessional care and collaboration as strategies for maximizing the contribution of health professionals and reaping the most value from increasingly scarce health human resources. Likewise, HPRAC's recommendations on a framework and process for drug regulations in Ontario focus on a more effective and efficient process for designated drug regulation approvals and to capitalize more fully on the education and training of health professionals in a wide range of disciplines to enhance their role in the safe prescribing and use of drugs for the benefit of their patients.

The remainder of this report is organized to provide insight into HPRAC's thinking on:

- Essential ways to introduce new measures to promote excellence in health profession regulation in Ontario, including advancing and supporting interprofessional collaboration;
- A new framework for scrutiny of requests for designated drug approvals and associated regulations under health profession Acts;
- Scope of practice reviews relating to interprofessional collaboration and drug regulations; and
- Reviews and recommendations on specific authorities for health professions to prescribe or use drugs in the course of practice.

Scope of Practice Reviews: the Context of Interprofessional Collaboration

As part of its work on interprofessional collaboration, HPRAC has completed reviews of the scope of practice of six professions. The findings of the first four reviews were presented in HPRAC's September 2008 interim report and the results of the final two appear in Chapters five and six of this report.

These studies have been carried out in response to the Minister's request for advice on supporting collaboration between colleges in the development of standards of practice where professions share the same or similar controlled acts. More broadly, HPRAC has undertaken these scope of practice reviews because of the imperative to realize the full potential for all health professionals to contribute to the quality of care.

A health care system where all health professionals function to the fullest extent of their education and training as part of integrated and collaborative teams is a key to improving access to seamless, effective, patient-centred care. Collaboration among health profession colleges, as

well as among their members, is essential to harness the full capabilities of all practitioners to deliver the best possible service to patients.

Enabling professionals to perform more tasks independently, consistent with their competence, will enhance their ability to work with others in health care teams. Professions will be able to take on new or altered roles in a collaborative environment as barriers that keep them from practicing to their full capacity are removed.

Moreover, increased transparency and clarity about scopes of practice will raise awareness of the abilities of various professions and open up new collaborative possibilities in care settings. It is HPRAC's expectation that the renewal and refinement of scopes of practice will promote mutual recognition of and respect for professional roles, creating a climate for the optimal use and mix of health professionals. In HPRAC's view, the revision of professional scopes of practice at the regulatory level is one important way to strengthen interprofessional care at the clinical level.

HPRAC has also reviewed the scope of practice of nurse practitioners and submitted its findings and recommendations in a separate report to the Minister in March 2008.¹⁹ The seven professions HPRAC has reviewed are those whose members work in settings where interprofessional relationships already exist and appear to have significant potential for further development. They play key roles in achieving health care system goals such as better management of chronic disease, improved access to primary care, reduced wait times and aging at home strategies.

How HPRAC Reviews a Profession's Scope of Practice

In spring 2007, HPRAC issued a paper on the definition of a scope of practice and the process for conducting a scope of practice review. This has served as a roadmap for each of the reviews conducted to date.

What is a Scope of Practice?

As HPRAC has emphasized, and as the Health Council of Canada has observed, the scope of a profession cannot be encompassed entirely in one document.²⁰

In Ontario, the legislative framework for the health professions comprises the *RHPA* and a series of profession-specific Acts. Each profession-specific Act includes a scope of practice statement as well as the controlled acts the profession is authorized to perform, the title or titles restricted to members of the profession and other provisions.

When HPRAC reviews a profession's scope of practice, it analyzes the scope of practice statement and the controlled acts authorized to the profession. In addition, HPRAC examines the implications of the harm clause contained in the *RHPA*, which prohibits everyone except health professionals acting

¹⁹ HPRAC. *A Report to the Minister of Health and Long-Term Care on the Review of the Scope of Practice for Registered Nurses in the Extended Class (Nurse Practitioners)*. March 2008.

²⁰ Health Council of Canada, *A Review of Scopes of Practice of Health Professions in Canada: A Balancing Act*, November 2005: 7.

within their scope of practice from treating or giving advice with respect to health where serious physical harm may result.²¹ As well, HPRAC considers regulations developed under the profession-specific Act and other legislation that may affect the profession. Also examined are the standards of practice, professional practice guidelines, policies and by-laws developed by the regulatory college.

All of these elements combined determine the profession's scope of practice. HPRAC has considered the full range of these elements in conducting its review of the scope of practice of medical radiation technologists and medical laboratory technologists that are presented in this report and in recent reviews of scopes of practice of other professions.

Individual vs. Professional Scope of Practice

As well as referring to the clinical activities authorized to a profession, the term “scope of practice” is employed by regulatory colleges to define the procedures, actions and processes that a specific registered individual may perform. This individual scope of practice is based on, among other things, the registrant's education, clinical experience and demonstrated competency. While a professional scope of practice describes the full scope of activity open to the profession as a whole, an individual scope of practice describes the scope of activity within which individual practitioners may conduct their practice.²² The individual scope of practice generally represents a subset of the larger professional scope of practice.

The Review Process

In developing its advice to the Minister, HPRAC strives to ensure that its processes are thorough, timely and efficient and reflect principles of fairness, transparency and evidence-based decision-making. HPRAC undertakes research to secure evidence for its conclusions, drawing on organizations and individuals with relevant expertise, both in Ontario and elsewhere. HPRAC tailors its consultation process to the matters under consideration. Given the wide interest in, and the significant implications of, the scope of practice issues under discussion, HPRAC conducted an extensive program of research and consultation for these two scope of practice reviews, as it did for the five previous reviews.

²¹ s. 30. Effective June 4, 2009 or on an earlier day to be established by proclamation, this section will be amended by striking out “physical” and substituting “bodily”. See *Health System Improvements Act*, 2007, S.O. 2007, c. 10, Sched. M, ss. 6 and 75 (1).

²² HPRAC. *Review of a Professional Scope of Practice under the Regulated Health Professions Act*. May 2007: .2-3.

Assessment Criteria

HPRAC has established a series of criteria for assessing proposals to change a profession's scope of practice. These are:²³

1. Relevance to the profession;
2. Risk of harm;
3. Relevance to the health care system and relationship to other professions;
4. Sufficiency of supervision and need for autonomy;
5. Body of knowledge;
6. Education and accreditation of educational institutions;
7. Leadership's ability to favour the public interest;
8. Profession's support and willingness to comply with regulation;
9. Economic impact, and
10. Public need.

HPRAC has developed a detailed questionnaire to elicit information related to these criteria from a profession seeking a change in its scope of practice. This questionnaire and these criteria have been applied to current scope of practice reviews.

The Consultative Process

In its work, HPRAC calls on many individuals and organizations to provide analysis and advice on both broad and narrow issues that come to its attention. Usually, the request for advice is based on a set deadline. HPRAC recognizes the difficulties this imposes on organizations that require confirmation of the content responses or comments through its governance structure. Nonetheless, HPRAC also hears calls for timeliness in making change so that health professions regulation can be current with the competencies of health professions and the obligations of health colleges.

HPRAC wants to extend its appreciation to governors, management and staff of health colleges, professional associations, health professionals, facilities and providers, and patients who have responded to its demanding questions and requests for confirmation of information. For its own part, HPRAC has been asked by the Minister to present advice that is based on solid examination and analysis. From time to time, that will be done on truncated schedules that recognize the importance of the issues that are being reviewed. HPRAC wishes to extend its gratitude to those who have been involved in a truly collaborative process. In the end, this will strengthen health professions regulation in Ontario.

²³ For further explanation of the criteria, see HPRAC, *Review of a Professional Scope of Practice under the Regulated Health Professions Act*. May 2007: 8-9. Also *An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals: Phase II, Part I*, September 2008: 11-12.

EXCELLENCE IN HEALTH PROFESSION REGULATION: RAISING THE BAR IN ONTARIO

Introduction

This chapter sets out HPRAC's recommendations to the Minister on mechanisms to facilitate and support interprofessional collaboration among health regulatory colleges in Ontario. It describes HPRAC's overall rationale and recommendations for enhancing interprofessional collaboration at the regulatory level to encourage and promote the delivery of more effective patient care.

The findings and conclusions in this chapter build on Phase I of HPRAC's work on interprofessional collaboration, including the initial workshops held in autumn 2007, the literature and jurisdictional reviews published in early 2008, as well as the responses to HPRAC's Consultation Discussion Guide, released in early 2008.

HPRAC's recommendations also build on the previous analysis in HPRAC's *Regulation of Health Professionals in Ontario: New Directions* report in 2006, and the Interim Report on interprofessional collaboration (Phase I) in March 2008. As well, HPRAC has relied on its findings in the scope of practice review for nurse practitioners, which was submitted in March 2008, and the six additional scope of practice reviews completed in 2008/2009 in the context of the Minister's request concerning interprofessional collaboration.¹

HPRAC's work on interprofessional collaboration has led the Council to propose far-reaching recommendations for modernizing the regulatory framework and restructuring the regulatory system.

The proposed reforms will drive continuous improvement in the way health professions are regulated, so Ontarians derive the maximum benefit from health human resources. As a result, health professionals will be able to work to the utmost of their knowledge and skill, to collaborate more closely to produce the best outcomes, and to adapt more readily to new medical technologies and rising patient expectations. What HPRAC envisages is a dynamic health profession regulatory system for the 21st century – one that will further the vision of a modern, accessible and sustainable health care system delivering the best care available in the world.

HPRAC's Central Response

Facilitating and Supporting Interprofessional Collaboration, Enhancing Regulatory Rigour and Promoting Excellence

HPRAC has concluded that its advice to the Minister on mechanisms to facilitate and support interprofessional collaboration among the Colleges

¹ These reviews were for dietetics, midwifery, pharmacy, physiotherapy (September 2008) and medical radiation technology and medical laboratory technology (January 2009).

should include recommendations that will achieve greater regulatory rigour and foster excellence in the way Colleges regulate their members.

It is time for the law to catch up to, and reflect, the changes that have emerged in the day-to-day practice environment. It is essential to strengthen self-regulation. To help achieve that goal, a new independent agency should be introduced to work with the Colleges to modernize the regulatory system, achieve greater transparency and accountability, and facilitate sustained quality improvement in the regulation of health professionals in Ontario.

The new agency that HPRAC proposes, the **Council on Health Professions Regulatory Excellence (CHPRE)**, would support and provide a strong monitoring and advisory role to ensure that Colleges fulfill their new objects under the *Health System Improvements Act, 2007 (HSIA)*. In doing so, the new agency would facilitate and coordinate interprofessional collaboration among Colleges and coordinate a drug approvals framework for health professionals who prescribe or use drugs in the course of their practice. The mandate of CHPRE would be to promote regulatory excellence and strengthen self-regulation so that health colleges continue to protect the public interest and foster the trust that patients place in health professionals.

CHPRE would have an explicit mission to promote interprofessional collaboration among health colleges. Self-regulation is fundamental to the Canadian health care system and Ontario is a world leader in the self-regulation of health professions. However, promising opportunities exist to enhance interprofessional collaboration at the regulatory level through the creation of a more flexible regulatory framework that is better positioned to evolve with and support the growing reliance in the health care system on interprofessional care and practice.

The proposed reforms reflect trends in other jurisdictions where growing attention is being paid to the role of regulators and systems of regulation in promoting collaborative practice among health care professionals. The reforms are proactive. They will drive continuous improvement in the way health professions are regulated, so Ontarians derive the maximum benefit from health human resources.

Background

Interprofessional Care and Interprofessional Collaboration

Interprofessional care describes teamwork among health professionals from different disciplines to provide comprehensive, high-quality, patient-centred care, whether in institutions or in the community. It takes place at the clinical level. Interprofessional care teams have long existed in certain settings and contexts, such as intensive care units, neonatal care, emergency departments, surgery units, and cancer care.

In recent years, interest has grown in collaborative models of health care, with interprofessional care teams emerging in a wider variety of geographic, clinical and professional settings. This trend has arisen in part because of

the recognition that health care teams have the potential to provide the best quality and most effective care to people who require multiple services, or who use both acute and primary care services.²

More emphasis on interprofessional care is a priority in the Ministry's HealthForceOntario strategy to make the most of valuable health human resources. For the purpose of this report, HPRAC has adopted the definition of interprofessional care developed by the Interprofessional Care Steering Committee for HealthForceOntario in *Interprofessional Care: A Blueprint for Action in Ontario*:

Interprofessional care is the provision of comprehensive health services to patients by multiple health caregivers who work collaboratively to deliver quality care within and across settings.³

In its February 2008 Consultation Discussion Guide, HPRAC proposed a definition of interprofessional collaboration as distinct from interprofessional care. This definition addressed interprofessional collaboration at the regulatory level and called on health colleges to work together toward such objectives as making the most of the skills and competencies of diverse health professionals, using regulatory resources efficiently and effectively and ensuring the highest standards of professional conduct and patient safety.⁴

Prior to its work on this request from the Minister, HPRAC made a number of recommendations to enhance interprofessional collaboration, regulatory rigour, transparency and accountability, dating back to its 2006 *New Directions* report.

In its Nurse Practitioner Report in March 2008, HPRAC outlined a new *enabling regulatory framework* under the *RHPA* to clarify the profession's scope of practice and authorize nurse practitioners to practise to their full competency. This new flexibility was balanced with increased regulatory rigour and accountability. The proposed enabling framework would create new opportunities for interprofessional care at the clinical level and require interprofessional collaboration to develop standards of practice at the regulatory level. HPRAC contemplated that this model could apply to other professions as their scopes of practice were reviewed. HPRAC applied the core elements of this model in its review of scopes of practice for other health professions in 2008/2009.⁵ This chapter builds on these recommendations.

² HPRAC (2008). *Interprofessional Collaboration: A Summary of Key Reference Documents and Selected Highlights from the Literature*: 4.

³ HealthForceOntario (2007). *Interprofessional Care: A BluePrint for Action in Ontario*: 7.

⁴ HPRAC (2008). *Consultation Discussion Guide on Issues Related to the Ministerial Referral on Interprofessional Collaboration among Health Colleges and Professions*: 26.

⁵ See, for example, dietetics, midwifery, pharmacy and physiotherapy in HPRAC (2008). *An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals, Phase II, Part I* and Medical Laboratory Technology and Medical Radiation Technology in Chapter 4 and 5 of this report.)

What HPRAC Learned from Consultation and Research

Summary of Responses to the Consultation Discussion Guide

In February 2008, HPRAC released a Consultation Discussion Guide.⁶ The purpose of the guide was to solicit comment on issues related to the Minister's question on interprofessional collaboration among Colleges and professionals. The guide presented background related to the Minister's request for advice and posed a number of questions about how to strengthen collaboration among the Colleges. The questions were designed to solicit views about possible mechanisms to remove or minimize unnecessary barriers and to consider new means for the Colleges to support and enable interprofessional care by their members at the clinical level.⁷

More than 100 responses were received from Colleges, provincial and national health associations, hospitals, long-term care facilities and a number of other health organizations and individual care providers. While the majority of submissions confirmed a high level of support for the concept of collaboration among health professions, including health colleges, a broad range of perceptions and opinions were expressed. There was little consensus on most of the issues and varying levels of support for advancing collaborative efforts at the regulatory level.

For some, the idea of “regulating collaboration” was seen as counter-intuitive to the fundamental principles of teamwork, which are based on mutual understanding and respect for professional roles. Most respondents believe that many of the barriers to collaboration among professionals stem from cultural and political issues, rather than legislative or regulatory restrictions. Some said there are “inherent inequities built into the *RHPA* and other statutes” that perpetuate the culture of hierarchy within the health care system. For example, duplication in *RHPA* provisions that require each health college to set up and maintain its own complaints, discipline and fitness to practise mechanisms was viewed by some as an obstacle to collaborative efforts. The importance of tackling these and other “system barriers” emerged as a recurring theme in the responses.

A majority of respondents, particularly health colleges themselves, opposed establishing an arms-length oversight body to supervise their work. Some said that health colleges should have the opportunity to work with the new objects, outlined in the *Health System Improvement Act (HSIA)*, and continue their voluntary collaborative efforts through the Federation of Health Regulatory Colleges of Ontario (FHRCO).⁸ Support for establishing a new coordinating body at the regulatory level related to specific areas such as facilitating mentoring programs for new health colleges and establishing third party structures to create efficiencies (e.g., a common insurance carrier to pool risk).

⁶ HPRAC. (February 2008). *Consultation Discussion Guide on Issues Related to the Ministerial Referral on Interprofessional Collaboration among Health Colleges and Professionals*. http://hprac.org/en/projects/Interprofessional_Collaboration_JD.asp

⁷ Ibid: 10.

⁸ While FHRCO is a voluntary association of self-regulating health colleges, it represents a higher degree of institutionalized collaboration among colleges than exists in many other parts of Canada.

Those who support the merits of promoting collaboration at the regulatory level believe that the greatest opportunities lie in improving communication and coordination among health colleges and in establishing common standards of practice. Educating the public, regulators, practitioners, insurance companies and other payers about overlapping scopes of practice and professional competencies was cited as one way to achieve collaboration and address cultural barriers that stem from the historical hierarchy among professions.

Responses to the guide also raised important questions about the lack of public awareness of the health colleges' roles, responsibilities and accountabilities. As well, responses revealed the need for a greater understanding by colleges themselves about how they can identify and respond to new, evolving roles and responsibilities in a changing health care system.

Another issue that emerged was the considerable variation that exists among health colleges in how they approach their functions. Specific examples concern: variation in the use of terminology (e.g., terms like guidelines, policies, rules and standards used interchangeably); inconsistent approaches to the development of standards of practice; and lack of policies in certain areas (e.g., quality assurance) or policies that lack sufficient rigour, accountability and transparency (e.g., Code of Ethics, conflict of interest, and advertising).

Highlights from the Literature and Jurisdictional Reviews

HPRAC published a literature review and a jurisdictional review on interprofessional collaboration in February 2008.⁹ These reviews confirmed the renewed interest in collaborative models of health care delivery across the care continuum, highlighted the need to address barriers that now restrict and prohibit transformation to collaborative practice (at the clinical, educational and regulatory levels) and raised the profile of current reforms being implemented in a number of jurisdictions to tackle these challenges.

Interprofessional Collaboration at the Regulatory Level: The Literature

In recent years, growing attention has been paid to the role that regulators and regulatory systems play in promoting collaborative practice.¹⁰ Interest in this issue is based largely on the assumption that the lack of

⁹ HPRAC (2008). *Interprofessional Collaboration: A Summary of Key Reference Documents and Selected Highlights from the Literature*, and *Interprofessional Collaboration: A Summary of Interprofessional Regulatory Collaboration in Other Jurisdictions*.
http://www.hprac.org/en/projects/Interprofessional_Collaboration_JD.asp.

¹⁰ See The Conference Board of Canada (2007). *Achieving Public Protection Through Collaborative Self-Regulation: Reflections for a New Paradigm*; Editorial, (2007) *The promise of 21st century professionalism: Regulatory reform and Integrated Care*. *Journal of Interprofessional Care* 21(3): 233; Lahey, William and Currie, R. (2005). *Regulatory and medico-legal barriers to interprofessional practice*. *Journal of Interprofessional Care*: 19 (Supp. 1); Romanow, Roy. *Commission on the Future of Health Care in Canada* (2002). *Building on Values: The Future of Health Care in Canada*; The Senate Standing Committee on Social Affairs, Science and Technology, *The Health of Canadians – The Federal Role: Final Report* (Ottawa: The Senate, October 2002): 199; U.K. Department of Health. *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century* (London: Department of Health, 2007): 18, 85, online at <http://www.official.documents.gov.uk/documents/cm70/7013/7013.pdf>.

collaboration at the clinical level is caused, or reinforced, by a system of professional regulation that depends on multiple independent self-regulators. Therefore, finding ways to facilitate greater collaboration between regulators is increasingly viewed as an important mechanism to support and reinforce greater collaboration among health professionals.

The evidence supports the underlying premise of the importance and value of preserving self-regulation:

Self-regulation has become a core institution of the Canadian health care system and it is not currently possible to definitely conclude that it is incompatible with the still evolving development of interprofessional practice.¹¹

Where self-regulation of the health care system is effective in achieving safe, high quality care, it should be supported.¹²

Self-regulation, as pointed out by Lahey and Currie in the *Journal of Interdisciplinary Care*, is one factor that differentiates occupations from professions.¹³ However, structures for professional self-regulation, especially legislatively defined scopes of practice, are perceived to be a barrier to interprofessional practice. Some believe that regulators may have a tendency to place their own professional interest in controlling occupational turf ahead of their obligation to serve the broader public interest. Others have reached this conclusion in recent reviews of health reform, both nationally and provincially. For example, the Romanow report noted: “Despite much rhetoric about inter-professional cooperation, in reality, the professions tend to protect their scopes of practice”.¹⁴ The tendency of self-regulating professions to protect their scope of practice as a means of benefiting their members has been consistently noted in studies of professional regulation inside and outside of health care.¹⁵

¹¹ Lahey, W. and Currie, R.: 198.

¹² Braithwaite, J., Healy, J., Dwan, K. The Governance of Health Safety and Quality Commonwealth of Australia, 2005. p. V.

¹³ Lahey, W. and Currie, R.: 200.

¹⁴ Romanow, Roy. Quoted in Lahey, W. and Currie, R.: 201.

¹⁵ Commission on the Future of Health Care in Canada, Building on Values: The Future of Health Care in Canada – Final report (Ottawa: Commission on the Future of Health Care in Canada, 2002): 93; Similar views were expressed in The Health of Canadians – The Federal Role: Final Report: 199 and in Commission of Study on Health and Social Services, Report and Recommendations: Emerging Solutions (Quebec City: Commission of Study on Health and Social Services, 2001): 121-123, online: www.iigr.ca/pdf/documents/759_Quebec_Emerging_Solutions.pdf. These conclusions align with the broader conclusion reached in many studies in and outside Canada and in and outside health care that self-regulation often protects self-interest at the cost of public interest. Many of these studies are noted and discussed in Tracey Epps, Chapter 2: Regulation of Health Professionals, in Jocelyn Downie, Timothy Caulfield and Colleen Flood, eds., Canadian Health Law and Policy, 3rd ed. (Toronto: LexisNexis, 2007): 69-74 and 81-82.

It has also been observed that self-regulation as an institution is not the problem.

While there are issues with the current system – including the way regulatory powers are being used by self-governing professions and, in particular, with inadequate regard for the pressing need for system level integration, cooperation and collaboration – they do not justify a radical departure from the existing system.¹⁶

Recent work undertaken by the Organization for Economic Cooperation and Development,¹⁷ the Council for Healthcare Regulatory Excellence (CHRE) in Great Britain, and the Australian Council for Safety and Quality in Health Care has also highlighted the need to improve self-regulation in the health care system. Initiatives undertaken by these organizations have increasingly tied the need for reforms in the system of self-regulation to the growing pressures to address medical errors, improve patient safety and enhance the quality of health care.

The regulation of health professions has an important contribution to make to patient safety, to public confidence in the skills and behavior of the people who care for them, and to the reputation and standing of the health professions.¹⁸

The abatement or control of risks to society, a key purpose of regulation, has emerged as central to health regulation...Where active regulatory strategies are necessary, they should be designed to establish conditions that are conducive to, and foster, good governance at the appropriate level in the system, so that responsibility and accountability can be maintained.¹⁹

The literature refers to Ontario as an example of a jurisdiction that has had success in preserving self-regulation while establishing a legislative framework that can be built upon to encourage greater interprofessional collaboration. The *RHPA* is viewed as an important catalyst that has laid the groundwork for reform in this area.

¹⁶ Lahey, W. and Currie, R.: 201.

¹⁷ See OECD (2007). *Background Document: Oversight bodies for Regulatory Reform*. Presented by Pedro Andres Amo and Delia Rodrigo, Policy Analysts, Regulatory Policy Division, Directorate for Public Governance and Territorial Development. February 15-16, 2007. www.oecd.org/dataoecd/45/59/38403668.pdf.

¹⁸ CHRE (2008). *Performance review of health professions regulators 2007/08: Helping Regulation to Improve*: 3. There are five standards which CHRE and the regulators use to assess their performance: standards and guidance; registration; fitness to practise; education; and governance and external relations. The standard related to governance and external relations includes consideration of how regulators foster a culture of continuous improvement within their organizations and, in doing this, how they take account of the views of their stakeholders.

¹⁹ Braithwaite, J., Healy, J., Dwan, K.: V.

Interprofessional Collaboration: Other Jurisdictions

In Canada and internationally, the environment for redesigning and modernizing self-regulation to adapt to the new models of integrated care delivery and pursue regulatory rigour is a dynamic one. Each jurisdiction's approach has been unique to the circumstances and health care environment and situations where the need for regulatory rigour has arisen. While no single approach has emerged, significant experimentation has taken place with mixed results in other Canadian jurisdictions, the United States, Great Britain and elsewhere.

As HPRAC noted in the Consultation Discussion Guide, while there have been some innovative approaches in other jurisdictions, on balance collaboration among health regulatory bodies does not appear to be as well developed as interprofessional initiatives at the clinical and educational levels.²⁰ However, in several of the jurisdictions that HPRAC surveyed – including Alberta, British Columbia, Quebec, Victoria (Australia), New Zealand and Great Britain, legislative reforms have been undertaken (or are ongoing) that seem likely to require or support interprofessional collaboration. Initiatives include:

- Legislative changes focused on removing barriers to collaboration between health care practitioners and regulators to collaborate with one another (Alberta, British Columbia, Quebec, Victoria (Australia), Oregon and New Zealand);
- Movement towards non-restrictive scopes of practice and/or a list of restricted activities to facilitate greater interprofessional collaboration in health care;
- Establishment of specific bodies dedicated to enhancing collaboration among health professions regulators (Quebec, Great Britain, Virginia), and
- Establishment of common structures, processes or policies for all health profession regulators for complaints, investigations, disciplinary processes and procedures (Quebec, Victoria (Australia), New Zealand, Denmark, Nebraska, Virginia and Washington state).

Today, both Quebec and Great Britain are at the forefront in developing and putting in place bodies whose roles are, among others, to enhance collaboration among regulators of health professions. These bodies are also mandated to review and monitor the accountability of regulatory bodies for regulatory effectiveness.

Quebec has a two-agency model: the Office des professions du Quebec (the OPQ)²¹ and the Interprofessional Council. The OPQ is responsible for monitoring the regulatory bodies to ensure that they fulfill their public

²⁰ HPRAC (2008). *Consultation Discussion Guide on Issues Related to the Ministerial Referral on Interprofessional Collaboration among Health Colleges and Professionals*: 23.

²¹ See www.professions-quebec.org/index.php/en/element/visualiser/id/6.

protection mandates. The role of the Interprofessional Council is to create opportunities for exchange and coordination – including advising the Minister on existing professions and colleges and the regulation of new professions, bringing to the Minister’s attention matters that require government action, bringing to the Minister and the OPQ measures it considers appropriate to enable the OPQ to perform its role, and advising on amendments to legislation, regulations or by-laws. The Quebec model is responsible for both health and non-health regulated professions, unlike the CHRE in Great Britain, which is focused only on certain health professions.

Great Britain recognized the need to reform its regulatory system to restore public confidence in regulated health professions following several high profile inquiries about physicians who harmed their patients.²² The government has accordingly taken major steps towards modernizing the regulation of health professionals including:

- Establishing the Council for the Regulation of Healthcare Professionals in 2003, with the passage of the *National Health Service Reform and Health Care Professions Act, 2002*.
- Publishing a White Paper entitled *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century* (2007). Among the White Paper’s initiatives was the consideration of areas in which regulatory practice and legislative provisions should be harmonized across regulators so that they all have the most up-to-date and comprehensive duties and powers.
- Publishing *Safeguarding Patients: The Government’s response to the recommendations of the Shipman Inquiry’s fifth report and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries* (2007).²³ This document sets out specific responses to a number of inquiries about physicians who harmed their patients.
- Based on feedback and consultations on these documents, introducing the *Health and Social Care Bill* in 2007.²⁴

²² U.K. Government Department of Health. Background and Overview of the Proposals to the Reforms of Professional Regulation and Clinical Governance. Accessed January 12, 2009. http://www.dh.gov.uk/en/Managingyourorganisation/Humanresourcesandtraining/Modernisingprofessionalregulation/DH_080049.

²³ U.K. Department of Health (2007). *Safeguarding Patients: The Government’s Response to the Recommendations of the Shipman Inquiry’s Fifth Report and to the Recommendations of the Ayling, Neale and Kerr/Haslam Inquiries*. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065953.

²⁴ The *Health and Social Care Act, 2008* received Royal Assent on July 22, 2008.

Now enacted, the Bill has brought further reforms to sustain confidence in the professional regulatory system.²⁵ Reforms implemented have included the establishment of a new body, the Office of the Health Professions Adjudicator (OHPA)²⁶ and the change in name of the Council for the Regulation of Healthcare Professionals to the Council for Healthcare Regulatory Excellence (CHRE).²⁷

The CHRE is an arms-length agency accountable to Parliament and responsible for overseeing nine health regulatory bodies.²⁸ Its main objective is to promote the health, safety and well-being of patients and other members of the public by promoting best practice, cooperation and consistency in the regulation of health professionals. It scrutinizes and oversees the health profession regulators, works with them to identify and promote good practice in regulation, carries out research, develops policy and gives advice.²⁹ As part of its role, the CHRE has the authority to direct regulators to make or change their rules if CHRE believes that such a change is necessary to protect the public. This authority is subject to approval by the Ministry and the legislative authority of Parliament. The CHRE also has a statutory duty to inform and seek the view of the public on the exercise of its functions.

The CHRE has special powers and responsibilities in reviewing fitness to practise decisions under the *National Health Service Reform and Health Care Professions Act, 2002*.³⁰ It reviews final-stage decisions made by health regulators on professionals' fitness to practise, but does not have investigatory powers. It can review the information that was available to the regulator's panel, and if the CHRE deems the panel's decision to be unduly lenient and inadequate for public protection, can refer it to the High Court. The CHRE maintains independent decision-making powers through the process and the Minister of Health does not play a role in the process.³¹

The CHRE considers this responsibility an opportunity for shared learning to feed back to the regulators.³² It cites the main purpose of s. 29 as "to improve the quality of fitness to practise processes and the quality of the [regulators'] fitness to practise process and the quality of the committees' and panels' decisions across the regulatory bodies".³³

²⁵ Government of the United Kingdom, Department of Health Briefing Sheet- Health and Social Care Bill – 2008, p. 1.
http://www.dh.gov.uk/en/Managingyourorganisation/Humanresourcesandtraining/Modernisingprofessionalregulation/DH_085888.

²⁶ *Health And Social Care Act, 2008*, Part 2, Clauses 93- 105.

²⁷ *Ibid*, Clauses 108 -113.

²⁸ These bodies include: the General Medical Council, the Nursing and Midwifery Council, Health Professions Council, the General Dental Council, the General Optical Council, the General Chiropractic Council, the General Osteopathic Council, the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland.

²⁹ CHRE. About Us. <http://www.chre.org.uk/about/>.

³⁰ *National Health Service Reform and Health Care Professions Act, 2002*. Chapter 17 (s) 29.
http://www.opsi.gov.uk/acts/acts2002/ukpga_20020017_en_5#pt2-pb1-l1g29.

³¹ CHRE. Fitness to Practise. Reviewing Fitness to Practise Decisions Under Section 29. Accessed January 9, 2009. www.chre.org.uk/practise/79/.

³² *Ibid*.

³³ *Ibid*.

Recently, the CHRE commissioned a scoping study of health care regulation. For the first time, the study examined in detail how the nine regulatory bodies overseen by the CHRE fulfilled their statutory functions of registration, education and training, standard setting and fitness to practise. The study also reviewed the governance arrangements of the nine regulators. It concluded:

[There is] considerable variation in practice between the regulators in how they carry out their functions. This is sometimes due to differences in legislation, sometimes to the specific needs of the professions they regulate and sometimes to differences in approach. We also find many examples of good practice and highlight some areas for improvement.³⁴

Observations on Regulatory Reform: Current and Emerging Trends

In addition to the literature and jurisdictional reviews on interprofessional collaboration, HPRAC has considered the broader issue of regulatory reform, that is not exclusive to the regulation of health professions.³⁵

The theme of “supervision of self-regulation” or “regulating the regulator” has been studied for more than a decade by the Organization for Economic Co-operation and Development (OECD), which has engaged in extensive work on the need for and the characteristics of regulatory reform. The OECD has found that continual and far-reaching social, economic and technological changes require governments to consider the cumulative and inter-related impacts of regulatory regimes, to ensure that their regulatory structures and processes are relevant and robust, transparent, accountable and forward-looking. Regulatory reform is not seen as a one-off effort but rather a dynamic, long-term, multi-disciplinary process.³⁶

The work undertaken by the OECD, as well as experiences in a number of jurisdictions, have drawn heightened attention to the potential of “oversight bodies” to act as key instruments in the process of regulatory reform:

³⁴ CHRE (2008). *Performance review of health professions regulators 2007/08: Helping Regulation to Improve: 2*.

³⁵ Ian Ayres and John Braithwaite. *Responsive Regulation: Transcending the Deregulation Debate* (New York and Oxford: Oxford University Press, 1992); Neil Gunningham and Peter Grabosky. *Smart Regulation: Designing Environmental Policy* (Oxford: Clarendon Press, 1998); Malcolm K. Sparrow. *The Regulatory Craft* (Washington, D.C.: The Brookings Institution, 2000); G. Bruce Doern, *Red Tape, Red Flags: Regulation for the Innovation Age* (Ottawa: The Conference Board of Canada, 2007); G. Bruce Doern, Margaret Hill, Michael Prince and Richard Schultz, eds., *Changing the Rules: Canada's Changing Regulatory Regimes and Institutions* (Toronto: University of Toronto Press, 1999); P. Eliadis, Margaret Hill and Michael Howlett, eds., *Designing Government: From Instruments to Governance* (Montreal and Kingston: McGill-Queen's University Press, 2005); G. Bruce Doern and Robert Johnson, eds., *Rules, Rules, Rules, Rules: Multilevel Regulatory Governance* (Toronto: University of Toronto Press, 2006). In the United Kingdom, the continuing focus on health profession regulation is explicitly linked to that country's broader concern with “better regulation”: see Department of Health, *Good doctors, safer patients: Proposals to strengthen the system to assure and improve the performance of doctors and the safety of patients: A Report by the Chief Medical Officer [the “Donaldson Report”]* (London: Department of Health, 2006): 162-167.

³⁶ See, for example, OECD (2008). *Building an Institutional Framework for Regulatory Impact Analysis (RIA): Guidance for Policy Makers*. (Version 1.1). http://www.oecd.org/document/49/0,3343,en_2649_34141_35258801_1_1_1_1,00.html.

Oversight bodies have been key pieces in the process of regulatory reform, working as “engines of reform”, maintaining a whole strategic point of view, coordinating inside the administration. Oversight bodies’ general role, besides supervision, control and coordination, consists in forcing regulators to demonstrate and justify the relevance of their regulation (potential and existing), using accountability and assessment mechanisms, as well as offering them technical advice and promoting regulatory reform.³⁷

“Supervision of self-regulation” may also develop more organically through a process of policy learning. In Australia, John Braithwaite and others have identified the process of “triple loop learning” in self-regulation as a strategy for spreading innovation throughout the healthcare system:

The first loop occurs when a good self-regulatory innovator monitors his/her own effectiveness at improving an outcome. The second loop is that this policy learning is then monitored by senior managers of the responsive firm, who change their corporate management systems, culture, and practices in response to the learning. The third loop occurs when government learns from monitoring the company’s double-loop learning, and evaluates and revises its regulatory goals and strategies for the whole field. International regimes can foster a fourth loop by assisting the world community to learn from a nation, such as Australia, which has a rich experience of triple-loop learning in the health sector.³⁸

Based on its research and consultations in the context of the Minister’s request and in consideration of advice included in HPRAC’s previous reports, HPRAC makes the following general observations:

1. The public demands transparency and accountability, and the demonstration of measurable results in both the public and private sectors.
2. In response, Canada and other jurisdictions have established agencies in the health sector and in other sectors (e.g., environment, finance) with mandates to coordinate specific elements of reform and improve transparency and accountability. In health care, many of these agencies are arms-length to government and are focused on improving health system performance and the quality and safety of patient care.
3. With the introduction of the *RHPA*, Ontario became a global leader in the regulation of health professions and protection of the public interest. The *RHPA* increased flexibility and innovation by shifting from professional monopolies to a controlled acts model and overlapping scopes of practice.
4. Since the introduction of the *RHPA*, the number of regulated health professions and Colleges has increased. Ontario will soon have 26 Colleges and is considering the establishment of others.

³⁷ OECD. *Background Document: Oversight bodies for Regulatory Reform*: 3.

³⁸ Braithwaite, J., Healy, J., Dwan, K.: 31.

5. Despite progress, the current regulatory system is complex. While self-regulation is not incompatible with interprofessional practice, defined scopes of practice and variations in standards can challenge the delivery of integrated care in general and interprofessional practice in particular.³⁹ Other interprofessional practice issues include:

- Cultural issues arising from the historical hierarchy and antipathy among professions;
- Lack of clarity on scopes of practice and overlapping scopes of practice;
- Reluctance to share information and engage in joint investigations;
- Inconsistent use of terminology (e.g., guidelines, standards, rules, policies), and
- Inconsistent regulations and standards of practice (e.g., Code of Ethics, conflict of interest regulations).⁴⁰

6. Self-regulation is fundamental to the Canadian health care system. There are promising opportunities to enhance interprofessional collaboration at the regulatory level – including the creation of a regulatory framework that is better positioned to evolve with and to support the growing reliance in the health care system on collaboration between and among health professionals from various professions at the clinical level.

7. Ontario can learn much from reforms elsewhere and the time is right to address a number of more fundamental challenges and opportunities at the regulatory level. HPRAC observes that the models from other jurisdictions may not be entirely transferable to Ontario. For example, some elements from approaches in Great Britain and New Zealand reflect challenges specific to their regulatory systems and may not be relevant to the Ontario context.

HPRAC continues to hold the view that changes to the regulatory system to establish interprofessional collaboration and improve transparency and accountability should be evolutionary and build on the current strengths of the self-regulatory model. This perspective was also expressed by Lahey and Currie as follows:

Overly broad or radical reform, such as abandonment of self-regulation, may be more than is necessary to address the problem. Indeed, it may miss the real sources of the problem altogether. In the meantime, it may cause significant collateral damage, particularly to provider morale and the major initiatives that are now under way to address the broader problems of the recruitment and retention of health care providers. There is a danger that the relative amenability of the regulatory system to legislative change and the sometimes illusory certainty of large legislative solutions will become

³⁹ Lahey, W. and Currie, R.: 200-201.

⁴⁰ Summary of Responses to HPRAC's Consultation Discussion Guide.

the de facto rationale for trying to “fix” a problem that is broader and more complex than the regulatory system through legislative changes that are directed only at the regulatory system. These risks argue for an approach to law reform that builds on the strengths of the existing system of self-regulation. This would be an evolutionary approach to law reform that advances in lockstep with understandings of interprofessional practice and of its relationship to regulatory structures.⁴¹

HPRAC’s Key Findings

Challenges to Self-Regulation in Ontario: The Case for Change

The *RHPA* was introduced more than 17 years ago. Since that time, several jurisdictions in Canada and internationally have emulated the *RHPA*’s overlapping scopes of practice concept. A new platform for change in Ontario has been established with the provision of the new objects that call on health colleges to take action to enhance interprofessional collaboration. In essence, these objects encourage the evolution of the regulatory environment, not only to support interprofessional collaboration but also to improve the consistency and performance of health colleges in addressing the full range of their functions and responsibilities in each aspect of their mandate.

HPRAC continues to endorse and support self-regulation. It has concluded, however, that stronger regulatory rigour and a higher level of excellence can and must be achieved in the current regulatory system. There is a need for reform to facilitate and support greater interprofessional collaboration. There is also a need to tackle more complex challenges that include: incorporating patient demands for choice and more patient and citizen participation in decision-making about their own health care; allowing the health colleges increased flexibility that results in better public interest protection; achieving overall improved efficiency and effectiveness within the health regulatory system; allaying concerns that individual health professions alone feel they know best and meeting the challenges that prevent the system from adapting to changing societal needs and realities in a new world of health care delivery.

We live in an age of accountability. Rising public expectations were recently acknowledged in an article by the Registrar of the Royal College of Dental Surgeons of Ontario:

We are now constantly under the microscope. Governments, no matter the party, and the public are demanding accountability from regulators. We have to prove that we are fulfilling our legislated mandate of public protection...We are definitely in an age where, as a regulator, we must be responsive to the context, culture and times in which we exist. Historically, the performance of regulators was not really evaluated. Now both governments and the public are constantly monitoring how we do our job.⁴²

⁴¹ Lahey, W. and Currie, R.: 201.

⁴² Fefergrad, Irwin. *Responsive regulation: governments and the public now constantly monitoring how we do our job*. *Dispatch* (Registrar Newsletter, Royal College of Dental Surgeons of Ontario). November/December 2008: 72.

These public expectations must be met. It is also crucial to address issues that inhibit the health colleges from carrying out their functions as effectively as possible, so patients will be served as well as possible. Among these issues are:

- Why does change in the regulatory system frequently lag behind changes at the practice level?
- What can be done to address the barriers reinforced by statutes, regulations and rules that now impede collaboration at the patient care level?
- How can the regulatory system better adapt to changing scopes of practice and professional competencies?
- What can be learned from other jurisdictions that have implemented mechanisms to facilitate interprofessional collaboration and in the process strengthen regulatory rigour and promote excellence?

Some of these challenges can be resolved by improving clarity about the roles and responsibilities of regulatory bodies in general and in promoting and supporting interprofessional collaboration more specifically. Other challenges will require more complex solutions focused on strengthening the current model of self-regulation by enhancing the accountability of the health colleges and adopting a more collaborative approach to self-regulation.

HPRAC's view is that Ontario must be proactive in addressing these challenges and removing current legislative and regulatory barriers that inhibit interprofessional collaboration. Others have reached similar conclusions.⁴³ In other words, the regulatory culture itself needs to be transformed to catch up with and support changes that are occurring in the evolution of health care practice and to meet public expectations for accountability.⁴⁴

Now is the time to implement needed reforms. HPRAC sees the new objects for health colleges under the *HSIA* as providing a unique opportunity to advance interprofessional collaboration among health colleges and thereby address some of the current barriers to interprofessional collaboration at the clinical level. A fundamental shift in thinking is needed. This shift requires the role, structure and focus of the Colleges to change from that of discrete organizations operating as silos, to a true system of regulators that are better aligned and work together to develop common structures, processes and standards. HPRAC foresees the development of a shared strategy among regulators that would drive them to:

⁴³ See Conference Board of Canada (2007). *Achieving Public Protection Through Collaborative Self-Regulation*: i. "Regulators can act now, wait for the demographically driven sustainability challenge to hit the health care system, or deal with the potential crisis of regulation, which could arise from a lack of focus in the areas of recertification, regulatory accreditation or standards."

⁴⁴ Lahey, W. and Currie, R.: 198.

- Embrace a strategic change management agenda that includes a declaration of collective will to modernize the regulatory system to the highest standards of regulatory excellence;
- Move beyond an individual profession-focused paradigm to one that encompasses an enabling framework (including commonly developed and enforceable standards of practice) to help achieve greater collaboration between and among Colleges;
- Encourage the development of best practices in self-regulation and collaborate with each other to seize new opportunities to promote and facilitate interprofessional collaboration and enhance regulatory rigour and excellence, and
- Enhance accountability through performance measurement and reporting to achieve greater consistency in how Colleges carry out their functions.

The recommendations in this report lay the foundation for achieving HPRAC's vision of a dynamic health profession regulatory system for the 21st century.

Regulatory Reform: Raising the Bar in Ontario

A Changing Context for the Minister's Question

The success of many new program initiatives of the Ministry of Health and Long-Term Care depends, to a great extent, on the development of new shared models of care that are supported and not impeded by the legislative and regulatory framework. Interprofessional collaboration at the regulatory level must be improved, not as an end in itself, but as a mechanism to increase regulatory effectiveness in a health care system that is and that will become more and more dependent upon interprofessional patient care.

HPRAC finds that interprofessional collaboration among health colleges will not always happen on its own. Moreover, in addition to enhancing interprofessional collaboration at the regulatory level, it is imperative to improve regulatory rigour and to strengthen the accountability of regulators themselves. This direction includes:

- Enhancing accountability for all health colleges to ensure that they govern in the public interest;
- Supporting and mentoring new health colleges;
- Fostering a culture that encourages and values collaboration (where it is helpful or necessary to effective protection of the public interest), trust, transparency and accountability to the public and other stakeholders;
- Identifying and adopting best practices common functions for health colleges to effectively deal with common challenges or problems, particularly those of a recurring nature;

- Streamlining the development of standards of practice on an interprofessional basis;
- Introducing more flexibility to allow the regulatory system to continue to evolve, and
- Facilitating resolution of conflict among Colleges and the professions (e.g., overlapping scopes of practice, economically-driven disputes).

The implications of these findings, coupled with the recommendations for a new drug approvals framework for non-physician prescribers (Chapter 3) and the reforms proposed in HPRAC's Nurse Practitioner Report and interim reports on interprofessional collaboration, change the environment significantly from when the Minister sought advice on how to enhance interprofessional collaboration. The approach and recommendations outlined in the following pages reflect this new context.

Achieving Excellence in Health Profession Regulation

While the *RHPA* was recently amended, further changes are necessary to ensure that the legislative and regulatory framework catches up to, continues to keep pace with, and better reflects patient-centred care today and what it may be in the future.

HPRAC's assessment began with the premise that strengthening collaboration among the health professions should be grounded in the following principles for regulatory reform:⁴⁵

- Meeting public expectations for improved access to high quality, safe services and patient-centred care;
- Optimizing the contribution of all health professionals;
- Applying rigorous standards for the regulation of health professionals;
- Using resources efficiently;
- Sustaining the health care system, and
- Maintaining self-regulation.

Based on these principles, HPRAC has established the following measurable results for its recommendations for a more responsive regulatory framework:

- Enhanced patient care and safety;
- Enhanced responsiveness and transparency among health colleges and to their members and the public;
- A shared accountability agenda that encourages and values collaboration and trust;

⁴⁵ HPRAC (2008). *An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals: Phase II, Part I*: 8.

- Greater consistency, responsiveness and effectiveness in all regulatory processes;
- An effective mechanism for conflict resolution, and
- Greater and more effective collaboration among health colleges.

HPRAC's Recommendations

HPRAC's recommendations aim to break down the barriers to interprofessional collaboration among health colleges and their members. But the recommendations go beyond removing obstacles to collaboration. They propose a regulatory system that is better aligned with the current and emerging realities of the modern health care system and has a more robust capacity to evolve. They aim to create a regulatory system that strengthens the accountability of health colleges to demonstrate effectiveness in protecting the public interest and in meeting their obligations under the *RHPA*, while maintaining and expanding the authority of colleges to innovate, show leadership and develop and adopt best practices. To achieve these objectives, HPRAC is making the following recommendations:

1. Establish a ***new enabling regulatory framework to enhance interprofessional collaboration and strengthen the self-regulation of health professions in Ontario***. This new way of doing business will give health colleges authority to establish legally enforceable standards of practice and, at the same time, provide colleges with the flexibility and nimbleness to adopt these standards and adjust and respond to changing practices and practice environments.
2. Establish a ***new agency to facilitate interprofessional collaboration, ensure regulatory rigour and excellence and achieve greater accountability within the health profession regulatory system***. This work will be advanced by identifying best practices and by setting new requirements for health colleges to measure and report on their activities and to improve their communication with the public.

1. An Enabling Regulatory Framework

In the Nurse Practitioner Report and in the Interim Report on Interprofessional Collaboration (Phase II, Part I), HPRAC has proposed what it has called an “enabling regulatory framework”, building on the principles of the *RHPA*. HPRAC's approach recommends ways to make the regulation of health professionals in Ontario more dynamic, flexible and adaptable, while strengthening the accountability of the Colleges and their members.

Standards of Practice

The starting point for this new way of doing business focuses on the requirement for colleges to develop comprehensive standards of practice for their members. For clarity, HPRAC defines “standards of practice” as the

rules, requirements, responsibilities and conditions that describe the college's expectations for the profession to provide high quality, ethical and safe care to patients.

Through standards of practice, health colleges preclude health professionals from undertaking certain activities within the scope of practice and controlled acts that they are authorized to perform unless they meet specified education and training requirements set by their respective colleges. The college standards may also set out requirements for members to maintain competency through additional education and training. Standards could also include the circumstances when a health professional must either discuss and consult with, or refer to another health professional.

Standards of practice are not the same as professional practice guidelines. In a previous report, in response to the lack of clarity and the interchangeable use of the terms “standards of practice” and “professional practice guidelines”, HPRAC described its interpretation of professional practice guidelines:

The regulatory colleges refer to professional practice guidelines in many ways. Some use this term, while others have employed the terms “guidelines”, “clinical practice guidelines” or some other term. Professional practice guidelines set out best practices and procedures for clinical care. ...It is not within HPRAC's mandate to develop professional practice guidelines. This falls within the mandate, competence and responsibility of the profession.⁴⁶

In short, HPRAC sees standards of practice as setting out how health professionals are determined to be competent and as defining the parameters within which they are authorized to perform specific functions as registered members of a College. HPRAC sees professional practice guidelines as detailed clinical requirements. Traditionally, these are developed on the basis of research and clinical studies and through this process become clinical best practices. For example, these guidelines could cover the efficacy of a particular drug and how it should be prescribed or the “best practice” for undertaking a certain diagnostic procedure. Professional practice guidelines are provided to professionals to reflect changing clinical standards and best practices that adapt to emerging technologies, drugs and other clinical advances.

Current Process for Developing and Approving Standards of Practice

The current *RHPA* framework requires standards of practice to be established in regulation under each health profession Act. For example, each health college develops a standard of practice, consults with its members, obtains approval from the College Council, and then submits it to the Minister. The Minister reviews the proposed regulation, provides comments and sends it back to the College for final approval.

⁴⁶ Ibid: 14 -16.

Once the College submits the final draft regulation, the Minister must follow the government's regulation-making process. This includes review and approval by the Cabinet Committee on Legislation and Regulation, approval by the full Cabinet and signature by the Lieutenant Governor. In many instances this process can take several years, often rendering the subject matter of the standard of practice outdated or irrelevant. This process creates endless challenges for health colleges that may not have standards of practice in place that are current and enforceable. In circumstances when a health professional is found in contravention of the proposed standard of practice, the college may have limited authority to discipline, or in the worst case, deregister a member who is no longer fit to practise. To fill this gap, many health colleges have decided that the regulation-making process is unworkable, do not submit regulations for approval, and have developed policies and guidelines to guide their members in lieu of regulations even though the legal status and enforceability of these mechanisms may be questionable.

In previous reports, HPRAC has found that the current process for developing and approving regulations is unacceptable and does not serve the public, the government or the health colleges well.

The regulation-making process is cumbersome and has not proven able to deliver timely changes in requirements to keep up with evolving technologies, clinical practices and population needs. The process of developing and passing legislation is even more unwieldy. A more flexible way must be found to balance access to controlled acts with safeguards to protect the public from risk of harm.⁴⁷

While some voluntarily do so, health colleges are not required by law to consult with other professions in the development of standards of practice, even in circumstances where professions share the same or similar controlled acts. HPRAC has found that there are inconsistencies, not only in how Colleges develop standards of practice, but also in what is included in these standards. This patchwork leads to confusion among colleges and the public about what is or should be included in standards of practice, and the status of other documents developed and published by health colleges to dictate, limit or direct the activities of their members.

With the increasing number of health colleges and the extent of overlapping scopes of practice under the *RHPA*, HPRAC has concluded that it is in the public interest for colleges to consult with other colleges in the development of standards of practice – most particularly where health professions share the same or similar controlled acts, or where their scopes of practice overlap. Such collaboration is critical to breaking down the barriers to interprofessional care, including the lack of understanding and appreciation among health professionals of the standards that other professionals are required to meet.

⁴⁷ HPRAC. *A report to the Minister of Health and Long-Term Care on the Review of the Scope of Practice for Registered Nurses in the Extended Class (Nurse Practitioners)*: 61.

A New Way of Doing Business: Enforceable Standards of Practice

HPRAC's recommendations for an enabling regulatory framework balance the need for colleges to develop enforceable standards of practice in real time and the need to involve other professionals in the development of those standards. The standards of practice under the enabling framework would cover: education; training; continuing competency; mandatory discussion, consultation and transfer of care; and standards, limitations and conditions relating to the performance of an act authorized to the profession.

Standards of practice are critical elements in what health colleges do to regulate their members. HPRAC has found that the current process for developing and approving these standards of practice does not work well and does not reflect the evolution in practice and the increasing prevalence of interprofessional care teams.

HPRAC is proposing a new way for standards of practice to be developed and approved. Fundamental to this new approach is the recommendation that standards of practice need no longer go through the regulation-making process to be approved or enforceable in law. Accordingly, HPRAC recommends that the *RHPA* be amended to authorize health colleges to adopt standards of practice that would still be enforceable in law but would be developed outside the regulation-making process, according to a prescribed process as detailed in HPRAC's legislative implementation proposals that are presented in Chapter four of this report. The clear authority for the implementation of the college's standards of practice would be recognized in statute.

This flexibility is balanced with the new requirement for health colleges to establish interprofessional standards committees to assist and take part in standards development. The committees would provide a forum for input from other professions that share the authorized acts or have an interest in the quality of their performance. The interprofessional standards committees would examine and discuss the standards in-depth, and carefully hone them to meet the most exacting requirements of professions who share the same responsibilities.

Committee members would be selected on the recommendation of health colleges whose members share the same or similar controlled acts, and bring particular expertise to the deliberations. The council of the college appointing the committee would benefit from its advice, representing the judgment and experience of its own members along with that of members of colleges who share the same or similar authorities. The college council would consider the committee's recommendations and would continue to have the power to accept, alter or reject the committee's advice. HPRAC believes that this approach represents a key first step toward fulfilling the colleges' new objects under the *HSIA*, and provides a measured approach with the appropriate checks and balances to protect the public.

In addition to the requirement for interprofessional standards committees, the health colleges' authority to develop standards of practice that have legal authority would be balanced by a number of mechanisms to increase accountability and ensure the protection of the public. These include a new legislative requirement that members practise within an individual scope of practice, to the limits of the individual's education, training and competency, as well as the responsibility of Colleges to establish and enforce more rigorous requirements for continuing competence and quality assurance.

HPRAC is making legislative recommendations to provide additional checks and balances to support the new process for the development of standards of practice. A key proposal is to allow the new agency, CHPRE, to play a role in the development of these standards in certain circumstances. For example, a college would be required to submit a copy of the proposed standard to the Minister, to the CHPRE and to every member, at least 60 days before establishing the standard. This is a change from the current process that requires a College to provide only its members with a copy of a proposed regulation. Giving CHPRE and the Ministry the opportunity to review, in a specified time period, the proposed standard before it is finalized provides additional safeguards and ensures that the public interest is protected. In addition, CHPRE could circulate a copy of the proposed standard of practice to other colleges, health professionals and expert advisors for comment and review. This provision would enable CHPRE to seek additional input into the proposed standard.

Matters to Be Addressed by Regulation

HPRAC is recommending that some health college responsibilities should continue to be addressed in regulations made by the Lieutenant Governor in Council, including conflict of interest rules, Codes of Ethics and common advertising rules. The process contemplated by HPRAC is that CHPRE would facilitate the joint development of common regulations for all Colleges to the extent possible. Once completed, the proposed rules and Code of Ethics would be submitted to the Minister to be considered as a regulation under the *RHPA*.

HPRAC has concluded that this is a workable approach for a number of reasons. One factor is that conflict of interest and advertising rules, as well as Codes of Ethics, are not matters that will need to be amended on a frequent basis.

With respect to conflict of interest rules, HPRAC recognizes that there are significant differences in the roles of the health professions, and that substantial examination of what is essential in an ethical approach to conflict of interest must take into account these differences. For some professions, the selling of drugs or products, along with the prescribing of these drugs or products, brings a particular concern; for other professions, business relationships with other health providers and corporations are a matter of interest.

If the government accepts HPRAC's recommendations for an enabling regulatory framework and for a new drug approvals framework, these regulations will be developed with the new frameworks, processes and college responsibilities in place.

HPRAC sees significant value in having common rules across all colleges for the matters identified above, as these issues are not directly related to a health profession's scope of practice. HPRAC acknowledges that there will be some conflict of interest rules that will apply to only some health professions (for example, those involved in certain retail activities). On balance, HPRAC finds that a process that involves all the colleges in developing the draft regulations will, in and of itself, begin to enhance interprofessional collaboration. To maintain efficiency and responsiveness, such a process must be kept on task by an organization that has the clear mandate to play that role – that is, by the new agency.

Having common rules under regulation will remove barriers among some health professionals who believe that their rules and Codes of Ethics are more comprehensive than others. Patients can expect the same high common standard, regardless of the regulated health profession. Moreover, establishing the Code of Ethics in regulation would elevate it to the status of law, as opposed to the current by-laws, which are unenforceable.

HPRAC outlined in its interim report on interprofessional collaboration in March 2008 some of the current discord and issues relating to collaboration by health colleges in the eye professions in Ontario. These included issues relating to conflict of interest regulations in the profession of optometry and standards of practice on refractometry in the profession of opticianry.

HPRAC expressed serious concerns about the degree of conflict between the colleges of these respective professions. Several meetings with the colleges, respective professional associations and others proceeded in the fall of 2008, while the parties were engaged in their independent discussions as well. Although there was a commitment made by the colleges to attempt to reach an accommodation on the issues, to date, no resolution has been reached, although consultations continue, and recommendations will be made to the Minister.

This experience highlighted the need for an interprofessional approach to establishing standards of practice. It also underlined the value of collaborative development of a common Code of Ethics and model conflict of interest rules. The engagement of colleges in this process, leading to clear and comprehensive regulations and enforceable standards of practice is essential to protection of the public interest.

2. A New Agency to Facilitate Interprofessional Collaboration, Ensure Regulatory Rigour and Excellence and Achieve Greater Accountability

HPRAC's enabling regulatory framework would enable health colleges to meet the new object of responding to "changes in practice environments, advances in technology and other emerging issues" through standards of practice, with terms, limitations and conditions adopted by a college without recourse to changes in legislation or regulation. With this additional

authority, it would become even more important for health colleges to function in a collaborative, transparent and accountable manner. It would also be imperative for health colleges to establish greater regulatory rigour and pursue excellence, beginning with clearer public understanding of their roles, responsibilities and accountabilities.

Currently, the role, responsibilities and accountabilities of health colleges are not well understood by the public. A college exists to serve and protect the public interest. It does so first and foremost by ensuring that its members are qualified and have the skills, knowledge and judgment to provide safe, effective and ethical patient care. It is critical that members of the public have a clear understanding of what health colleges do, as well as trust and confidence that the colleges are exercising their duties in the public interest.

Strengthening the health profession regulatory system also requires an increased focus on accountability. Each health college should be fully accountable to the public for its actions and decisions. Accountability measures, including performance goals and targets to monitor the progress of Colleges, should be made public. This approach has been adopted by the CHRE in Great Britain, which sets out a process for performance review and publishes the results of the review. The focus is on ensuring that colleges meet public expectations and demands for best practice.

The principles of good regulation are: proportionality; accountability; consistency; transparency; and targeting. These principles apply across all regulatory functions and are central in the definition of draft standards that describe what the public should expect from regulators and enunciate principles of good practice.

(CHRE, Performance Review of Health Professions Regulators 2007/08, Helping regulation to improve, August 2008)

In Ontario, current legislative requirements for colleges to be accountable to the public provide a starting point. These include:

- Providing the Minister with an annual report on activities and financial affairs, which may be published;
- Providing information to HPRAC on patient relations programs,
- Having a website, and including on the website information required in regulations, and
- Providing statistical data to the Minister.

Other jurisdictions have struggled with the need to find the right balance between the autonomy of each profession and the collective responsibility for the regulatory system as a whole.

The work undertaken by the OECD, as well as experiences in a number of jurisdictions, have drawn heightened attention to the potential of “oversight bodies” to act as key instruments in the process of regulatory reform:

Oversight bodies have been key pieces in the process of regulatory reform, working as “engines of reform”, maintaining a whole strategic point of view, coordinating inside the administration. Oversight bodies’ general role, besides supervision, control and coordination, consists in forcing regulators to demonstrate and justify the relevance of their regulation (potential and existing), using accountability and assessment mechanisms, as well as offering them technical advice and promoting regulatory reform.⁴⁸

HPRAC has concluded that a new dedicated agency should be established in Ontario to strengthen the regulation of health professionals in the province. The agency should combine HPRAC’s existing advisory roles to the Minister concerning the regulation of health professionals, and incorporate a number of new roles that will improve standards development, quality reporting and overall accountability within and across regulators. The agency should provide strategic direction to health regulatory colleges, monitor standards development and regulatory performance, and report to the public and government on how health colleges are fulfilling their mandates. It should demand excellence in the work of the Colleges, whether in quality assurance, patient safety or collaborative working relationships, and communicate and guide the adoption of best practices in regulatory functions and ethics.⁴⁹

The models of self-regulation unfolding in some jurisdictions, particularly Great Britain, and New Zealand, are considered by some to be a departure from professional self-regulation. For example, the CHRE has significant powers to independently review regulators’ fitness to practise decisions and refer them to High Court if the CHRE does not consider the decision to be adequately protecting the public.⁵⁰ In New Zealand, the Health and Disability Commissioner has particular responsibilities in investigating complaints under the Code of Health and Disability Services Consumers’ Rights. The Commissioner has precedence over the regulators in undertaking investigations and decisions regarding health professionals’ fitness to practise.⁵¹

HPRAC has concluded that Ontario’s system of self-regulation can be enhanced while avoiding the imposition of undue regulatory burden that some commentators have suggested has been the result of the reforms in

⁴⁸ OECD. *Background Document: Oversight bodies for Regulatory Reform*: 3.

⁴⁹ Judith Healery and John Braithwaite, (2002) *Designing safer health care through responsive regulation* 184:10 Medical Journal of Australia (Supplement), S56, building on C. Parker, *The open corporation: effective regulation and democracy* (Cambridge: Cambridge University Press, 2002).

⁵⁰ CHRE. *Fitness to Practise. Reviewing Fitness to Practise Decisions Under Section 29*. Accessed January 9, 2009.

⁵¹ Health and Disability Commissioner. *Complaints Resolution*. Accessed January 9, 2009. <http://www.hdc.org.nz/complaints>.

Great Britain.⁵² The granting of enforcement and other authorities to the CHRE may erode the fundamental principles of self-regulation by shifting some of the responsibilities for regulating to an independent agency of government.

Deliberations on Establishing a New Agency

HPRAC considered four options in shaping its advice to the Minister for an appropriate new agency to fulfill the mandate described above:

1. Expand the role of the Federation of Health Regulatory Colleges of Ontario (FHRCO),
2. Maintain HPRAC and create an additional agency (two-agency model),
3. Expand the role of other bodies,
4. Create a new agency (absorbing HPRAC's current mandate).

1. Federation of Health Regulatory Colleges of Ontario (FHRCO)

In the responses to the Consultation Discussion Guide, the concept of an oversight body was met with reticence, particularly from the Colleges themselves. However, some respondents offered some support to mandate FHRCO to act as a coordinating body.

FHRCO has undertaken several projects on behalf of Colleges, including coordinating joint advertising efforts and developing a document on medical directives, orders and delegation. The organization also conducts joint education projects in quality assurance from time to time.

FHRCO is a voluntary body whose membership is made up of chief executive officers or registrars of health regulatory colleges in Ontario. The organization does not include any professional associations, health care providers, public representatives or members of college councils as members. Its role is to bring health college leadership together to discuss policy and administrative issues of the day, such as communications and quality assurance programs, but it is rare that broader strategic matters are addressed. Subcommittees deal with cross-college issues, and provide management insight and options. FHRCO has particularly concentrated on attempts to broaden public understanding of the role of health colleges.

For FHRCO to fulfill the needed role that HPRAC has identified in the current system, it would have to change fundamentally from a member-driven organization to an independent body accountable to the government. Its mandate would have to change, and current funding mechanisms would require change to facilitate and coordinate the functions contemplated, and the accountability to funding organizations.

⁵² See Rudolph Klein, (2004) *Britain's National Health Service Revisited* 350:9 N. Eng. J. Med, 937.

HPRAC acknowledges that FHRCO plays a valuable role in supporting health colleges but has concerns that the organization may not be, or be seen to be, objective when reporting on college activities. HPRAC has concluded that designating FHRCO as the agency to monitor the health colleges in Ontario would be inappropriate. FHRCO can continue to play an important role to support the success of the proposed regulatory framework by working with colleges to achieve and maintain regulatory excellence. However, HPRAC does not believe that FHRCO has sufficient arms-length independence from the colleges to carry out the new mandate in the public interest.

2. A Two-Agency Model

This option would be similar to the Québec model, with two separate agencies whose combined mandates are responsible for the oversight of all regulated professions in Québec.

A two-agency model would require both the establishment of a new agency and the continuing operation of HPRAC, with each agency providing partial monitoring or advice relating to the health profession regulatory system. While the Minister would retain a stewardship role over the regulatory system, there could be duplication of effort and inadequate clarity about the roles of each of the agencies.

It would be a significant communications challenge for the public, and the health colleges themselves, to gain a clear understanding of how business is conducted and where the mandates of the two agencies are the same, overlap or differ. The cost implications of establishing and continuing a new agency and maintaining the existing agency cannot be overlooked. There would also be considerable transition and ramp up time for a new agency to build trust with the public, key stakeholders and the colleges.

HPRAC has concluded that the various disadvantages make this option unattractive.

3. Other Bodies

In addition to the options discussed above, HPRAC examined other approaches for enhancing accountability and establishing interprofessional collaboration at the regulatory level, including the possible expansion of the mandate of existing agencies other than HPRAC. In the end, HPRAC rejected these approaches given the following concerns:

- A new mandate could reduce an existing agency's capacity to address its core business and would require transition time to become versed in the specific issues of health professions regulation. This would be the case with, for example, the Ontario Health Quality Council.
- As HPRAC is recommending an agency that would have advisory and evaluative responsibilities, existing adjudicative bodies would not be appropriate (e.g., the Health Professions Appeal and Review Board, a tribunal that responds to complaints). Adapting a tribunal would require significant philosophical, structural and legislative changes to the *RHPA* framework.

- Other bodies with an investigative, complaint-driven mandate would also be inappropriate, given their potential conflict with the underlying principles of self-regulation. For example, the Ombudsman's office may be perceived as duplicating the existing complaints and discipline process of the colleges, and the "oversight" function performed by the Ombudsman could be seen as compromising the independence of health professions.

4. Create a New Agency: Absorbing HPRAC's Current Mandate

The option HPRAC recommends is the creation of a new independent agency that effectively absorbs HPRAC's current mandate and adds significant responsibilities for coordinating the work of the health colleges and challenging the colleges' performance, along with providing support for the key goal of facilitating interprofessional collaboration. Drawing on the experience and knowledge garnered through HPRAC's previous activities, the new agency can become a progenitor of a new type of interprofessional regulation.

The new agency would effectively take over HPRAC and build on its experience with health professions regulation in Ontario and its current advisory mandate on the regulation of new and existing professions. It would also have the authority to initiate reviews of scopes of practice and to monitor the performance of Colleges in fulfilling their objects and duties in the public interest.

It would take a broader, more proactive and strategic approach to the regulation of new professions and scope of practice reviews to address systemic issues facing the health care sector. In addition to incorporating HPRAC's current mandate, the new agency would facilitate and coordinate interprofessional collaboration among Colleges, promote regulatory best practices and measure college performance. The agency would assist the colleges to move to the new enabling regulatory framework by supporting the development of college standards of practice and the work of the interprofessional standards committees, as they get underway.

This option would require legislative amendments to the *RHPA*, incorporating the existing mandate of HPRAC and adding new responsibilities (see legislative implementation recommendations).

HPRAC proposes that the new agency be named the **Council on Health Professions Regulatory Excellence (CHPRE)**, to signal the expectations of the public and government that the performance of regulators will be evaluated and that the Minister will continue to receive independent advice on the regulation of the health professions in Ontario.

As indicated in Chapter three of this report, an infrastructure will be needed to accommodate a new drug approvals framework for non-physician health professionals who prescribe or use drugs in the course of their practice. The new agency would provide this infrastructure. It would also incorporate a Drug and Therapeutics Formulary Committee as an independent collaborative panel to give expert advice to CHPRE, whose

decisions would have legal force and supplement the regulations under profession-specific statutes.

Introducing a new proactive agency to support the system of self-regulation is in line with trends in other jurisdictions. The new comprehensive agency would also be consistent with the Ministry's stewardship role, allowing the Ministry to play less of a direct management role in the monitoring of self-regulated health professions.

Mandate of Proposed New Agency

The new agency would absorb HPRAC's current mandate as set out in section 11 of the *RHPA*⁵³ and incorporate its elements into a larger mandate to work with the Colleges to achieve the following three goals:

Interprofessional Collaboration	Monitor the health colleges in fulfilling their new objects and facilitate, coordinate and enhance interprofessional collaboration among colleges.
Regulatory Rigour & Excellence	Achieve excellence in the work of health colleges by reviewing and evaluating quality assurance, patient safety and collaborative working relationships and communicating best practices in regulatory functions and ethics.
Accountability, Transparency & Public Interest	Monitor the performance of health colleges and report to the public and government on how they have fulfilled their individual mandates as regulators and their collective mandate as part of a system of professional collaborative regulation.

⁵³ Section 11 of the *Regulated Health Professions Act, 1991*:

Duties of Advisory Council

- 11.** (1) The Advisory Council's duties are to advise the Minister on,
- (a) whether unregulated professions should be regulated;
 - (b) whether regulated professions should no longer be regulated;
 - (c) suggested amendments to this Act, a health profession Act or a regulation under any of those Acts and suggested regulations under any of those Acts;
 - (d) matters concerning the quality assurance programs undertaken by Colleges; and
 - (e) any matter the Minister refers to the Advisory Council relating to the regulation of the health professions, including any matter described in clauses (a) to (d).

Additional duty

- (2) It is the Advisory Council's duty to monitor each College's patient relations program and to advise the Minister about its effectiveness.

1. To monitor the Colleges in fulfilling their new objects and facilitate, coordinate and enhance interprofessional collaboration among Colleges.

In fulfilling this goal, the agency would advise the Minister on:

- Whether unregulated professions should be regulated;
- Whether regulated professions should no longer be regulated;
- Suggested amendments to the *RHPA*, a health profession Act or a regulation under any of those Acts and suggested regulations under any of those Acts;
- The recommended scope of practice of regulated professions;
- The need for collaboration among health colleges;
- Any conflicts between and among the health colleges or between colleges and others that the concerned colleges have not been able to resolve;
- Any health college that does not fulfill its objects and duties;
- Suggested amendments to any provincial Act or regulation affecting the role of health professions or health professionals in health care or health care delivery.

The agency would also facilitate linkages among health colleges, professions and others, including practice settings, to ensure broader institutional integration and continuity of care; identify barriers in laws affecting interprofessional collaboration; and understand and build on the changing roles of health professionals, emerging trends and other matters relevant to the regulation of health professionals.

Examples of the kinds of activities that would be carried out by the agency in fulfilling its responsibilities to promote collaboration between and among Colleges would include:

- Initiating scope of practice reviews of health professions;
- Identifying processes to improve and streamline standards development and quality reporting;
- Resolving conflicts among health colleges and between colleges and others, and
- Developing stronger partnerships with educators.

In conducting scope of practice reviews and participating in conflict resolution, the agency would be responsible for advising the Minister of other instances when it would be appropriate to require the establishment of interprofessional standards committees to develop enforceable standards of practice.

2. To achieve excellence in the work of Colleges by reviewing and evaluating quality assurance, patient safety and collaborative working relationships and communicating best practices in regulatory functions and ethics.

In fulfilling this goal, the agency would promote best practices by Colleges in the:

- Registration, complaints, investigations, discipline, fitness to practise, quality assurance, patient relations, enforcement, record-keeping and reporting functions; and
- Development of regulations, standards of practice and professional practice guidelines for their members.

Examples of the kinds of activities that would be carried out by the agency in fulfilling its responsibilities to promote good professional self-regulation and best practices would include facilitating and supporting the development of a common Code of Ethics, common conflict of interest rules and common advertising rules by all of the Colleges that would be applicable to all regulated health professionals. The code and rules would be developed on a collaborative basis and established by way of regulation under the *RHPA*.⁵⁴ By enhancing interprofessional collaboration at the regulatory level, individual health colleges or colleges working together could share successes and best practices in identifying and addressing specific sources of harm or risk to patients.

3. To monitor the performance of Colleges and report to the public and the government on how they fulfill their mandates.

In fulfilling this goal, the agency would:

- Monitor each College's efforts in serving and protecting the public interest and in achieving its objects;
- Identify and share best practices;
- Inform the public on matters relating to health profession regulation and the public's rights and recourses associated with health profession regulation;
- Bring to the Minister's attention any other matter that requires government action;
- Inform the public, through a publicly available annual report tabled in the Legislature, about the activities of the health regulatory colleges and any issues with respect to the obligations of a college or colleges to protect the public interest, and
- Coordinate a new drug approvals framework and recommend to the Minister designated drug regulations for health professions in Ontario.

⁵⁴ Once developed, section 94(1)(k) of the Health Professions Procedural Code would be repealed. Once developed, section 95(1)(i) of the Health Professions Procedural Code would be repealed. This section allows the Council of a College to make regulations prescribing what constitutes a conflict of interest in the practice of the profession and regulated or prohibiting the practice of the profession in cases in which there is a conflict of interest. Once developed, section 95(1)(1) of Schedule 2, Health Professions Procedural Code would be repealed. This section allows the Council of a College to make regulations respecting the promotion or advertising of the practice of the profession.

HPRAC is recommending that the new agency be required to report annually to the Minister of Health and Long-Term Care, and that the report be tabled by the Minister in the Legislature. HPRAC believes that this provision will significantly enhance the health colleges' direct accountability to the public, and balance the colleges' new authority to develop enforceable standards of practice. HPRAC sees the new element of public reporting through the Legislature as a strong incentive for the colleges to meet their responsibility to regulate in the public interest.

HPRAC's recommendations will significantly change the way health colleges regulate their members, but they do not fundamentally change the balance of authority under the *RHPA* regulatory framework. The changes being recommended are consistent with HPRAC's comments in *New Directions* outlining the need for the role of the colleges to evolve in the context of the Minister's stewardship role:

It is important that the colleges function in a way consistent with the transformation of the Ministry of Health and Long-Term Care. In particular, HPRAC notes the Ministry's shift to a stewardship role, its focus on health human resources planning, and an enhanced focus on accountability, and monitoring performance and outcomes. Regulated health professions are in many ways out in front of these proposed changes. For example, responsibility for the day-to-day management of the regulation of health professionals is the role of the colleges, enabling the Ministry to be effectively involved in the oversight of the system (its stewardship role).⁵⁵

Later in *New Directions*, HPRAC noted that the Minister has the duty under the Act to ensure that the health professions are regulated and coordinated in the public interest, that appropriate standards of practice are developed and maintained and that individuals have access to services provided by the health professions of their choice and that they are treated with sensitivity and respect in their dealings with health professionals, the Colleges and the Board.⁵⁶

It will be the responsibility of the Minister to address the new agency's report once it is tabled in the Legislature.

Additional Legislative Recommendations to Support the Enabling Regulatory Framework

HPRAC is recommending that health colleges be granted the authority to establish enforceable standards of practice respecting education, training, continuing competency, mandatory discussion, consultation and transfer of care, and standards, terms, limitations and conditions relating to the performance of authorized acts. Another key feature of the new enabling

⁵⁵ HPRAC (2006). *Regulation of Health Professionals in Ontario: New Directions*. Chapter 2 – Legislative Framework: 32.

⁵⁶ Ibid. 63-64.

framework calls for colleges to establish interprofessional standards committees to develop standards of practice where a profession's scope of practice overlaps with another profession's, or where professions share the same or a similar controlled act. Legislative amendments are proposed in Chapter four to implement these directions.

To reflect the new mechanisms under the enabling regulatory framework, HPRAC intends that standards of practice should be interpreted as if they formed a part of a regulation under a health profession act. HPRAC is also recommending amendments to move the rolling incorporation provisions that now refer to standards of practice developed through the regulation-making process, and apply them to the new enforceable standards of practice.

In addition, HPRAC is proposing amendments to require health colleges to publish all established standards of practice on the Internet on a publicly accessible and freely available website and to make them available as a document or in any other format, on request and at cost, to members of the public. This is consistent with HPRAC's recommendations in the scope of practice reviews to require colleges to post standards of practice on their websites. These earlier proposals were made in the context of regulations under health profession Acts. HPRAC is now recommending an amendment to the *RHPA*, the umbrella act, that would apply to all colleges. While changes in the *HSIA* that come into force in June 2009 move in this direction, HPRAC is recommending an explicit requirement for standards of practice to be posted on each College's website.

As well, HPRAC is making recommendations on liability insurance. It is proposed that all regulated health professionals be required to have and maintain professional liability insurance, or belong to a specified association that provides protection against professional liability, or be covered by their employers' insurance policies. HPRAC also recommends a requirement for all regulated health professionals to give proof of the insurance or membership to the Registrar of the college upon their registration or otherwise when requested by the Registrar. This recommendation is intended to remove any real or perceived barriers posed by liability issues to professionals working together effectively in interprofessional teams.

System-wide Challenges

While changes to the legislative and regulatory framework will go a long way toward enhancing interprofessional collaboration, they are not the whole solution. HPRAC recognizes that health system reform has many aspects.

In its September 2008 interim report, HPRAC noted numerous challenges for members of certain professions that were critical to their ability to practise to their maximum capabilities but could not be met by changes to the scopes of practice alone. HPRAC highlighted several structural and process changes necessary to resolve some of these issues.

HPRAC acknowledges that HealthForceOntario, through its *Blueprint for Interprofessional Care*, is addressing some of the key structural barriers to interprofessional care, such as implementing changes to support interprofessional education. Another important lever to promote interprofessional collaboration is the implementation of an electronic health record system. HPRAC understands the government is working to create an electronic health record for all Ontarians by 2015.

As HPRAC learned, numerous barriers to interprofessional care and interprofessional collaboration at the regulatory level require changes to funding and compensation models. In its consultations, HPRAC heard many examples from health professionals who were limited in referrals to physicians since referral fees were not paid unless the referral was made by another physician. HPRAC considers this to be a key structural barrier creating a disincentive to interprofessional collaboration. HPRAC has commented on this issue in the context of the review of the scopes of practice of midwifery and nurse practitioners. It has also been identified in the discussion of relations between optometrists and ophthalmologists in Chapter thirteen of this report. Throughout both Phase I and II of its work on interprofessional collaboration, HPRAC has repeatedly heard that compensation models and restrictive referral policies under the *Health Insurance Act* need to be addressed to better reflect current health care delivery practices. These changes are critical if Ontario is to fully embrace interprofessional care and to provide the right care, at the right time, by the right professional.

In Conclusion

In this third report on interprofessional collaboration, HPRAC has described some of the vast changes that have taken place in the provision of health care services since the *RHPA* came into force in 1993. This analysis has considered population growth and Ontario's changing demographic make-up, as well as clinical advances, the focus on chronic disease management, the impact of new and emerging technologies and the implications of all these trends for health human resources.

In particular, HPRAC's recommendations take into account the significant changes in professional practice that have occurred over the last two decades. These include progress in interprofessional education and continuing education as well as the emergence of new and varied models of team-based care such as community health centres, family health teams and nurse practitioner-led clinics. All of these heighten the need to increase the momentum behind interprofessional collaboration.

HPRAC's role is to provide advice to the Minister to ensure that Ontario's health professions are regulated in the most effective way possible to advance the public interest, protect the public from harm and ensure patient safety.

HPRAC's recommendations will not only better position Ontario's health colleges to carry out their regulatory responsibilities, but will also strengthen the overall system of regulation through creation of a new

advisory and monitoring agency. The new agency will help keep Ontario's regulatory system adaptable to changes unfolding in the practice environment. The proposals will also strengthen the core principles of patient-centred care, patient safety and the public interest as the foundation of Ontario's regulatory system.

HPRAC is convinced that the changes it is proposing to the health profession regulatory framework are necessary and fundamental to achieving successful reform and integration within the broader health care system. Continued progress in health care depends on maximizing the contribution of all health professionals, improving the way they work together, and facilitating their adoption of new knowledge and new technologies. Excellence in health profession regulation will lead to excellence in health care.

In Chapter three of this report, HPRAC outlines its proposals for a new framework and process for approval of designated drug regulations under the health professions Acts. Those recommendations integrate with the ones outlined in this chapter for a new agency, CHPRE, and for a new enabling regulatory framework for health colleges in Ontario. Implementation proposals are presented in Chapter four of this report.

EXCELLENCE AND EFFICIENCY: A NEW DRUG APPROVALS FRAMEWORK FOR ONTARIO

I. Introduction

HPRAC was asked by the Minister of Health and Long-Term Care in June 2007 to:

examine the authority given to non-physician health professions to prescribe and/or use drugs in the course of their practice under the *Regulated Health Professions Act, 1991 (RHPA)* and the health profession acts.

The Minister asked that:

the Council provide advice specific to each of these professions respecting whether lists, categories or classes of drugs should be prescribed by regulation for the profession, or whether restrictions on prescribing of drugs should be placed in regulation under the respective health profession Act.

Further, the Minister requested that HPRAC:

provide advice on a framework and process for the ongoing evaluation of requests by Colleges for changes to regulations in this regard to ensure that such regulations reflect efficiency, best practices of the profession and provide maximum public protection.¹

Throughout this review, HPRAC's goal has been to ensure that Ontario has a framework and process for evaluation of designated drugs under health professions' legislation that is efficient, prudent, reflects best practices and provides maximum public protection.

As part of this review, HPRAC considered submissions from a number of health professions seeking access or changes to their current authority for prescribing or use of drugs or who wished to comment on the framework for regulation-making and approvals. HPRAC also considered requests for access or changes to the controlled act of administering a substance by injection or inhalation.

Definitions

To assist in HPRAC's review, the following working definitions were adopted:

“Drug”, “Prescriber” and “Prescription” are as defined in the *Drug and Pharmacies Regulation Act*.

¹ Letter from Hon. George Smitherman, Minister of Health and Long-Term Care to Barbara Sullivan, Chair, Health Professions Regulatory Advisory Council, June 28, 2007.

“Drug” means any substance or preparation containing any substance,

- (a) manufactured, sold or represented for use in,
 - (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state or the symptoms thereof, in humans, animals or fowl, or
 - (ii) restoring, correcting or modifying functions in humans, animals or fowl,
- (b) referred to in Schedule I, II or III,
- (c) listed in a publication named by the regulations, or
- (d) named in the regulations, but does not include,
- (e) any substance or preparation referred to in clause (a), (b), (c) or (d) manufactured, offered for sale or sold as, or as part of, a food, drink or cosmetic,
- (f) any “natural health product” as defined from time to time by the *Natural Health Products Regulations* under the *Food and Drugs Act* (Canada), unless the product is a substance that is identified in the regulations as being a drug for the purposes of this Act despite this clause, either specifically or by its membership in a class or its listing or identification in a publication,
- (g) a substance or preparation named in Schedule U,
- (h) a substance or preparation listed in a publication named by the regulations, or
- (i) a substance or preparation that the regulations provide is not a drug.

“Prescriber” means a person who is authorized under the laws of a province or territory of Canada to give a prescription within the scope of his or her practice of a health discipline.

“Prescription” means a direction from a prescriber directing the dispensing of any drug or mixture of drugs for a designated person or animal.²

“Administer” means to supply a dose of a drug to a person for the purpose of immediate ingestion, application, inhalation, insertion or injection. In Ontario, administering drugs or substances by injection or inhalation are controlled acts under the *Regulated Health Professions Act, 1991 (RHPA)*.

“Compound” means to mix together two or more ingredients of which at least one is a drug for the purpose of dispensing a drug or drugs, but does not include reconstituting a drug with only water.³

² *Drug and Pharmacies Regulation Act*, R.S.O. 1990, c. H.4, s.1.; viewable at <http://www.canlii.org/on/laws/sta/h-4/20080821/whole.html>.

³ *Government Organization Act*, R.S.A. 2000, c. G-10, Schedule 7.1, s.1(b). Accessed September 18, 2008; viewable at <http://www.canlii.org/ab/laws/sta/g-10/20080818/whole.html>.

“Medication”, also referred to as medicine, can be generally defined as any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Other synonyms include pharmacotherapy, pharmacotherapeutics, and drug treatment.^{4,5}

“Use of drugs” means administration of a drug through various methods including administration by mouth, in-mouth, rectal application, topical application, injection or inhalation.^{6,7,8}

The *RHPA* categorizes as controlled acts those health procedures that carry a risk of harm if performed by someone who is not appropriately trained. While the administration of a drug or substance is not a controlled act, certain methods of administration are considered to carry extra risks. Thus, the administration of a drug or substance by injection or inhalation is a controlled act, and requires statutory authorization to members of health professions who have the knowledge, skills and judgment to perform the procedure. Members of the professions of chiropractic, podiatry, dentistry, medical radiation technology, medicine, midwifery, naturopathy, nursing and respiratory therapy are authorized to administer a drug by injection or inhalation. Members of other professions, such as physiotherapy, may administer a drug or substance by injection or inhalation under delegation from a health professional who has the authority to perform the procedure.

Only a limited number of health professions have the authority to perform all or part of the controlled act of prescribing, dispensing, selling or compounding drugs, or supervising the part of a pharmacy where such drugs are kept. These include the professions of chiropractic, podiatry, dentistry, medicine, midwifery, nursing, optometry, and pharmacy.

HPRAC responded to the Minister’s requests for advice through a review of authorities relating to drugs in the following professions:

Chiropractic and Podiatry	Nursing – Registered Nurses, Registered Practical Nurses, and Nurse Practitioners
Dental Hygiene	Optometry
Dentistry	Pharmacy
Medical Radiation Technology	Physiotherapy
Midwifery	Respiratory Therapy
Naturopathy	

⁴ US Federal Food, Drug, and Cosmetic Act, SEC. 201., (g) (1) (B); viewable at <http://www.fda.gov/opacom/laws/fdcaact/fdcaact1.htm>.

⁵ Directive 2004/27/EC of the European Parliament and of the Council of 31 March, 2004. Accessed 18 September, 2008; viewable at

http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/dir_2004_27/dir_2004_27_en.pdf.

⁶ Raman-Wilms, L (Ed.). 2006 Guide to Drugs in Canada. Singapore: Dorling Kindersley Limited.

⁷ Oxford Concise Colour Medical Dictionary (4th ed.) (2007) New York, New York: Oxford University Press.

⁸ Swart, B (Ed.). 2007. Toronto: Photo Atlas of Drug Administration in Pharmacology and the Nursing Process in Canada. Toronto: Elsevier.

HPRAC's Review

HPRAC recently completed a scope of practice review for nurse practitioners.⁹ In its *New Directions* report, HPRAC reviewed the use of therapeutic pharmaceutical agents in the profession of optometry.¹⁰ As part of the Minister's request for advice on interprofessional collaboration, HPRAC reviewed the scopes of practice of the professions of pharmacy, physiotherapy, dietetics and midwifery.¹¹ Scope of practice reviews for the professions of medical laboratory technology and medical radiation technology are included in this Critical Links report.

In the course of those reviews, HPRAC indicated that, where relevant, it would consider specific issues concerning the prescribing and use of drugs by non-physician health professionals in greater detail in its examination of the Minister's request for advice on this subject. For each of these professions, HPRAC conducted extensive examinations of the education, quality assurance and continuing competence. Literature and jurisdictional reviews were prepared for each of the health professions, as well as a limited jurisprudence review. Interviews and meetings with educators, members of the profession, other health professions, health care facilities and institutions and community-based agencies were held to capture concerns and comments. Proponents' submissions were posted on HPRAC's website, and responses to the submissions were invited from those with an interest in the subject.

HPRAC's conclusions on the administration of drugs and substances in the professions of medical laboratory technology and medical radiation technology are addressed as part of the scope of practice reviews for these professions and included as chapters five and six of this report.

How HPRAC Conducted the Review

In conducting this review, HPRAC undertook a literature review to investigate current information about the rationale, history and background of non-physician prescribing and drug administration. The literature review focused on identifying key documents in the scholarly and grey literature as well as publicly available reports and websites on the subject. HPRAC also examined non-physician prescribing in other jurisdictions to identify emerging trends.

A jurisprudence review was also conducted. It included a review of Canadian case law concerning the prescribing and administration of drugs and substances by non-physician regulated health professionals.

⁹ HPRAC, *Report to the Minister of Health and Long-Term Care on the Review of the Scope of Practice for Registered Nurses in the Extended Class (Nurse Practitioners)*, March 2008.

¹⁰ *New Directions* Health Professions Regulatory Advisory Council: April 2006 115-126.

¹¹ HPRAC, *An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals: Phase II, Part 1*. September 2008.

HPRAC also retained the services of a pharmacology expert to assist in its review of the educational competencies of the health professions requesting additional authorities in the prescribing or use of drugs, assist in the examination of the question of the designation of classes versus individual lists of drugs in regulations under health professions' Acts and to provide expert advice on recommended drug classes, specific agents and terms, limitations and conditions to be considered for each health profession in the review.

This work was supplemented by interviews and round-table discussions with health colleges, health professions' organizations, and leadership in professions, facilities and organizations, including Health Canada, community and long-term care sectors, key physicians, patient safety organizations, and experts in leading Canadian and international jurisdictions.

The health colleges whose authorities were being considered were asked to submit responses to a questionnaire relating to prescribing and using drugs in the course of the practice of the profession. Their responses are posted on the HPRAC website, along with any responses to them received by HPRAC.

Impetus for Change

Ontario's health care system faces challenges around access, efficiency and sustainability. Allowing additional qualified health professions to prescribe, dispense, compound, sell, administer or use drugs might support more efficient and effective patient-centred care. The use of drugs is an increasingly important form of therapy in chronic and acute care. It is a trend that has particular relevance for clinical care in hospitals, home care and long-term care. Innovations in pharmacology have revolutionized treatments of numerous diseases and conditions.

Ontario's aging population, coupled with comparable demographic shifts in health human resources, means that many people in Ontario are unable to access primary care in a reasonable time, and others have no primary care physician. Efforts such as initiating family health teams, community health centres and nurse-led clinics are attempts to meet the escalating shortage of health professionals and to further collaboration between professions. The health human resource shortage is particularly severe in rural and remote communities. Access to care can be a major obstacle for Ontarians living in these areas.

At the same time, health professions have evolved, gained additional knowledge and skills, and developed the competencies to provide quality care in areas where these new skills are in singular demand. Whether in the management of chronic illness, or in providing expert services in highly specialized care, health professionals are seeking the opportunity to practise to the full range of their scope of practice and individual abilities.

Systemic changes are needed to ensure that individuals with the right professional skills are providing appropriate patient care. This will enable members of some health professions, such as medicine, to focus on areas where their expertise is essential. “Chasing orders” is no longer an option in a health care system that is pressured and when members of health professions have the qualifications to provide safe and effective patient care. It will also facilitate chronic care and disease management, particularly where patients move from one setting to another. Patients often move from home care to long-term care to hospital and back, as their needs change, and are often cared for by a number of health professionals.

During its consultations, HPRAC heard that a lack of access to such health professionals as physicians and dentists is an issue in a number of settings, including long-term care homes. Broadening authorities for prescribing and administering drugs and substances, and ensuring collaborative working relationships between health professionals, can help to meet the needs of a growing number of people in Ontario.

The Ontario government has indicated that interprofessional collaboration is one approach to addressing the health human resource shortage and ensuring appropriate patient care. For interprofessional collaboration to be successful, each profession must be able to practice to the full extent of its competencies, including in some cases, prescribing, dispensing, selling or compounding drugs. These authorities must be within the health profession’s scope of practice, and meet the most exacting standards to ensure patient safety.

In this review, HPRAC found there is a clear understanding and readiness to accept the accountabilities that are attached to the controlled act of prescribing, dispensing, selling and compounding drugs among a number of health professions. In some cases, health professions agree that terms, limitations and conditions should be attached to the controlled act or components of the act. In many cases, the education and training has been established, and the health college is ready to make necessary changes to ensure that any required upgrades to education and training are in place to maximize patient safety and ensure health professionals have the needed skills.

HPRAC stresses the importance of keeping patient safety at the forefront when making changes to prescribing rights. In many cases, expanded prescribing rights necessarily must be accompanied by terms, limitations and conditions for those authorities. Health colleges will be expected to develop relevant standards of practice for their members. Additional safeguards might be needed to further protect the public. Appropriate pharmacotherapeutic education and training, continuing competency requirements, and standards for safe prescribing, record-keeping and retention, referral protocols and medication therapy management are essential components of health college programs.

The Minister’s question to HPRAC recognizes the inefficiencies of the current regulation-making and approval process that often takes years for a single drug to be added to regulations under a health profession Act. During its

review of the *RHPA*, HPRAC continued to be apprised of serious concerns relating to the timely approval of regulations, and the impacts of the delays on the quality of professional practice. In its *New Directions* report, HPRAC concluded that “a timely, responsive regulation approvals process is a critical component in the delivery of quality, accessible health systems”.¹²

The Minister responded to HPRAC’s conclusion in his letter of June 28, 2007 outlining the parameters of the current request and seeking advice on a new framework and process for drug approvals under health professions’ Acts.

In this report, HPRAC includes recommendations for a framework for drug approvals that will maintain the oversight of government through the regulation-making and approvals processes, while ensuring a more effective and efficient regulation-making and approvals process.

In summary, HPRAC is convinced this review is a key component in ensuring the province’s health profession regulatory system keeps pace with and supports the health care needs of Ontarians. HPRAC’s advice addresses the need to modernize authorities for the prescribing and use of drugs so professions can work to their full competencies. It also provides a framework for a transparent and efficient drug approvals process for health professions in Ontario.

Trends Toward Non-Physician Prescribing

It is well documented that prescription drugs are the fastest growing component of Canadian health care expenditures¹³. In Ontario, similar to other provinces, drug expenditures in 2007 increased by 6.5 percent over 2006, representing 17.6 percent of per capita health expenditures in the province.¹⁴ Health system policies, availability of new drugs, and changes in clinical practice, prescribing practices or consumer preferences all lead to changes in the amount or types of drugs dispensed.¹⁵

The first professions to receive legal authority to prescribe drugs in Canada, as in most other jurisdictions, have historically been physicians, dentists and veterinarians. In recent years, this has expanded in several provinces to include other health professions such as nurse practitioners, pharmacists, midwives, optometrists, podiatrists and registered nurses. Government initiatives to extend prescribing authority to non-physicians have typically made reference to the need to improve patient care without compromising patient safety. The goal is to make it easier for patients to obtain the medicines they need, to increase patient choice in health professionals, to make better use of the skills of health professionals, and to contribute to the introduction of more innovative health care teams.¹⁶

¹² HPRAC. *New Directions*: April 2006:70.

¹³ Tierney, M., Manns, B. (2008) *Optimizing the use of prescription drugs in Canada through the Common Drug Review*, CMAJ, v.178(4): 432-435.

¹⁴ Canadian Institute for Health Information: *Drug Expenditure in Canada 1985-2007*. Ottawa, 2008.

¹⁵ Ibid.

¹⁶ *Improving Patients’ Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the NHS in England*. UK Dept. of Health, April 2006.

The role of prescriber is evolving – with the goal of enhancing collaboration between physicians and other health care providers to potentially increase accessibility, choice, and quality of care for patients.¹⁷

Experiences in Other Leading Jurisdictions

In other jurisdictions, there is evidence both of an increase in the health professions that have authority to prescribe or administer drugs, and in new models of collaborative practice and medication management that involve more than one health profession.

Great Britain has become a leader in non-physician prescribing. It has adopted a comprehensive approach to implementing non-medical prescriptions through the Department of Health's *Non-Medical Prescriber Programme*¹⁸ (NMPP) and the *National Prescribing Centre*.¹⁹ It became legal in 2006 under the NMPP for nurses to prescribe any licensed medicine, except controlled drugs, without clinical management plans from physicians. Other professions, including optometrists, podiatrists, radiographers, and physiotherapists have been granted 'supplementary prescriber' status with the potential for acquiring 'independent prescriber' status in the future.²⁰

HPRAC's literature review found that while there are not many studies that evaluate the effect of non-physician prescribing on the health care system, on balance, prescribing by non-physicians has been well received in other jurisdictions.

There are a number of positive references to non-physician prescribing in Great Britain in particular. Generally, evaluative reviews of the implementation of nursing prescribing authority have identified that prescribing by nurses was well received and understood by patients and other health professionals, and provided an enhanced patient experience and continuity of care.^{21,22,23}

In its survey of the "internationally accumulated quantitative and qualitative research into various aspects of nurse and midwife prescribing" over the past thirty years, the Irish Department of Health & Children and

¹⁷ Sketris, I., Langille Ingram E., Lummis, H. *Optimal Prescribing and Medication Use in Canada: Challenges and Opportunities*. Toronto: Health Council of Canada, May 2007.

¹⁸ *The Non-Medical Prescribing Program*, UK Department of Health; viewable at <http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/TheNon-MedicalPrescribingProgramme/index.htm>.

¹⁹ *Non-medical Prescribing*, National Prescribing Centre, UK Department of Health; viewable at http://www.npc.co.uk/non_medical.htm.

²⁰ Bradley, E. and Nolan, P. (2008). *Non-Medical Prescribing*. Cambridge, UK: Cambridge University Press.

²¹ Evaluation of non-medical prescribing within the Essex Health Economy (2005-2006).

²² Latter, S., Maben, J., Myall, M., Courtney, M., Young, A., Dunn, N. (2005) *An Evaluation of Extended Formulary Independent Nurse Prescribing. Executive Summary of Final Report*. Policy Research Program at the Department of Health and University of Southampton.

²³ Latter, S., Maben, J., Myall, M., Young, A. *Evaluating Nurse Prescribers' Education and Continuing Professional Development for Independent Prescribing Practice: Findings from a National Survey in England* (2007) *Nurse Education Today*. 27: 685-696.

the National Council for the Professional Development of Nursing and Midwifery reported that “nurses and midwives are safe prescribers; patients view nurse and midwife prescribers favourably because of attributes such as responsiveness and empathy, and their ability to communicate effectively and provide adequate information about a patient’s condition and treatment; nurse and midwife prescribing is cost- and time-effective for service providers; rates of patients’ compliance with nurse and midwife prescriptions are high; and nurses and midwives take detailed medical histories before making a decision about an intervention and may be more likely to prescribe a non-pharmacological intervention”.^{24,25,26,27}

In a current review of pharmacy and nursing supplementary prescribing in Great Britain, R. Cooper and others noted that supplementary prescribing was generally viewed positively, particularly as it relates to the benefits of improved access to medicines and reduced delays. Stakeholders’ safety concerns were minimal while views on economic impact varied. The report also noted challenges to non-physician prescribing. These challenges include a need to increase the general awareness of and reduce interprofessional tensions related to skill and training.²⁸

In summary, HPRAC’s literature review indicates that the limited evaluative reviews published to date generally support the introduction of new prescribing authority, particularly related to nursing and pharmacy.

Some reports have also identified a number of barriers and challenges that remain to be resolved, particularly around implementation logistics, public awareness, education and training, and continuing interprofessional tensions.

V. Patient Safety and Drug Administration

HPRAC conducted a general literature and jurisdictional review which included an overall review of information on patient safety. Additionally, HPRAC carried out a more specific review of literature on patient safety and held interviews with patient safety organizations including representatives of the Institute for Safe Medication Practices Canada (ISMP), Ministry of Health and Long-Term Care patient safety leaders, Canada Health Infoway and the Canadian Patient Safety Institute. HPRAC also met with experts in electronic health records to discuss the issues of patient safety and e-health.

²⁴ *The Introduction of Nurse and Midwife Prescribing in Ireland: An Overview* (2007), Department of Health & Children, Ireland.

²⁵ Evaluation of non-medical prescribing within the Essex Health Economy (2005-2006).

²⁶ Latter, S., Maben, J., Myall, M., Courtney, M., Young, A., Dunn, N. (2005) *An Evaluation of Extended Formulary Independent Nurse Prescribing. Executive Summary of Final Report*. Policy Research Program at the Department of Health and University of Southampton.

²⁷ Latter, S., Maben, J., Myall, M., Young, A. (2007), *Evaluating Nurse Prescribers’ Education and Continuing Professional Development for Independent Prescribing Practice: Findings from a National Survey in England* *Nurse Education Today*. 27: 685-696.

²⁸ Cooper, R., Anderson, C., Avery, T., Bissell, P., Guillaume, L., Hutchinson, A., Lymn, J., Murphy, E., Ratcliffe, J., Ward, P. (2008) *Stakeholders’ views of UK nurse and pharmacist supplementary prescribing*, *J Health Serv Res Policy*. 13(4): 215-21.

The impact of drug-related errors on both health and system outcomes is well-documented. Virtually every jurisdiction in and outside Canada appears to share common and prevalent adverse events in medication prescribing, dispensing, administration, management and use. In their 2007 report, *Optimal Prescribing and Medication Use in Canada: Challenges and Opportunities*, Sketris and others note that “both suboptimal prescribing and variation in prescribing practices exist in Canada, leading to under-use, overuse and inappropriate use of drugs”.³⁰

The U.S. Institute of Medicine report, *To Err Is Human* (1999), helped spark a widespread call to action with its estimate that between 44,000 and 98,000 U.S. citizens die each year as a result of medication errors. While Canada did not immediately follow suit in highlighting this issue, mostly due to a lack of data, now the country and each of its provinces have patient safety strategies in place due to growing awareness and concern among the public.³⁰ Approximately one in every ten Canadians, according to a recent international health survey, reported receiving the wrong medication or dose from a health professional in the previous two years.³¹

Patient safety is a prime concern in considering new or expanded authorities in the area of non-physician prescribing and drug administration. HPRAC’s literature review referenced a substantial body of literature focused on physicians, nurses and pharmacists. However, reviews specifically targeting patient safety found limited information on prescribing and drug administration by health professions other than physicians.

Still, there is strong consensus among those whom HPRAC consulted that increased patient safety should be a fundamental outcome of HPRAC’s review and recommendations.

HPRAC heard in its key informant interviews that the possibility of increased risks of errors as a result of multiple prescribers and professionals dispensing medications to patients is a particular concern. To mitigate this risk, the following strategies were identified:

- Clearly define shared protocols and standards of care; Develop interprofessional education requirements for a common curriculum on medication;
- Provide access to common sources of information on safe medication practices and to common clinical decision support tools;
- Develop more up-to-date processes for care coordination (technological, operational etc.) that take into account multiple providers;
- Effectively sharing clinical information (health records) among health professionals;

³⁰ Canadian Patient Safety Institute.

³¹ *Patient Safety in Canada: An Update* (August 2007), Canadian Institute for Health Information, p.18; viewable at http://www.cihi.ca/cihiweb/en/downloads/Patient_Safety_AIB_EN_070814.pdf.

- Active participation and leadership of pharmacists in medication management at all levels and stages along the continuum of care;
- Engage the public in developing solutions and empowering patients in the management of their care; and
- Engage all stakeholders, including physicians, in the development of solutions.

To maximize patient safety, HPRAC's investigations showed a need to develop explicit and comprehensive approaches to safe prescribing and medication administration in care settings where multiple health professions provide care to the same patients. This is foundational work. Current activities are limited in focus.

In Great Britain there is a new initiative to produce common prescribing guidelines for health professions, although physicians still account for 98 percent of all prescriptions in that jurisdiction.

There is no evidence to date of focused activity in this area in Canada. The Ontario Long-Term Care Association and the Institute for Safe Medication Practices are jointly examining issues concerning the administration of medications by unregulated health providers. Individual hospitals have developed interprofessional medication management protocols that begin to move in this direction. However, there is no systemic or comprehensive public policy or regulatory focus on this emerging issue in Ontario or elsewhere in Canada.³²

Stakeholders consulted by HPRAC stressed the need to address patient safety concerns associated with expanded drug authorities on a specific or case-by-case basis: by profession and broader scope of practice issues (e.g., comprehensive information on education, expertise and level of responsibility is needed); by clinical condition or treatment protocol (e.g., addressing a minor condition, part of a broader treatment plan); by medication activity (e.g., new prescription versus adjustment to current medication) and by drug product or category (e.g., complexity: risk, side effects, administration and monitoring of some drugs and drug groups versus others).

Emerging information technology solutions

Drug information systems and patient electronic health records (EHRs) that are accessible to designated health professionals are seen as a useful tool to support safer drug prescribing, administration and use by both physician and non-physician providers.

In Ontario, only limited drug information systems are in place. Currently, a secure, interoperable EHR system will not be active until 2015 at the earliest.³³

³² HPRAC interviews with key informants, December 2008 and January 2009.

³³ Consultation with Ministry of Health and Long-Term Care. December 2008 and January 2009.

Over the next few years, a key focus for the province's e-Health strategy will be drug information initiatives such as *ePrescribing*. *ePrescribing* will electronically transmit prescriptions from physicians and other prescribers to the pharmacists or dispensers using the provincial drug repository. To date, this program is at the pilot stage. The province is also expanding access to a drug profile viewer that currently allows authorized health professionals in hospital emergency departments to access drug claims information of 2.3 million Ontario Drug Benefit recipients. Access to this system will be expanded to full drug information system capability over the next few years.

HPRAC heard repeatedly from stakeholders that there is a need to proceed expeditiously with an EHR for Ontarians.

Drug Approvals in Ontario Today

The system for approving designated drugs in regulations under health professions' Acts is frequently described by health colleges as slow, frustrating and cumbersome. This process is rooted in Ontario's regulation-making and approvals process. It involves a series of complex steps that cause delays that can make the adoption of best practices for prescribing and administering of medications difficult to achieve. With expedited approval, a drug regulation will take a minimum of a year to move through the system. HPRAC reported in *New Directions* of regulation requests that have remained in the approval process for several years.³⁴

In the course of earlier reviews of the *RHPA*, HPRAC was made aware of serious concerns related to government examination and approval of proposed regulations made under health profession Acts. HPRAC's review indicated that the consideration of proposed regulations was often tardy, inconsistent and unresponsive.

HPRAC learned that many of the proposals submitted to the Ministry by health colleges remained outstanding for several years. Some colleges reported that proposals submitted to the Ministry remained outstanding so long they eventually became outdated, requiring them to be rescinded. One request for an "expedited approval" of an emergency proposal for approval of a drug took a year to complete.

The Case for Change

Clearly, serious problems in the general regulation-making and approval process create an unnecessary risk to members of the public, who may not be able to access the most up-to-date pharmaceuticals from their health professionals. Non-physician prescribers may not be able to follow best practices by prescribing or using based on the latest research and practices within the profession. Inefficiencies in the drug approval process use resources that could be allocated elsewhere.

³⁴ *New Directions*, Health Professions Regulatory Advisory Council. April 2006: 62-71.

Given the rapid rate of change in pharmacotherapy, health professions wish to remain current using the most effective medications and discontinuing use of those drugs that are found to be less effective or that might present too many contraindications. Drug regulations are inconsistent across health professions. While regulations for many professions list them individually, some professions list drugs according to the conditions, diseases or illnesses for which they may be prescribed. Some professions are authorized to prescribe drugs contained within a specified class or category, but regulations continue to list drugs individually.

Lack of transparency further diminishes the accountability of the health professions. A more rigorous and efficient drug approval process, involving experts in pharmacology, authorities from the colleges, and interprofessional representation, will help to ensure a consistent approach across the health professions.

The Minister's Request for Advice: A New Framework and Process

In his letter of June 2007, the Minister took note of these issues and asked HPRAC to provide advice on a new drug approvals framework and process in Ontario and on whether lists, categories or classes of drugs should be prescribed by regulation or whether restrictions on prescribing of drugs should be placed in the health professions' Acts.

HPRAC has developed its advice to the Minister to improve the drug approvals process and framework with a goal of ensuring regulatory rigour and excellence and supporting an efficient, transparent and accountable process.

Deliberations on a New Drug Approval Framework for Ontario

According to HPRAC's literature and jurisdictional reviews, governments in other jurisdictions have struggled with this question. With the implementation of a new drug approvals framework, Ontario will be a leader in promoting regulatory excellence.

In forming its advice, HPRAC considered three options for a drug approvals framework for Ontario:

1. Maintain the current drug list and regulation-making approval processes;
2. Enable health colleges to establish their own drug lists without Ministerial or Cabinet review or approval; or
3. Enable an independent authority to establish the list of specific agents outside of the regulation-making and approval processes.

These options included the need:

- For an efficient, timely, consistent, effective and rigorous process;
- To ensure maximum public protection;
- For confidence and certainty in the approvals process;
- For an interprofessional and systemic approach; and
- To ensure transparency and accountability.

1. Maintain the Current Drug List and Regulation-Making/Approval Process

The current process requires colleges to submit proposed regulations to the Ministry. The Ministry then reviews the request, and if satisfied, brings the request to the Lieutenant Governor in Council for approval.

HPRAC has concluded that the current process is not sufficiently rigorous, responsive or flexible enough to respond to the evolving clinical practice environment. It does not include a transparent review of a requesting profession's scope of practice or involve pharmacotherapy expertise to establish terms, limitations and conditions for approved drugs within the profession's scope of practice.

HPRAC maintains that the serious gaps in the current process create an unnecessary risk to the public, while diminishing the transparency and accountability of the self regulatory process. It is also an obstacle to state-of-the-art practice and efficiency. For these reasons, HPRAC has concluded that the current regulation-making and approvals process is not the best approach for a drug approvals framework.

2. Enable Colleges to Establish their own Drug List without Ministerial review or Cabinet Approval

This option involves devolving the authority for listing drugs or classes of drugs to the health colleges themselves. This model is similar to the Alberta framework for midwives and optometrists and the British Columbia framework for dentists. In some instances, the option requires an interprofessional collaborative process. In Alberta, drugs are added to the midwifery drug list by the health college, following a consultation process initiated with pharmacists and other stakeholders. In Nova Scotia, for nurse practitioners, the College of Nurses establishes an interprofessional Drug and Therapeutics Committee, including physicians and pharmacists, to determine the appropriate drugs that should be authorized to the profession. In New Brunswick, similar legislation is in force however the committee determines which drugs nurse practitioners are excluded from prescribing. In Prince Edward Island, for optometrists, the College of Optometry establishes a committee chaired by the registrar that includes pharmacist but not physician representation. In the Yukon, a recent consultation paper on regulation of nurse practitioners contemplates a committee comparable to that in Nova Scotia.

HPRAC has concerns regarding this model. HPRAC is convinced that the drug approval process should start with a scope of practice review to consider whether the drug request is also a request to expand a profession's scope of practice that may or may not be appropriate depending on the circumstances. HPRAC has reservations with the objectivity of the colleges, in some instances in this rule-making model, and that they may not consider the professional scope of practice fully in their deliberations.. There is a risk that the desire for the expansion of a profession's scope of practice might outweigh patient safety considerations. Colleges with smaller memberships might not have sufficient resources to retain pharmacotherapy and other interprofessional expertise when determining appropriate terms, limitations and conditions for an approved drug.

Lack of consistency between health professions sharing similar controlled acts is also a matter of concern. Patients should be assured that if health professions share overlapping scopes of practice, including prescribing authority, mechanisms to ensure equivalent, objective evaluation of drugs and drug products should be in place. Patients should not be disadvantaged by rules made in one profession that differ from those of another profession that provides the same clinical care. Overall, HPRAC is not convinced that this model will provide adequate safeguards for patients, and therefore is not recommending this option.

3. Enable an Independent Agency to establish the Designated Drugs or Agents outside the regulation-making and approval process

Under this option, regulations under health professions' Acts would designate the therapeutic classes of drugs that can be administered, prescribed, dispensed, sold or compounded by each authorized health profession. The Minister would receive advice from an independent agency respecting the therapeutic classes of drugs for each health profession, following an extensive review. The agency would also be charged with providing advice on other health profession matters and would be familiar with regulatory issues affecting the health professions.

The list of drugs or specific agents within each therapeutic class for each health profession would be recommended to the agency by an objective, expert, independent committee, outside the regulation-making and approval processes, following the agency's comprehensive review process, including a review of the scope of practice of the profession. The review by the expert committee would recommend the specific agents that should be included in a therapeutic class, and take into account whether terms, limitations or conditions should be placed on the agents within a therapeutic class that is included in the profession's regulation.

This model is in many ways similar to the Quebec model for chiropractors, podiatrists and midwives, where the list of drugs is controlled by the Office des professions du Québec after consultation with the affected orders as well as the orders of medicine and pharmacy. It also draws from Great Britain's Council for Healthcare Regulatory Excellence (CHRE) model.

This approach would take a broader, more proactive and strategic approach to drug approvals by ensuring a consistent process and full review of requests for approvals of therapeutic classes of drugs in the regulations, and a thorough examination of the agents that would be authorized for the profession based on its scope of practice.

A New Drug Approvals Framework for Ontario

After reviewing these options, HPRAC concludes that a rigorous two-stage process is required for all designated drug approvals and that the process should be conducted by an independent agency to ensure that patient safety considerations prevail.

The first stage of the process would entail a comprehensive review of a health profession's request for a new class of drug or other authorities respecting drugs, to determine if the request is within a profession's scope of practice, if a change in scope of practice is needed, and if this change is appropriate.

Following the determination that it is in the public interest that a new class of drugs be added to a profession's prescribing authority, a recommendation would be made to the Minister to include the therapeutic class in the health profession's designated drug regulation. An expedited regulation-making and approvals process would follow this recommendation.

To accomplish this, HPRAC is recommending that the proposed **Council on Health Professions Regulatory Excellence (CHPRE)** oversee the development of recommendations for the addition and removal of therapeutic drug classes for health professions in Ontario. CHPRE would receive requests directly from health regulatory colleges for authority to:

- Perform controlled acts of prescribing, dispensing, compounding or selling drugs;
- Administer substances by injection or inhalation;
- Use drugs in the course of the practice of the profession, and
- Add new therapeutic classes of drugs to regulations under health profession Acts for any of these purposes.

Following specific protocols, CHPRE would conduct a scope of practice review, investigating whether the request falls within the existing scope of practice of the profession, or whether there was a legitimate reason to alter or expand the scope of practice.

CHPRE would also examine whether the health profession has appropriate competencies to perform the controlled act requested and whether additional education, training, standards of practice or other safeguards needed to be put into place. If CHPRE finds the request for the addition of a drug class to be reasonable and that it addresses patient safety considerations, CHPRE would make a recommendation to the Minister that the process for regulation approval should proceed.

HPRAC is convinced that the expedited regulation-making and approval process is an important consideration. When a full, fair and open external review and diligent examination has been conducted, HPRAC considers that the Minister and the government should have confidence in moving the regulations forward in an expeditious manner.

In addition to the central role of CHPRE, HPRAC is also recommending the creation of an interprofessional **Drug and Therapeutics Formulary Committee (DTFC)** to provide technical and scientific advice to CHPRE. Its work would encompass the second stage of the review. In its examination, the DTFC would determine the specific drugs or agents that should fall within the designated therapeutic classes that are authorized under regulation, and any terms, conditions or limitations that should be attached to their use, and make its recommendations to CHPRE. The DTFC would be made up of health professionals and other experts in pharmacotherapy. The DTFC's recommendations for the Drug List would be submitted to CHPRE for final approval, and if found to be in the public interest, would have the force of law.

If a health profession requests one or more additions or deletions to an already designated list of drugs within a therapeutic class, the request would be directed, after an initial review by CHPRE, to the DTFC for immediate consideration and recommendation.

HPRAC contends that this two-stage process would provide the substantial protections required to ensure patient safety, to increase efficiency and to reflect best pharmacotherapeutic practices for the health professions. It retains the government's accountability for regulation approval, while providing health professions with the flexibility and responsibility to carry out their own functions. The public would be assured of a transparent and thorough process, and that health professions are examined and held accountable for requests that reflect the evolution of the profession.

Regulation by Classes or Lists of Drugs

The Minister asked HPRAC to determine if drug regulations for health professionals should be based on classes of drugs or on a listing of individual drugs.

HPRAC heard the argument that using lists of individual drugs in designated drug regulations is the safest way to ensure that a health professional would be restricted to prescribing or dispensing specific drugs in limited circumstances, and to ensure patient safety. Allowing health professionals for the first time, to prescribe drugs from broad therapeutic classes might not provide maximum public protection.

Lists of individual drugs in regulation are difficult to change, and can limit the ability of a health professional to make use of the most appropriate medication therapy for their patients. Frequently the most appropriate drug to treat a condition or disease might not be included in the designated drug list for a health profession, and either a referral to another health professional to obtain the best drug therapy is required, or a suboptimal drug is prescribed.

HPRAC also heard that there are thousands of regulated drugs, natural health products, vaccines, and other therapeutic agents available to health professionals in Ontario. Each agent might have several potential uses, contraindications, adverse effects, and drug interactions. Regulating each therapeutic agent on a case by case basis for numerous different regulated health professions would be an extremely labour-intensive, time-consuming, and slow process, thereby decreasing efficiency and becoming a road block to best practices for the health professions.

HPRAC was informed that there is no universal system of drug classification. The terms “category” and “class” are used interchangeably. Drugs may be classified by the body system most often targeted by the drug (e.g., cardiovascular), by the function most often performed by the drug (e.g., lowers blood pressure), by the mechanism of their action (e.g., beta blocker), or by their chemical structure or composition. In addition, some drugs are used for numerous purposes (e.g., cardiovascular and anti-glaucoma).

HPRAC views therapeutic class descriptions that encompass both the body system and the mechanism of drug action as the most effective way of consistently defining drug classes. As a result of consultation with numerous experts, HPRAC decided to rely on the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System, which is used in most jurisdictions and is familiar to most health professionals, as the basis for its determination of therapeutic classes of drugs that should be authorized by regulation to each profession.³⁵ HPRAC also created three additional classes of drugs: “Prescription Therapeutic Products” to describe those natural health products that are restricted by Health Canada but are not classed as drugs, “Emergency Medicines” to describe agents used to treat health emergencies, and “Uterotonics” to specify agents used to contract the uterus after childbirth. Due to the ever-changing health care and drug landscape, the CHPRE or DTFC may be required to develop additional classes of drugs in the future.

To balance efficiency and safety, HPRAC concluded that any increased risks from identifying classes of drugs in regulation could be mitigated by attaching terms, limitations or conditions to the use of specific drugs or agents. These conditions might include the identification of specific treatments for its use, or whether the drug could be used to initiate or to renew a prescription, depending on the health profession and its qualifications and scope of practice. This allows the benefits of therapeutic classes designated by regulation, with additional safeguards for the public that reflect the scope of practice and knowledge of the health profession. For example, antibiotics could be approved as a class for a health profession, and that profession could use antibiotic agents as necessary within its scope of practice. Sub-classes of antibiotics (e.g., penicillins, tetracyclines, macrolides) could be approved instead of the entire class of antibiotics.

³⁵ www.pspa.net/gadoc/AmHospForm.htm.

Within these classes of drugs, specific agents can be listed by CHPRE with or without additional restrictions (e.g., penicillin, penicillin for oral use, penicillin for the treatment of strep throat, penicillin for patients over 18 years of age) or any combination of these and additional restrictions.

The Approval Process

In sum, HPRAC is recommending a new regulatory framework, with a two-step approvals approach that would place therapeutic classes of drugs within the regulations under the health profession Acts. A separate process would define the Drug List, by adding or removing individual drugs or agents from the authorized classes, and attaching terms, limitations or conditions, if any, to the use of drugs within the classes authorized for each profession. This process would not involve regulation approvals, but should be carried out by the new DTFC, and approved and published by CHPRE.

As part of this process, CHPRE would be expected to establish generic criteria that a health profession would respond to when applying for a new drug authority or a new class of drugs. The criteria would include the following essential elements:

- Competencies and educational requirements;
- Collaborative relationships with other health professions;
- Continuing competence; and
- Quality assurance and improvement programs.

Once criteria are established, CHPRE will begin to receive applications from health professions for the addition of classes of drugs to their profession-specific drug regulation. For each request for a class, CHPRE will conduct a scope of practice review to determine whether the request requires an expansion to the scope of practice and whether the request is reasonable and appropriate. CHPRE would follow established methods in its review including research, literature and jurisdictional reviews, and a consultative program with key informants and interested parties.

In some cases, the addition of a new class of drug in a designated drug regulation would require colleges to enhance their existing standards of practice. Each college council would continue to establish its own standards, limitations and conditions for the drug authority concerning matters that would fall within their standards of practice, based on the involvement of a collaborative standards of practice committee. The standards of practice include the competencies required (education and training), quality assurance and improvement and mandatory referral and consultation with others.

Based on the results of the scope of practice review and the advice of experts in the fields of medicine, pharmacology and others, CHPRE would then recommend that the Minister add a new class of drugs to a regulation under a health profession Act. If CHPRE is not satisfied that the request should go forward, it would return the request to the health college, identifying where additional work may be required. CHPRE could also reject the request.

If a proposal for a new class of drugs is approved by CHPRE and forwarded to the Minister for inclusion as a regulation, the DTFC would examine the specific agents that should be included in the class designated in the regulation. The DTFC could also recommend terms, limitations or conditions to be attached to selected drugs or agents, for approval by CHPRE. On approval of the regulation, the profession would be authorized to use the new drugs included in the Drug List and falling within the approved therapeutic class without lengthy delays.

Recommendations to the Minister for changes or additions to a drug regulation under a health professional Act should be accompanied by a request for expedited approval in order to avoid the serious delays that have impacted health professions in the past.

CHPRE would keep issues of patient safety, evidence-based decision-making, efficiency and interprofessional collaboration at the forefront of its decision-making process. To support an open and transparent process, CHPRE would make all requests and its process public.

Maintaining the Drug List

HPRAC expects that CHPRE would be responsible for retaining, maintaining and publishing the Drug List. The Drug List would have the status of law, and be based on recommendations received from CHPRE by the DTFC.

CHPRE could designate a drug or substance on the Drug List where CHPRE considers it to be in the public interest to do so, but would not approve a drug if it is of the opinion that the new addition to the Drug List is not in the public interest.

The Drug List would include the approved terms, limitations and conditions attached to each drug or specific agent for each health profession. Terms, limitations and conditions could include:

- Considerations relating to the use or the possibility of the use of other drugs or substances or therapies for particular patients or a particular class of patients;
- Requirements that the use of a drug or substance for particular patients or a particular patient class requires a prescription from another health profession or member of a class of another health profession specified by CHPRE, or
- Requirements that a specified drug or substance only be used on particular patients or a particular class of patients.

Annually, CHPRE would make a report in writing to the Minister concerning its reviews and approvals for that year and the Minister would publish the report within 30 days of receiving it.

Minister's Review

HPRAC recognizes the importance of the legislative process in ensuring public safety, appropriate access to drugs, and balancing economic considerations with the benefits of new drugs on the market. It is HPRAC's expectation that the Minister would be notified of and would review the Drug List before it comes into force. Unless the Minister considers the recommendations of CHPRE, including the contents of the Drug List, not to be in the public interest, the recommendations will be deemed to be accepted by the Minister within a specific timeframe.

Drug and Therapeutics Formulary Committee

As part of the approval process for drug authorities under the RHPA, HPRAC is recommending the establishment of a new Drug and Therapeutics Formulary Committee (DTFC). This committee would serve as an independent technical and scientific advisory body providing expert advice to CHPRE. It would be established under the RHPA to advise CHPRE on the inclusion or exclusion of new drugs and substances on the lists of authorized drugs and substances of a given health profession, and on terms, limitations and conditions that should be attached to drugs on a profession's Drug List.

The DTFC would receive referrals from CHPRE to recommend drugs or substances to be included in a new or existing therapeutic class in a health profession's drug regulation, or for other changes to drug regulations for a health profession. The DTFC would then complete an expert review of the specific drugs or therapeutic products it recommends for inclusion on the Drug List, and whether terms, limitations and conditions are required to restrict the use of a specific drug or agent.

When its review is complete, the DTFC would provide advice to CHPRE on:

- The clinical case and rationale for the inclusion of a drug or substance on the list of drugs and substances within a particular therapeutic class of drugs that are authorized for a health profession; and
- The required terms, limitations and conditions for specific drugs and substances recommended for the Drug List.

The DTFC may also provide advice to CHPRE on any other relevant matter, such as drug alerts and patient safety information, as requested by CHPRE or on its own initiative.

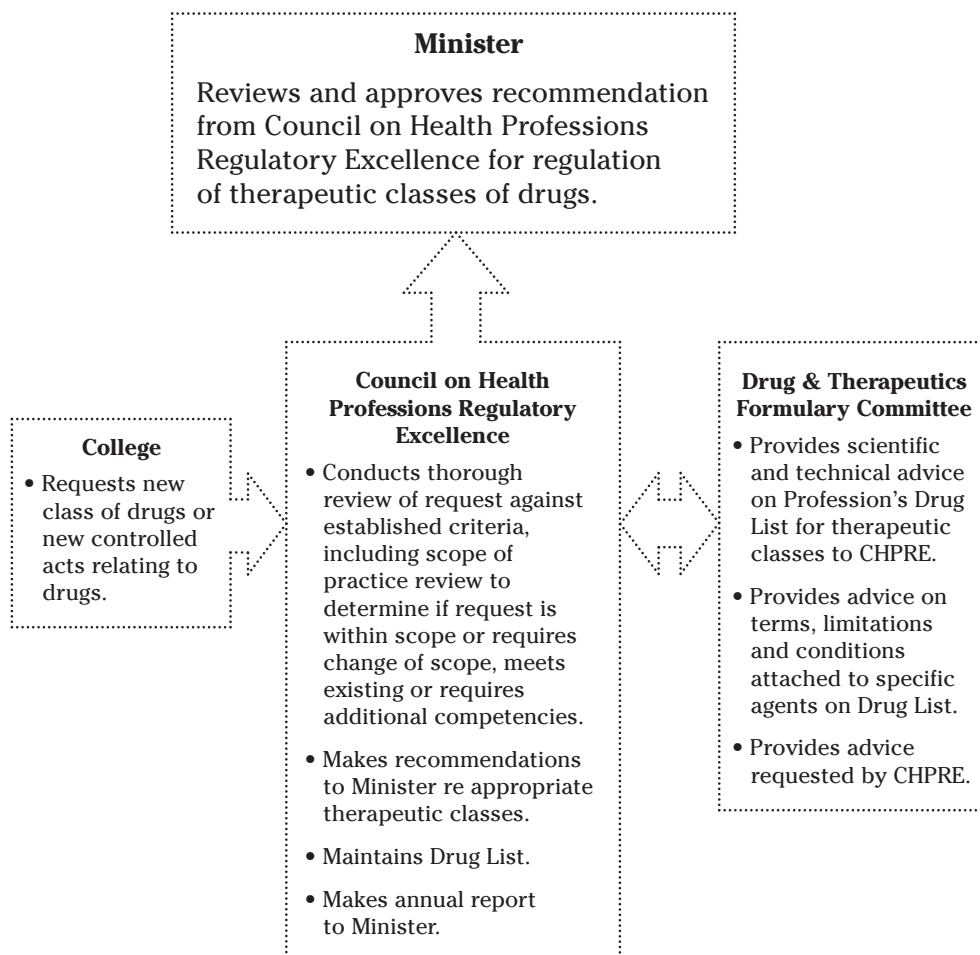
HPRAC anticipates the members of the DTFC would be appointed by the Lieutenant Governor in Council on the recommendation of CHPRE. HPRAC also recommends that the Chair of CHPRE be the chair of the DTFC. Members of the DTFC would be appointed to three to five year renewable terms. As a technical committee, its composition would include pharmacological expertise and leadership from the health professions. HPRAC reviewed the number and frequency of requests for new drug regulations in recent years, and expects the DTFC members to serve on a part-time basis. Meetings would be held at the call of the chair, as needed,

with monthly meetings likely. Infrastructure, including staff support, would be provided by CHPRE. To ensure success, appropriate appointments and succession planning for the DTFC would be critical. As this is a technical committee, its composition must include expert pharmacology representation.

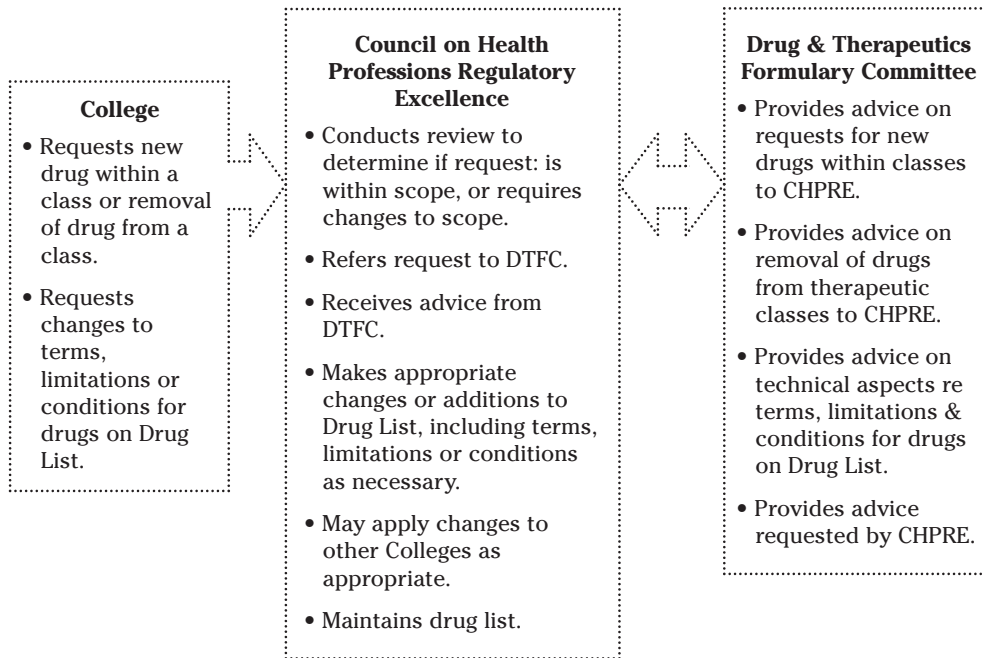
As the work of the DTFC matures, it may evolve to include other responsibilities, such as education for health professionals on prescribing authorities and drug safety.

Examples of the proposed drug approvals process

Request for New Therapeutic Drug Class in Regulation Made under the *Health Profession Act* or a New Controlled Act Relating to Drugs



Request for New Drugs within a Therapeutic Class or Changes to Terms, Limitations or Conditions for Drugs on Drug List



Additional Safeguards and an Enabling Regulatory Framework

HPRAC contends that Ontario's health professions regulatory framework, working within the *RHPA*, must evolve to meet the requirements of the 21st century. Building on the *RHPA*, HPRAC is recommending ways to make the regulatory framework more flexible and adaptable, while strengthening the accountability of colleges and their members.

As outlined in chapter two, the proposed approach allows for the evolution of professional practice over time, through standards of practice with legal force adopted by health colleges. This is balanced with an enhanced role for the colleges to more actively regulate the health profession in the public interest.

As such, additional safeguards are proposed for standards regarding authorities to prescribe, dispense, sell, compound or administer drugs or substances. Under the proposed system, health professionals will follow standards of practice established by their colleges. These standards of practice will often be developed through an interprofessional collaborative process, providing an additional safeguard to the system.

If HPRAC's scope of practice review recommendations are implemented, all health professions will require their members to identify and practice within their individual scope of practice. Essentially, members would not be allowed to practice in areas where they are not competent, even if this is within the profession's scope of practice. This rule would apply to new drug authorities. Going forward, individual health professionals will be required to recognize and set their own limits.

1. For many health professions, new professional misconduct regulations will be needed to account for the new drug authorities. In this review, HPRAC found inconsistencies between health professions in drafting styles and approaches. These will likely require updating to meet new standards. As a result, HPRAC's recommendations include proposals to standardize professional misconduct regulations respecting drug authorities, to improve consistency and clarity across all health professions.
2. In its review of interprofessional collaboration, HPRAC recommends that all health professions should be required to have mandatory professional liability insurance. Colleges will need to determine the appropriate levels of insurance given any new drug authorities that are approved.

Other Issues for Consideration

i. Is Oxygen a Drug?

In Ontario, oxygen suppliers generally require a prescription or license before selling oxygen to consumers. This is a prudent policy of the manufacturers, rather than an adherence to provincial and federal law. In Ontario, prescriptions are required for reimbursement from government programs such as the Home Oxygen Program or third party insurers.

Under the *Food, Drug, and Cosmetics Act* in the United States, oxygen is a prescription drug when it is used to improve breathing or is administered by another person. It can be used without a prescription for emergencies. The major hazards with respect to oxygen involve flammability, transport, and storage.

Because of the risks of transport and storage, and its use in emergency situations and conscious sedation, HPRAC considers oxygen to be a drug for the purposes of this review and includes it in the class of medical gases or emergency medications.

ii. Emergency Medication "Crash Carts"

A number of health professions have requested the authority to have emergency medication kits available to deal with unexpected in-clinic events of various types during the course of their practice.

The standard emergency medications are as follows:

- **Oxygen:** 100 percent for most medical emergencies (same concentration for both adults and children).
- **Epinephrine:** Used for anaphylactic shock, severe asthmatic attack not responsive to inhaled salbutamol, and cardiac arrest. Injected into the muscle (0.3-0.5 mg) or IV (0.1 mg).
- **Nitroglycerin:** Used to treat angina (chest pains). Administered under the tongue (sublingual) at 0.3 to 0.4 mg.
- **Diphenhydramine or chlorpheniramine:** Used for moderate to severe allergic reactions. Administered in the muscle or IV at 10-50 mg, or 1 mg/kg in children.
- **Salbutamol:** Bronchodilator for asthmatic bronchospasm. 2 puffs (100 micrograms/puff) or 1 puff for children.
- **ASA:** Administered if acute heart attack suspected. 160-325 mg in adults.

HPRAC considered the issue of the need for an emergency medications kit, or “crash cart” as it is generally described by health professionals. HPRAC heard during the consultations with colleges and other stakeholders that any health profession carrying out a procedure in-office should have the knowledge and necessary tools to handle an emergency situation.

HPRAC considers that the benefits of having access to an emergency kit outweigh the risks and is recommending that emergency medications be available to members of the professions of chiropractic and podiatry, midwifery and nurse practitioners.

The potential of a training program, based on the dentistry model, that could benefit all health professions, was discussed with HPRAC. Whether such an opportunity proceeds or not, colleges would have the responsibility of ensuring that all members who might need the emergency kit have the requisite training and members would have the responsibility of ensuring that staff or others who work with the members are fully conversant with emergency procedures and the maintenance of equipment and supplies.

iii. Dispensing

The *RHPA* includes “prescribing, *dispensing*, selling or compounding a drug” as one of the controlled acts.³⁶ None of these acts is defined in the *RHPA*.

A controlled act related to prescribing and dispensing is “communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis”.³⁷

³⁶ *Regulated Health Professions Act, 1991*, S.O. 1991, s. 27(2)8 [Emphasis added].

³⁷ *Ibid.*, c. 18, s.27(2).1.

Currently, dentists, physicians and pharmacists are the only health professions authorized to perform the controlled act of dispensing drugs. Dentists and physicians are authorized to perform the related controlled acts of communicating a diagnosis, prescribing drugs and dispensing drugs. Optometrists are able to communicate a diagnosis, prescribe drugs and dispense subnormal vision devices, contact lenses or eye glasses, but they may not dispense drugs. They may also use drugs for diagnostic purposes. Pharmacists are currently authorized to dispense drugs but cannot communicate a diagnosis or prescribe drugs.

As part of this review, chiroprodists and podiatrists, dental hygienists, nurses and naturopathic doctors requested the authority to dispense drugs. Each of these requests is considered in the profession-specific chapters of this report.

While there is no consistent definition of dispensing, statutes in other jurisdictions do contain some definitions, many of which are similar. They generally define dispensing as providing a drug pursuant to a prescription. Most of the definitions state that dispensing does not include the administration of a drug, which is a separate function.³⁸

In its request for the authority to dispense drugs, the College of Nurses of Ontario (CNO) has interpreted dispensing to mean providing medication to clients for self-administration. In other words, the CNO argues that a nurse should be authorized to take one or multiple doses from a medication stock (e.g., a ward stock), repackage the medication and give it to the patient or patient's representative for the patient to take at a later time. Although many principles are the same, the CNO does not consider dispensing to refer to a nurse taking one or multiple doses from a medication stock and immediately administering the medication to a patient or client.

Several colleges in Ontario have published their interpretation of dispensing. One interpretation comes from those professions that may currently dispense drugs. For example, the College of Physicians and Surgeons of Ontario (CPSO) recently collaborated with the Ontario College of Pharmacists (OCP) to create a draft policy for physicians who dispense drugs. The policy states that dispensing involves two elements.³⁹

The first element is the technical aspect of dispensing. This element includes:

- (a) Providing the correct amount of medication;
- (b) Selecting the appropriate container for the medication;
- (c) Accurately measuring liquids or diluents for reconstitution, and
- (d) Application of appropriate labelling.

³⁸ Northwest Territories' *Pharmacy Act*, Newfoundland's *Pharmacy Act*, Manitoba's *Pharmaceutical Act*, Alberta's *Government Organization Act*, Prince Edward Island's *Pharmacy Act*, Newfoundland's *Pharmacists, Pharmacy and Drug Scheduling Act*.

³⁹ The College of Physicians and Surgeons of Ontario, *Dispensing Drugs* (Draft policy); viewable at http://www.cpso.on.ca/uploadedFiles/DispensingDrugs_draft.pdf.

The second element is applying professional judgment. Professional judgment includes:

- (a) Determining the appropriateness of the medication therapy;
- (b) Consultation, if necessary, with other health professionals, and
- (c) Any communication or counselling provided to the patient or other health professionals.⁴⁰

It is important to note that the policy does not require a dispensing physician to follow a prescription.⁴¹ This requirement is unnecessary because a physician is authorized both to prescribe and dispense. *The Pharmacy Act, 1991* does not define dispensing, but the OCP published an interpretation of dispensing which is similar to the one published by the CPSO.⁴² Another interpretation has been put forward by professions that do not currently have the controlled act of dispensing. For example, the CNO recently published a practice standard that includes a definition of dispensing:⁴³

- (1) Adjusting the order according to an approved policy, if appropriate;
- (2) Selecting the drug to dispense;
- (3) Checking the expiry date;
- (4) Labelling the product, and
- (5) Completing a final check to ensure the accuracy of the finished product.⁴⁴

This description does not include the cognitive element of dispensing. However, a recent issue of *The Standard*, a magazine produced by the CNO, states that prior to dispensing a medication, a nurse must have a professional relationship with the client, consider the client's needs and best interests, and make certain that the client's condition warrants the medication. Nurses, based on knowledge and judgment about the medication, need to determine the appropriateness of the drug for the client. The inference in this passage is that the CNO acknowledges that dispensing involves a cognitive element.⁴⁵

The main difference between the two interpretations is that the latter presupposes that following a prescription is a necessary component of dispensing. Therefore, providing drugs will be considered dispensing only if the provider is authorized to prescribe or act pursuant to a prescription.

Based on these findings, HPRAC has concluded that dispensing as used in the *RHPA* should be interpreted, in the context of drugs, to mean:

⁴⁰ Ibid.

⁴¹ Ibid.

⁴² Ibid.

⁴³ Ibid.

⁴⁴ Ibid.

⁴⁵ College of Nurses of Ontario. "You Asked Us" *The Standard* 33:2 (Summer 2008): 34.

The provision of prescription drugs to a patient by a professional authorized by law to prescribe drugs or a professional acting pursuant to a prescription after the professional:

- (a) Records, selects, measures, reconstitutes, inspects, packages and labels the drug; and
- (b) Uses professional judgment to confirm the appropriateness of supplying the drug in the particular situation.

It is not intended to cover administration of a drug, as would be the case when a drug is used or administered in a clinical or office setting for diagnostic or therapeutic purposes. Dispensing implies that the patient takes the medication home to use at a later time, or has the drug available for use at a later time, such as in a long-term care home.

Safeguards for Dispensing

Health professions authorized to dispense drugs should develop, circulate and enforce standards of practice for dispensing drugs. The CPSO, for example, recently published a draft policy that includes “Dispensing Standards”.⁴⁶ This policy provides a starting point in developing a health profession’s standards.

The College of Physicians and Surgeons of Ontario draft policy on dispensing requires members to:

- “Dispense” drugs only to patients that the member has a professional relationship with;
- Use proper methods of procurement in order to be assured of the origin and chain of custody of drugs being dispensed;
- Store the drugs securely;
- Have an audit system in place in order to identify possible drug loss;
- Store drugs appropriately to prevent spoilage (for example, temperature control, where necessary);
- Keep records which allow for the retrieval and/or inspection of prescriptions;
- Not dispense drugs past their expiry date;
- Provide appropriate packaging, labelling and patient-related material for the drugs they dispense; and
- Dispose of drugs that are unfit to be dispensed (expired or damaged) safely and securely and in accordance with any environmental requirements.

⁴⁶ *Supra* note.

In addition to these standards, health professions authorized to dispense drugs should consider including additional requirements such as: reporting any loss or theft of drugs to the applicable authorities within a reasonable time; methods to properly destroy a drug; dispensing drugs in “child-resistant” packages; proper labelling and record-keeping.^{47,48}

Prescribing and Dispensing

Except for pharmacists, no health professions are currently authorized to dispense drugs without also being permitted to prescribe drugs. Pharmacists are currently authorized to dispense drugs only pursuant to a prescription from an authorized prescriber or pursuant to a proper delegation of authority to dispense.⁴⁹

HPRAC has concluded that this is an important safeguard, and that health professionals should only be authorized to dispense pursuant to a prescription that is their own or from another authorized prescriber, or if there is a delegation from an authorized prescriber.

Safeguards need to be in place to ensure that the person making the decisions to provide drugs to a patient is aware of the patient’s medical history and other medications he or she is taking. Otherwise, there are risks that the patient will be given drugs that are either not appropriate or have contraindications with other medication.

HPRAC concluded in its recent scope of practice reviews of several health professions that it is not always necessary for a health professional to make or communicate a diagnosis in order to prescribe a drug. Nonetheless, HPRAC holds that the *DPRA* definition of a prescription as “a direction from a prescriber directing the dispensing of any drug or mixture of drugs for a designated person” should not change.⁵⁰

Drug Samples

The *Food and Drugs Act* (Canada) prohibits manufacturers from providing drug samples unless the sample is provided to physicians, dentists, veterinary surgeons or pharmacists, and the drug is not a narcotic, a controlled drug or a drug that is not yet approved; and the drug is labelled in accordance with the regulations.

When a manufacturer distributes a sample of a drug, it must maintain records showing: the name, address and description of the sample recipient; the brand name, quantity and form of the sample distributed; and the date upon which the sample was provided.

⁴⁷ The College of Physicians and Surgeons of Ontario, “Regulations Concerning Benzodiazepines and Other Targeted Substances” Online: College of Physicians and Surgeons of Ontario; <http://cpso.on.ca/policies/policies/default.aspx?ID=1822>.

⁴⁸ College of Dental Surgeons of British Columbia, “Policy Statement: Prescribing and Dispensing Drugs”, January 2005.

⁴⁹ *Drug and Pharmacies Regulation Act*, R.S.O. 1990, c. H.4.

⁵⁰ *Ibid.*, s.1(1).

Despite the restrictions stated in the *Food and Drugs Act* and the *Regulations*, the regulation of health professionals remains a provincial responsibility, and if permitted in provincial regulation, health professionals are permitted to provide drug samples according to the applicable provincial legislation and regulations.

The CPSO and the OCP have interpretations and guidelines on dispensing drug samples.

The CPSO policies apply to all physicians and outline their obligations with respect to drug samples. They include:

- Medication samples (clinical evaluation packages) should only be distributed to patients in order to allow physicians to evaluate the clinical performance of the medication outside of the context of post-marketing surveillance studies, to initiate therapy, or for a similar purpose. Any departure from this must be justifiable in terms of principles of ethical medical practice (for example, where the normal means of obtaining drugs or other medical products would result in an excessive financial burden or other hardship to the patient).
- The distribution of samples should not involve any form of material gain for the physician or for the practice with which he or she is associated.
- Physicians must not participate in the trading, selling, or bartering of drug samples for cash or other goods. The use of drug samples is to be restricted to the purpose for which the samples were provided.
- Physicians who accept samples and similar devices are responsible for ensuring their age-related quality and security. They are also responsible for the proper disposal of unused samples. Physicians must document all samples provided to patients in the patient health record.⁵¹

In this review, HPRAC considered whether distributing drug samples falls within the scope of practice of those health professions who make samples available to patients and whether distributing samples constitutes dispensing, in which case it should only occur pursuant to a prescription. A number of health professions, nursing in particular, cited economic considerations as one reason for dispensing samples to patients.

HPRAC observes that the distribution of prescription drugs currently requires two separate acts. The drugs must be: (a) prescribed; and (b) dispensed. In some cases, both acts may be completed by one person. Physicians, for example, are authorized to prescribe and dispense drugs.

⁵¹ College of Physicians and Surgeons of Ontario, Policy #2-02; www.cpsso.on.ca/policies/policies/default.aspx?ID=1828.

Prescribing and dispensing are both controlled acts under the *RHPA*. They can only be performed by health professionals with the legislative authority or by those to whom they have delegated the acts.

HPRAC concluded that the provision of free drug samples should not be an exception to the general rule on dispensing prescription drugs. Samples should be dispensed under a prescription. This ensures that patients will receive drugs that are appropriate for their individual therapeutic needs, that the drugs respond to an assessment or diagnosis, and that the patient has been counselled on the use of the drug. Further, when drugs, including samples, are dispensed under a prescription, the patient has added assurance that the drugs have been inspected for quality, stored properly, and the date of expiry has not passed.

Since providing a drug sample to a patient constitutes dispensing, the same rules that apply to dispensing in general should apply to dispensing drug samples. For these reasons, health professionals should not be allowed to distribute free samples of drugs unless they are authorized to dispense drugs. Even with this authorization, professionals should only be authorized to provide drug samples under a prescription.

As well, professionals who are able to dispense samples of drugs should be held to the same minimum standards as physicians, and should set standards of practice for dispensing samples.

v. Drug Dispensing Machines

Drug dispensing machines are relatively new innovations in the drug distribution system in Ontario, and are being piloted in hospitals in the province. These machines are drug storage devices or cabinets that electronically dispense medications in a controlled fashion. The machines carry an inventory of branded and generic drugs in preset doses ready for dispensing.

The following is one example of the operation of a drug dispensing machine. Following a patient visit, a physician or other prescriber faxes a prescription to a pharmacist who makes an entry into a computer, and then sends an electronic message to the dispensing machine. The patient's profile is displayed on the machine to the pharmacist assistant at the machine's location. The assistant is provided with a password to access the machine, retrieves the pre-filled bottle, and affixes a label with relevant information and warnings that are specific to the patient. The patient may speak directly to a pharmacist through technology built into the machine or by direct personal contact.

In Ontario, several hospitals are investigating the use of drug dispensing machines. Sunnybrook Health Sciences Centre has two machines in use for outpatients and one for inpatients and it is evaluating the benefits of this automated dispensing system. Currently drug dispensing machines are in operation in physicians' offices, clinics, emergency rooms and other health facilities in the United States.

There are no specific regulations for drug dispensing machines in Ontario. It is likely that each vending machine would be considered to be a pharmacy under the *Drug and Pharmacies Regulation Act*.

In some jurisdictions, a certification of accreditation must be issued to operate the machine and the machine must be under the supervision of a pharmacist who is physically present. A drug can only be sold through a machine by a pharmacist, intern, registered pharmacy student, or pharmacy technician acting under the supervision of a pharmacist who is physically present. To test the technology, the California Board of Pharmacy issues a waiver from the requirement that pharmacists be physically present to dispense prescription drugs.

While drug dispensing machines are currently under evaluation in Ontario, HPRAC acknowledges that they might have a useful role to play in the future. This might be particularly true in more remote locations, where pharmacies are not located in a community, or in locations such as long-term care homes where the pharmacist is not always physically present, but can be contacted via video or teleconference. Hospitals might also find that the dispensing machines add to pharmacy efficiency, while enabling pharmacists to concentrate on their cognitive roles. Further examination is needed to determine the risks and any additional safeguards that may need to be put in place. Changes to the regulatory framework are required if drug dispensing machines are to be introduced in Ontario outside of the hospital setting.

Amendments to other Statutes and Regulations

If the Minister accepts HPRAC's recommendations and implements the legislative recommendations set out in chapter four of this report, then the Minister will also need to consider making ancillary amendments to several other Ontario statutes and regulations, to ensure a consistent legal framework governs the expansion of prescribing and dispensing authority to non-physician professions. The statutes and regulations that will need to be considered for amendment include: the *Charitable Institutions Act*, *Child and Family Services Act*, *Community Psychiatric Hospitals Act*, *Day Nurseries Act*, *Drug and Pharmacies Regulation Act*, *Drug Interchangeability and Dispensing Fee Act*, *Health Care Consent Act, 1996*, *Health Insurance Act*, *Health Protection and Promotion Act*, *Immunization of School Pupils Act*, *Independent Health Facilities Act*, *Long-Term Care Homes Act, 2007*, *Ontario Disability Support Program Act, 1997*, *Ontario Drug Benefit Act*, *Prepaid Hospital and Medical Services Act*, *Retail Sales Tax Act* and the *Public Hospitals Act*.

Conclusions

The overarching goal of a new drug approvals framework for Ontario is to ensure the following results:

- Improved timelines in the regulation-making and approval process;
- Thorough research, consultation and analysis to ensure that health professionals have the appropriate knowledge, skills and judgment to prescribe, dispense, sell, compound and administer drugs and substances;

- Transparency in the approvals process for patients, providers and health professionals;
- Complete documentation of patient health records, including medication records, and their availability to the patient and professionals who are involved in patient care;
- Safe prescribing and continuing competence to prescribe safely;
- Professional accountability;
- Timely access to care and treatment for patients; and
- Enhanced interprofessional collaboration.

Taken together, the introduction of a new CHPRE, along with the expertise of a new DTFC should lead to a significantly improved drug approvals process for health professions in Ontario, balancing the need for patient safety with the need to ensure patients have access to the most appropriate medications. These changes place patient-centred care, patient safety and protection at the forefront of our regulatory system, and will see Ontario continue in its role as a leader in regulatory excellence.

HPRAC regards a new drug approvals framework and process, along with its recommendations in chapter two for new structures, processes and standards to raise the bar on health professions' regulation in Ontario, as critical links to promote regulatory excellence and transform and support patient care. To that end, it proposes implementation steps in chapter four of this report.

CRITICAL LINKS: PROPOSALS FOR IMPLEMENTATION

In preparing its advice to the Minister of Health and Long-Term Care, HPRAC has found it of particular value to present not only the ideas and policy proposals that are the result of its examination of an issue, but also to include implementation proposals: what the laws might look like if the policy recommendations are adopted. Implementation proposals incorporate the recommendations that HPRAC is making to the Minister into draft statutory language. HPRAC uses this as an internal device as it develops its recommendations, and has incorporated this work into its reports to provide greater clarity to those who have an interest in the advice that is given to the Minister.

This approach has been received enthusiastically. People who are interested in the advancement of health professions legislation in Ontario have welcomed this opportunity to discover what their obligations might be, or what additional statutory protection they might have.

For legislators who review Bills as they move through the Ontario legislature, this first step is an important way to understand how public policy proposals might unfold when written into law. For regulators of health professions, this is an opportunity to identify strengths and flaws in laws they might be required to uphold and to provide sound advice to the government about where there might be conflicts with other statutory requirements, or additions that may strengthen public protection. For organizations involved in health care delivery, this provides a means to analyse actions that might be required, and the effect of legislative or regulatory change on day-to-day operations. For health professionals, this is a way to have a first look at new criteria that will shape the way they learn or provide care. For patients and clients or members of the public, this approach provides the benefit of knowing not only what public interest expectations are, but how they will potentially be met by obligations set out in the law.

In this report, HPRAC is recommending significant structural and process changes that will affect the way health colleges operate and the way patient care is supported and transformed. HPRAC has titled the report “Critical Links” to underline a new paradigm in regulatory reform, involving new systems, new obligations and new directions in the regulation of health professions in Ontario. The recommendations are based on support of self-regulation for the health professions, new options to advance interprofessional collaboration, a need for new ways to ensure rigour and accountability in the regulation of health professionals, along with the flexibility that will enable health colleges to protect the public interest.

Chapters two and three of this report speak to matters that HPRAC is convinced will make a significant difference to the way our health professions work together and are monitored and evaluated on their performance, to the efficiencies that need to be brought into processes in the health regulatory system, and to the way members of the public can be informed of work of the institutions who are there to protect them.

This chapter provides an overview of what Ontario's laws might look like if HPRAC's recommendations are adopted to create a new Council on Health Professions Regulatory Excellence (CHPRE), along with a new drug approvals framework and process for health professions.

To implement HPRAC's recommendations in these areas, the following changes to statutes and regulations are proposed:

Establishment of a New Agency to Facilitate and Support Interprofessional Collaboration and Best Practices at the Regulatory Level and to Establish a New Drug Approvals Framework

1. That the definition of "Advisory Council" in section 1(1) of the *Regulated Health Professions Act, 1991* be repealed and the following substituted:

"Agency" means Council for Health Professions Regulatory Excellence;

2. That all references to "Advisory Council" in the *Regulated Health Professions Act, 1991* be replaced with references to "Agency".

That section 1(1) of the *Regulated Health Professions Act, 1991* be amended by adding the following definitions:

"drug" means a drug as defined in the *Drug and Pharmacies Regulation Act* and includes prescription therapeutic products as defined in the *Food and Drugs Act* or the regulations made thereunder;

"Drug List" means, for each health profession that has the authority to perform the controlled act of administering a substance by injection or inhalation, or prescribing, compounding, dispensing or selling drugs during the course of practice of the profession, other than medicine or dentistry, the list of individual drugs that are designated by the Agency as falling within a class of drugs authorized to the health profession by the regulations made under the health profession Act;

"Formulary Committee" means the Drug and Therapeutics Formulary Committee.

3. That section 6 of the *Regulated Health Professions Act, 1991* be repealed and the following substituted:

Annual report

- 6.(1) Each College shall report annually to the Minister on its activities and financial affairs.

Audited financial statement

- (2) Each College's annual report shall include an audited financial statement.

Content and form

- (3) The Minister may specify the content and form of the annual report submitted by the College and, where the Minister has done so, the annual report shall contain that content and be in that form.

Minister may publish information

- (4) The Minister may, in every year, publish information from the annual reports of the Colleges.

No personal information

- (5) Information from the annual reports published by the Minister shall not include any personal information.

4. That sections 7 through 17 of the *Regulated Health Professions Act, 1991* be repealed and replaced with the following:

Agency**Agency**

The Agency is established under the name Council for Health Professions Regulatory Excellence in English and Conseil de l'excellence de la réglementation des professions de la santé in French.

Composition

The Agency shall be composed of at least five and no more than nine persons who shall be appointed by the Lieutenant Governor in Council on the Minister's recommendation.

Chair and vice-chair

The Lieutenant Governor in Council shall designate one member of the Agency to be the chair and one to be the vice-chair.

Qualification of members

A person may not be appointed as a member of the Agency if the person,

- (a) is employed under Part III of the *Public Service of Ontario Act, 2006* or by a Crown agency as defined in the *Crown Agency Act*; or
- (b) is or has been a member of a Council or College

(c) Terms of members

The chair and vice-chair shall be appointed for a fixed period not to exceed ten years and the other members for a fixed period not to exceed three years. Members of the Agency are eligible for reappointment. Upon expiry of their term, members of the Agency shall remain in office until reappointed or replaced.

Replacement members

A person appointed to replace a member of the Agency before the member's term expires shall hold office for the remainder of the term.

Initial members

Other than the chair and vice-chair, the initial members of the Agency may be appointed for terms of one, two or three years.

Remuneration and expenses

The members of the Agency shall be paid the remuneration and expenses the Lieutenant Governor in Council determines.

General Functions of Agency

The general functions of the Agency are:

- to see that each College serves and protects the public interest;
- to promote good professional self-regulation and best practices by the Colleges; and
- to promote collaboration between and among Colleges and others.

Powers and Duties of Agency

The Agency shall have the following powers and duties:

- to advise the Minister on,
 - whether unregulated professions should be regulated;
 - whether regulated professions should no longer be regulated;
 - suggested amendments to this Act, a health profession Act or a regulation under any of those Acts and suggested regulations under any of those Acts;
 - the recommended scope of practice of regulated professions;
 - the need for collaboration among the Colleges;
 - any conflicts between and among the Colleges and others;
 - any College that does not fulfill its objects and duties;
 - suggested amendments to any provincial act or regulation affecting health care or health care delivery;
- to promote best practices by Colleges in their:
 - registration, complaints, investigations, discipline, fitness to practice, quality assurance, patient relations, enforcement, record-keeping and reporting functions; and
 - development of regulations, standards of practice and professional practice guidelines for their members;

- to monitor each College's efforts in serving and protecting the public interest and in achieving its objects;
- to inform the public on matters relating to health profession regulation and the public's rights and recourses associated with health profession regulation;
- to establish criteria, rules and procedures that must be followed for the designation of a drug on the Drug List, and to publish those criteria, rules and procedures on its website and in any other format it considers advisable;
- to designate drugs on the Drug List for a regulated health profession, with any terms, limitations and conditions associated with those drugs, and to remove or modify those designations or terms, limitations or conditions from time to time;
- to keep, maintain and publish the Drug List; and
- to bring to the Minister's attention any other matter that requires government action.

Requirement to provide information

For the purposes of fulfilling its general functions and duties under this Act, the Agency may require a Council to provide information other than personal information to the Agency either in response to a specific request, or at regular intervals.

Time and form

The Agency may specify the time at which and the form in which the information must be provided.

Compliance required

The Council shall comply with every requirement to provide information under this section.

Drug List

The Agency shall keep, maintain and publish a Drug List.

The Drug List shall set out,

- (a) the individual list of drugs that a health profession is authorized to administer by injection or inhalation, prescribe, compound, dispense or sell within the class of drugs authorized to the health profession under the regulations made under its health profession Act;
- (b) the terms, limitations and conditions associated with those drugs for the health profession; and
- (c) any other information or material the Agency considers necessary or advisable.

The Agency shall publish the Drug List on its website.

A drug becomes authorized to a health profession on the effective date of its being designated in the Drug List for that health profession, and ceases to be authorized to a health profession on the effective date of that designation being removed.

The Agency may designate a drug in the Drug List where the Agency considers it to be in the public interest to do so, but shall not do so if its criteria for approval have not been met.

Any modification of a designation takes place on the effective date of its being designated in the Drug List as a modification.

A drug or substance that was authorized to a health profession by regulation made under its health profession Act immediately before •, 2009 is deemed to be designated on the Drug List until it is removed from the Drug List under this section. The terms, limitations and conditions contained in the regulation made under the health profession Act continue to apply until modified under this section.

In deciding whether or not to designate a drug on the Drug List, to remove a drug from the Drug List, or to impose, amend or remove any terms, limitations or conditions associated with a drug, the Agency may consider anything it considers advisable in the public interest, including, without limiting the generality of the foregoing, the education, training, competence or standards of practice of the health profession, the needs of the public, or matters concerning patient safety.

The Agency shall obtain expert advice from the Formulary Committee and may consult with other persons or organizations on matters of concern arising out of the maintenance of the Drug List.

The Agency must accept the recommendations of the Formulary Committee unless doing so is not advisable in the public interest.

A person or organization may request, in writing, that the Agency amend the Drug List but the Agency is not obligated to act on the request.

At least 60 days before the Agency makes an amendment to the Drug List, the Agency shall submit a copy of the proposed amendment to the Minister, to the members of the Formulary Committee and to the affected Council for review.

The Agency shall be entitled to circulate a copy of the proposed amendment to other College Councils, health professionals and expert advisors.

If there is no written objection to a proposed amendment to the Drug List by the Minister within 60 days after it is submitted by the Agency, the Agency shall amend the Drug List in accordance with the proposed amendment.

The Minister shall only object to a proposed amendment to the Drug List if the proposed amendment is not advisable in the public interest.

The Drug List for each health profession established under this section shall be interpreted as if it formed part of a regulation made under the applicable health profession Act.

The *Statutory Powers Procedure Act* does not apply to any decision or action of the Agency under this Act.

The Lieutenant Governor in Council may make regulations,

- (a) clarifying, modifying or restricting the functions and powers of the Agency concerning the Drug List; and
- (b) providing for additional functions and powers of the Agency concerning the Drug List.

Function is advisory only

Except for the maintenance of the Drug List, the function of the Agency is advisory only.

Procedure

The Agency shall sit in Ontario where and when the chair designates.

Idem

The Agency shall conduct its proceedings in the manner it considers appropriate.

Employees

Such employees as are considered necessary for the proper conduct of the affairs of the Agency may be appointed under Part III of the *Public Service of Ontario Act, 2006*.

Experts

The Agency may engage experts or professional advisors to assist it.

Secretary

The Agency shall appoint one of its employees as the Secretary.

Duties

The Secretary's duties are,

- (a) to have the custody and care of the records and documents of the Agency; and

- (b) to carry out the functions and duties assigned by the Minister or the Agency.

Reports

The Agency shall report annually to the Minister, and the Minister shall submit the report to the Lieutenant Governor in Council and shall then lay the report before the Assembly if it is in session or, if not, at the next session.

Same

The annual report shall include,

- (a) a report on the work of the Agency;
- (b) any information that the Agency considers appropriate concerning the activities of the Colleges in protecting the public interest; and
- (c) any information requested by the Minister.

Same

The first report under subsection • shall be submitted in the first half of 2011 and shall cover the period beginning on the day this Act receives Royal Assent and ending on December 31st, 2010.

Special reports

The Agency may make a special report to the Minister at any time on any matter related to this Act that, in the opinion of the Agency should not be deferred until the annual report, and the Minister shall submit the report to the Lieutenant Governor in Council and shall then lay the report before the Assembly as soon as reasonably possible.

No personal information

The annual reports and special reports made by the Agency shall not include any personal information.

5. That the *Regulated Health Professions Act, 1991* be amended by adding the following after section 17:

Drug and Therapeutics Formulary Committee

Formulary Committee

The Formulary Committee is established under the name Drug and Therapeutics Formulary Committee in English and Comité du formulaire des médicaments et des thérapeutiques in French.

Composition

The Formulary Committee shall be composed of such number of members as may be appointed by the Lieutenant Governor in Council and shall consist of:

- (a) the Chair of the Agency, ex officio;
- (b) equal representation from the College of Physicians and Surgeons of Ontario, and the Ontario College of Pharmacists;
- (c) an expert in pharmacology or pharmacotherapy who may be an educator,
- (d) one member of a College that is not already represented under subsection (b);
- (e) a representative of the Ontario Drug Benefits Program of the Ontario Ministry of Health and Long-Term Care.

The Lieutenant Governor in Council shall appoint the representatives listed in subsections (b) (c) (d) and (e) on the Agency's recommendation.

Chair

The Chair of the Agency shall serve as the chair of the Formulary Committee.

Terms of members

The members listed in subsections (b) (c) and (d) shall be appointed for a fixed period not to exceed three years. Members of the Formulary Committee are eligible for reappointment. Upon expiry of their term, members of the Formulary Committee shall remain in office until reappointed or replaced.

Replacement members

A person appointed to replace a member of the Formulary Committee before the member's term expires shall hold office for the remainder of the term.

Initial members

The initial members of the Formulary Committee listed in subsections (b) (c) and (d) may be appointed for terms of one, two or three years.

Independence

The members of the Formulary Committee listed in subsection (b) and (d) shall perform their functions in an independent manner, and not as representatives of their employers, their Council or their College.

Lobbying

A member of the Formulary Committee shall not, with respect to any matter related to this Act,

- (a) act as a consultant lobbyist within the meaning of subsection 4 (10) of the *Lobbyist Registration Act, 1998*; or
- (b) act as an in-house lobbyist within the meaning of subsection 5 (7) or 6 (5) of the *Lobbyist Registration Act, 1998*.

Remuneration and expenses

The members of the Formulary Committee shall be paid the remuneration and expenses the Lieutenant Governor in Council determines.

Functions of the Formulary Committee

The Formulary Committee shall:

- (a) compile and recommend to the Agency a Drug List for each health profession, other than medicine and dentistry, that the Committee is satisfied the health profession may be competent to administer by injection or inhalation, prescribe, compound, dispense or sell if the Agency confirms their qualifications and they fall within a class of drugs authorized to the health profession under the regulations made under their health profession Act;
- (b) provide expert advice to the Agency on the terms, limitations and conditions that should be imposed on the Drug List authorized for each health profession; and
- (c) provide expert advice to the Agency as requested by the Agency.

Meetings

The Formulary Committee shall meet at least once a year and as requested by the Agency.

Idem

The Formulary Committee shall conduct its proceedings in the manner it considers appropriate.

Other Advisors

The Formulary Committee may, from time to time, seek the advice of other regulated health professionals when the Formulary Committee deems such advice is required.

Provision of Advice

The Formulary Committee shall send a copy of its recommendations to the Minister at the same time it sends its recommendations to the Agency

Best Practices

6. That the Agency facilitate and support the development of a common Code of Ethics by all of the Colleges that is applicable to all regulated health professionals. That, once developed, section 94(1)(k) of the Health Professions Procedural Code be repealed and the common Code of Ethics be passed as a regulation made under the *Regulated Health Professions Act, 1991*.
7. That the Agency facilitate and support the development of common conflict of interest rules by all of the Colleges that are applicable to all regulated health professionals. That, once developed, section 95(1)(i) of the Health Professions Procedural Code be repealed and the common conflict of interest rules be passed as a regulation made under the *Regulated Health Professions Act, 1991*.
8. That the Agency facilitate and support the development of common advertising rules by all of the Colleges that are applicable to all regulated health professionals. That, once developed, section 95(1)(l) of Schedule 2, Health Professions Procedural Code be repealed and the common advertising rules be passed as a regulation made under the *Regulated Health Professions Act, 1991*.

Standards of Practice

9. That section 95(1)(n) of Schedule 2, Health Professions Procedural Code be repealed and the following substituted:

95(1) Subject to the approval of the Lieutenant Governor in Council and with prior review of the Minister, the Council may make regulations prohibiting members from acting beyond the scope of practice of the profession in the course of practicing the profession.

That sections 95(1.4), (1.5), (1.6) and (1.7) be moved to follow section 95(1).

10. That sections 95(1.1) through (1.3) be repealed and the following substituted:

- 1) The Council may establish standards of practice of the profession relating to required education, training, continuing competency, mandatory discussion, consultation and transfer of care, and standards, limitations and conditions relating to the performance of an act authorized to the profession.

- 2) Without limiting the generality of subsection (1.1), a standard of practice may be limited in its application to specified classes of members or certificates.
- 3) At least 60 days before a standard of practice is established by the Council under subsection (1.1), the Council shall submit a copy of the proposed standard of practice to the Minister, to the Agency and to every member for review
- 4) The Agency shall be entitled to circulate a copy of the proposed standard of practice to other Colleges, health professionals and expert advisors.
- 5) If there is no written objection to a standard of practice by the Minister or by the Agency within 60 days after it is submitted by the Council, the standard is deemed to be established by the Council.
- 6) The Council shall send a copy of each standard of practice made under subsection (1.1) to each member, the Agency and the Ministry.
- 7) The Council shall publish all established standards of practice on the Internet at a publicly accessible and freely available website and shall make them available as a document or in any other format, on request and at cost, to members of the public.
- 8) The standards of practice of a profession established under this section shall be interpreted as if they formed part of a regulation made under the applicable health profession Act.
- 9) Without limiting the generality of subsection (1.1), the Council's power to establish standards of practice may be exercised by adopting by reference, in whole or in part and with such changes as the Council considers necessary, any code, standard or guideline relating to standards of practice of the profession and require compliance with the code, standard or guideline as adopted.
- 10) If a standard of practice so provides, a scientific, administrative or technical document adopted by reference shall be a reference to it, as amended from time to time, and whether the amendment was made before or after the standard of practice was established.
- 11) A document adopted under subsection 1.10 must be a document created by a recognized body and must not be a document created by the College.
- 12) A copy of every code, standard or guideline adopted by reference under subsection 1.9 and every scientific, administrative or technical document adopted by reference under subsection 1.10 shall be available for public inspection during normal business hours in the office of the College and shall be posted on the College's website or be available through a hyperlink at the College's website.

- 13) The Minister may, on written notice, require that the Council establish, amend or revoke a standard of practice that the Council has the authority to make, amend or revoke, as described in subsection (1.1).
 - 14) If the Council does not establish, amend or revoke the standard of practice as required by the Minister within 30 days after receiving notice from the Minister, the Minister may establish a standard of practice that carries out the intent of the Minister's requirement.
11. That as the Agency conducts scope of practice reviews or otherwise participates in conflict resolution between and among Colleges, that the Agency identifies to the Minister other instances when it would be appropriate for the regulations under one or more health profession acts to be amended to require interprofessional standards committees to be established and mandated to develop enforceable standards of practice on an interprofessional basis.

Professional Liability Protection

12. That all regulated health professionals be required to have and maintain professional liability insurance, or belong to a specified association that provides protection against professional liability, or be covered by their employers' insurance policies. That all regulated health professionals be required to give proof of the insurance or membership to the Registrar upon their registration or otherwise when requested by the Registrar. That this requirement be effected by an amendment to the Registration provisions under the Health Professions Procedural Code as follows:

That section 22.4 of Schedule 2, Health Professions Procedural Code be amended by adding the following subsection:

Each application for registration must be accompanied by evidence of professional liability insurance, or membership in a specified association that provides protection against professional liability, or an employer's insurance coverage of the applicant. Each registrant shall provide the Registrar with evidence of the maintenance of such coverage following registration and when requested by the Registrar from time to time. Such coverage shall satisfy the requirements specified in the standards of practice developed by the College.

That once this is effected, section 94(1)(y) of the Health Professions Procedural Code be repealed.

Addressing Transparency, Accountability and the Public Interest

13. That the Minister make a regulation under section 43(1)(h.2) of the *Regulated Health Professions Act, 1991* requiring each College to publish on its website on the Internet, without password protection, as contemplated under section 3.1(1) of the Health Professions Procedural Code, general information including, but not limited to:

- a. its role, responsibilities and accountabilities;
- b. its functions, programs and processes;
- c. the scope of practice of the health profession(s) it governs;
- d. the use of titles by its members;
- e. what constitutes professional misconduct for its members;
- f. how to access the public portion of the register;
- g. its audited financial statements;
- h. general and statistical information on its registration reviews and hearings, complaints reviews and hearings, discipline hearings, fitness to practise assessments, quality assurance assessments; and
- i. other information that the Minister specifies.

REVIEW OF THE SCOPE OF PRACTICE OF MEDICAL LABORATORY TECHNOLOGY

Introduction and Scope of HPRAC's Review

The College of Medical Laboratory Technologists of Ontario (CMLTO), the Ontario Society of Medical Technologists (OSMT) and the Canadian Society for Medical Laboratory Science (CSMLS) submitted a joint response to HPRAC's questionnaire on the review of the scope of practice of medical laboratory technology.¹ HPRAC carefully considered this submission, as well as input from extensive research and consultation, in developing its recommendations.

The joint submission was divided into two parts. Part A requested changes to the scope of practice of medical laboratory technology and was supported by all three proponents. Part B was a request to regulate medical laboratory assistants/technicians (MLA/Ts). Part B request was not supported by the OSMT.

While medical laboratory technologists (MLTs) are regulated health professionals with the knowledge, skill and judgment to perform laboratory analyses that provide critical information to physicians and other health professionals, MLA/Ts are individuals who perform, under direct supervision, laboratory functions that require limited technical skill and responsibilities.² MLTs are educated at the post-secondary level and must pass a national certification exam. The minimum educational requirement for MLA/Ts is completion of high school. This is supplemented by vocational and/or on-the-job training. The OSMT has, for the last 20 years, offered a certification exam for MLA/Ts who have completed a recognized training regime.

HPRAC reviewed the rationale for the request to regulate MLA/Ts, held meetings with key stakeholders and conducted preliminary research on the issues raised in the submission. HPRAC determined, however, that the analysis of whether to regulate a new profession is much different than the consideration of whether to alter the scope of practice of an already regulated profession. In October 2008, HPRAC notified the proponents and the Minister of Health and Long-Term Care of its decision to defer consideration of the regulation of MLA/Ts and suggested that it would review this matter in the context of a separate request for advice by the Minister. The research, consultations and recommendations referred to in this report relate solely to the review of the scope of practice of MLTs.

¹ College of Medical Laboratory Technologists of Ontario, Ontario Society of Medical Technologists, Canadian Society for Medical Laboratory Science. *Submission to Health Professions Regulatory Advisory Council Regarding Medical Laboratory Technologists' Scope of Practice, Regulation of Medical Laboratory Assistants/Technicians*. June 30, 2008.

² Ontario Ministry of Health and Long-Term Care. *Laboratory Technicians*. June 1996. Available at: www.cmlto.com/public/technician_assistant/pdf/mohltc_mlat_duties.pdf.

Proposed Scope of Practice for MLTs

Part A of the proponents' joint submission to HPRAC sought changes to the scope of practice statement and controlled acts set out in the *Medical Laboratory Technology Act, 1991 (MLTA)*,^{3,4} as well as consequential amendments to other legislation to reflect those proposed changes.

1. Controlled Acts

The proposed controlled acts are:

- Taking blood samples from arteries,
- Administering a substance by injection for the purpose of performing vaccinations and diagnostic interventions such as allergy testing,
- Putting an instrument, hand or finger:
 - Beyond the urethra (catheterization)
 - Beyond the labia majora (Papanicolaou (Pap) tests).

In addition, the proposal requests that MLTs be authorized to perform a controlled act on their own initiation or on the order of another MLT.

2. Scope of Practice Statement

Although no specific wording is provided, the proposal requests that a new scope of practice statement be developed to reflect the above requested authorities.

3. Amendments to related legislation

- That Ontario Regulations 682⁵ and 683⁶ made under the *Laboratory and Specimen Collection Centre Licensing Act (LSCCLA)*⁷ and Ontario Regulation 257/08 (the Hospital Management Regulation) made under the *Public Hospitals Act, 1990 (PHA)*⁸ be amended to add MLTs to the list of individuals authorized to order laboratory investigations.
- That Ontario Regulations 682 and 683 under the *LSCCLA*⁹ be amended to require that all MLTs employed in licensed laboratories or specimen collection centres be members of the CMLTO.

³ R.S.O. 1991, c.28.

⁴ Ibid.

⁵ *Laboratories*, R.R.O. 1990.

⁶ *Specimen Collection Centres*, R.R.O. 1990.

⁷ R.S.O. 1990, c.L.1.

⁸ R.S.O. 1990, c.P.40.

⁹ R.S.O. 1991, c.28.

HPRAC's Central Response

MLTs play a crucial role in the delivery of health care. They support diagnosis, monitor treatment and play a significant role in public health. The technical and scientific expertise of MLTs is critical to meeting the growing and increasingly complex needs of Ontarians. The profession is in a position to exemplify the benefits of interprofessional collaboration: the use of the right professional at the right time to produce optimal patient outcomes. MLTs practise in Ontario's respected laboratory services system, which is highly regulated by legislation and regulations and subject to rigorous licensing, accreditation and quality control. There are significant opportunities to maximize the use of MLTs in the delivery of quality care by addressing many systemic barriers identified in the course of this review. HPRAC is not recommending changes to the scope of practice of MLTs, neither as a solution to these barriers nor as a part of the broader evolution of the delivery of health care.

Background on Medical Laboratory Technology in Ontario

The Profession

Medical laboratory technologists are health professionals who perform laboratory analyses and provide information to physicians and other health professionals to diagnose and treat patients, as well as to monitor and prevent disease.¹⁰ They perform diagnostic analytic tests on human body fluids, blood and tissues. Most technologists work in clinical laboratories at hospitals, community laboratories, public health laboratories or physicians' offices, in medical research or in the biotechnology industry. MLTs do not provide direct patient care.

Each of the three proponents has a distinct interest in medical laboratory science.

- The CMLTO is the registering and regulatory body for MLTs in the province. In 2007, there were 7,533 MLTs registered with the CMLTO, with just over 7,000 in active practice.¹¹
- The OSMT is the professional association representing both MLTs and MLA/Ts in Ontario. OSMT advocates for the common interests of its membership. OSMT also approves MLA/T training programs and has been certifying MLA/Ts in Ontario for two decades.
- The CSMLS is the national certifying body for MLTs and MLA/Ts in Canada. The national MLT certification exam is administered by CSMLS. Writing and passing the CSMLS certification exam is a

¹⁰ The Michener Institute for Applied Health Sciences. Medical Laboratory Science Advanced Diploma Program. "What does a Medical Laboratory Scientist do?" Available at: www.michener.ca/ft/medlab.php#whatdo.

¹¹ CMLTO, OSMT, CSMLS. *Submission to HPRAC Regarding Medical Laboratory Technologists' Scope of Practice, Regulation of Medical Laboratory Assistants/Technicians*. June 30, 2008: 2.

registration requirement in those provinces where MLTs are regulated. Even in those provinces where MLTs are not a regulated profession, employers require CSMLS certification.

- CSMLS is also a voluntary professional society for medical laboratory professionals. CSMLS represents 14,000 members in Canada and around the world. Membership is voluntary, except for MLTs in New Brunswick whose regulatory body, the New Brunswick Society of Medical Laboratory Technologists, requires CSMLS membership as a condition of licensure. Some employers require CSMLS membership as a condition of employment.¹²

Medical laboratory technology is a highly complex and technical profession. There are a number of specialties within medical laboratory science:¹³

- **Biochemistry** is the study of the chemical and physiochemical processes of living organisms. MLTs perform biochemical analyses including those to determine cholesterol and thyroid levels, enzyme levels for heart disease and glucose levels for the diagnosis and management of diabetes.
- **Cytogenetics** is the study of chromosomes and the diseases associated with an abnormal number or structure of chromosomes. Technologists in this discipline analyse prenatal samples, cancer cells, blood and tissues for genetic disease.
- **Cytology** is the study of the origin, formation, structure, function and classification of cells. The identification of normal and cancerous cells also falls within this discipline. Cytotechnologists are responsible for specimen preparation and staining, as well as microscopic evaluation and interpretation of patient samples. One of the roles of the cytotechnologist is to identify cancer of the cervix through the microscopic examination of Pap test smears. Cytology results are used in diagnosis, patient management and treatment follow-up.
- **Haematology** deals with blood, blood forming tissues and related cellular components. This analysis can identify cells associated with a wide variety of blood disorders such as leukemia and anaemia. Investigation and management of bleeding or coagulation disorders, such as haemophilia, are also performed as part of this specialty.
- **Histology** deals with the microscopic identification of cells and tissues. Technologists working in histology are responsible for the preparation and staining of tissues for diagnostic examination under the light microscope. Working with tissue biopsies and larger specimens from operating rooms, often on an urgent basis, MLTs help surgeons decide how to proceed with the patient undergoing surgery.

¹² CSMLS. Frequently Asked Questions." Available at: <http://www.csmls.org/english/faq.cfm>.

¹³ CMLTO. "Specialties in Medical Laboratory Science." Available at: <http://www.cmlto.com:80/public/mlts/default.asp?load=specialties>.

- **Microbiology** is the study of bacteria, fungi, viruses and parasites that invade the body. An MLT authorized to practise in microbiology may work in one, or a combination of, the following subspecialties:
 - Bacteriology deals with the identification of bacteria that cause disease in the human body. Technologists in this discipline also test the effectiveness of various antibiotics. MLTs specializing in bacteriology may also deal with public health issues (e.g., water quality testing) or disease control (e.g., diagnose hospital-acquired infection or communicable disease).
 - Mycology is the study and identification of fungi and fungoid diseases such as ringworm and thrush.
 - Parasitology is the examination and identification of parasites found on or in the human body. These include some of the most common parasites such as pinworm, roundworm and tapeworm.
 - Virology is the science devoted to the study of viruses and viral diseases. Technologists in this subspecialty have gained greater recognition since the increased awareness of the prevalence of AIDS and HIV. They focus on the identification and management of viral diseases.
- **Molecular Genetics** is the examination of DNA and RNA to find changes in genes. Abnormal or changed genes are, in many cases, associated with specific conditions or diseases such as breast cancer and hemophilia. Molecular techniques can be used to identify the stages of cancer and various genetic diseases.
- **Phlebotomy** is the taking of blood from a vein, and part of the controlled act of performing a procedure on tissue below the dermis. This procedure obtains the blood specimens needed to perform many of the laboratory tests ordered by physicians and other authorized professionals.
- **Transfusion Science** (Immunohaematology) studies antigens and antibodies associated with blood transfusions and certain complications of pregnancy. The technologist in this specialty may assess the blood to be used in surgery for accident victims or provide an analysis of various specialized blood products such as plasma for haemophiliacs or platelets for patients with leukemia. The technologist practising in this area must have an understanding of immunology, serology and genetics. In larger centres, transfusion science technologists may perform tests associated with tissue and organ transplantation.

Where MLTs Practise and with Whom

Laboratory services are provided in hospital laboratories, community laboratories, specimen collection centres, public health laboratories, Canadian Blood Services clinics and physicians' offices. The latter three are

exempt from the licensing requirements of the *LSCCLA* but voluntarily adhere to the accreditation and external quality assessment program that will be described below.

Laboratory personnel include MLTs registered with the CMLTO, medical pathologists, and senior clinical scientists who have completed extensive postgraduate education and training in selected subdisciplines of laboratory medicine. Not all laboratory personnel who perform functions in the laboratory are members of the CMLTO. MLA/Ts are employed in laboratories and are not registered members of the CMLTO. Similarly, many senior scientists are also not regulated by the CMLTO but may have earned doctoral degrees in basic or life sciences as well as fellowships with national professional bodies.¹⁴ While these individuals perform critical functions including administration, validation and interpretation of tests, they do not do so using the title MLT, and are therefore not in contravention of the *MLTA*. As the functions they perform are not controlled acts, they are similarly not in contravention of the *RHPA*.

It was suggested that a shortage of MLTs is looming in the face of ever increasing demand for laboratory services. In its presentation to HPRAC, the CMLTO provided evidence that unemployment among MLTs is very low at only two percent and that the vast majority (85 percent) is employed full-time. MLT is the slowest growing health profession and it is projected that by 2015, fifty percent of the profession will be over the age of 55¹⁵

It was clear from the evidence provided that the delivery of laboratory services depends on functional, collaborative relationships among individuals with varying levels and types of expertise. The licensing and accreditation processes require that the credentials and qualifications of individuals employed in laboratories and specimen collection centres meet stringent requirements so as to ensure quality and safety.

The Laboratory Investigation Process

An important step that HPRAC took in reviewing the proponents' submission was to understand as clearly as possible the intricacies of the laboratory system and the complex laboratory investigation process.

There are three phases to the laboratory investigation cycle. The first phase, the pre-analytical phase, starts when an order for a test is made; that is, when it is determined that an investigation is required for preventive, diagnostic or treatment purposes. This phase includes selecting the appropriate test, filling out a requisition, instructing and educating the patient, registering the patient, obtaining and labeling the specimen, transporting the specimen, preparing the slides and loading the specimen onto the laboratory equipment. This phase takes place in numerous settings including hospitals, community laboratories, and physicians' offices. Various health professionals including physicians and nurses as well as unregulated staff such as MLA/Ts, are involved in this phase. The role of

¹⁴ Ontario Society of Clinical Chemists. Letter to HPRAC dated August 5, 2008. Available at: www.hprac.org/en/projects/Medical_Laboratory_Technology_Scope_of_Practice.asp.

¹⁵ CMLTO. *Presentation to HPRAC: Scope of Practice Review*. September 17, 2008.

MLTs in this phase varies depending on the laboratory, but for the most part, they are not significantly involved. HPRAC learned that MLTs in rural or remote settings have a greater role in the pre-analytical phase than MLTs in urban communities or large hospitals, for example.

The second phase is the analytical phase. It encompasses the assessment and investigation of the specimen by MLTs. This involves determining the suitability of the specimen, observing the specimen, and identifying findings that would indicate the presence or absence of a disease or condition requiring further attention. An MLT might provide advice to the ordering health professional that follow-up or further testing is required to confirm the patient's condition. The MLT is also required to run quality assurance tests and to ensure that elaborate laboratory equipment is functioning properly.

The third phase is the post-analytical phase. It involves the recording of data and information from the laboratory investigation, data entry, follow-up with the ordering health professional, storage of specimens, quality assurance and the management and maintenance of laboratory supplies. The role of MLTs in this phase varies depending on the laboratory.

Evolution of the Profession and the Impact of Technological and Scientific Advances

Significant technological and scientific advances have impacted greatly on MLT practice. Many investigations have become highly automated, and instruments have replaced people in some cases. However, MLTs are still relied upon for the proper functioning and use of the complex equipment.

Point-of-care testing (POCT) is also rapidly expanding. This is also known as “bedside” or “patient-side” testing where the diagnostic testing is done at or near the site of patient care. Technological advancements have made it possible to use transportable instruments for an increasing number of laboratory investigations, such as meters to test blood glucose levels. However, the term “point-of-care testing” can also refer to tests that are performed on samples gathered from patients in close proximity to the actual laboratory (i.e., in hospitals).¹⁶ HPRAC was informed that the accreditation process for laboratories provides guidance for the use and monitoring of point-of-care testing to ensure quality and integrity of the results.

Legislative and Regulatory Framework for the Practice of Medical Laboratory Technology

In Ontario, the legislative framework for health professions includes the *Regulated Health Professions Act, 1991(RHPA)*¹⁷ and a series of profession-specific Acts, including the *MLTA*.¹⁸ The *RHPA* lists a series of controlled or restricted activities that, if performed by unqualified, unregulated individuals, pose a substantial risk of harm to patients.

¹⁶ CMLTO. *Medical Laboratory Technologists and Point-of-Care Testing*.

¹⁷ 1991, S.O. c.18.

¹⁸ S.O. 1991, c.28.

MLTs' scope of practice is defined in the *MLTA* as follows:

The practice of medical laboratory technology is the performance of laboratory investigations on the human body or on specimens taken from the human body, and the evaluation of the technical sufficiency of the investigations and their results.¹⁹

In addition, MLTs may perform one controlled act, on the order of an authorized health professional. The *MLTA* provides that:

In the course of engaging in the practice of medical laboratory technology, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to take blood samples from veins or by skin pricking.²⁰

However, the regulations provide for an exemption from the restrictions²¹ on the performance of this controlled act when the taking of blood from a vein or by skin pricking is performed by a person employed by a laboratory or specimen collection centre licensed under the *LSCCLA*.²²

The *MLTA* restricts the use of the title “medical laboratory technologist”, a variation or abbreviation or an equivalent in another language.²³

In addition to the *RHPA* and *MLTA*, MLTs must practise in accordance with the laws regulating their place of work. Specifically, the *LSCCLA* establishes the Laboratory Licensing and Inspection Service whose responsibility it is to set conditions for licensure for laboratories and specimen collection centres and to inspect these facilities regularly.

The Director of Laboratory and Specimen Collection Centre Licensing, an officer of the Ministry of Health and Long-Term Care, is responsible for ensuring that these conditions are met for the issuance and renewal of licences. The licence may specify conditions such as the types of specimens that are collected in a given specimen collection centre, or the type or classes of tests that may be performed in a given laboratory.²⁴ The government, through the Laboratory Licensing and Inspection Service, plays a significant role in ensuring the safe and effective provision of laboratory services in the public interest.

Ontario Regulation 682, made under the *LSCCLA*, prescribes several conditions for the licensure, ownership and operation of laboratories in Ontario. Of particular interest to this review are the sections specifying the qualifications of laboratory directors, laboratory supervisors, laboratory technologists and laboratory technicians.²⁵ These stipulate the minimum educational requirements for these positions but allow the Director of

¹⁹ *Medical Laboratory Technology Act*, 1991. s.3.

²⁰ *Ibid.* s.4.

²¹ *RHPA*, s.27(1).

²² Ontario Regulation 107/96 made under the *Regulated Health Professions Act*, 1991, s.11.

²³ *Ibid.* s.9(1).

²⁴ *Laboratory and Specimen Collection Centre Licensing Act*, s.9.

²⁵ Ontario Regulation 682, made under the *LSCCLA*, 1990. s.6.

Laboratory and Specimen Collection Centre Licensing the discretion to approve the qualifications and experience of individuals as meeting the requirements for employment in a laboratory. Public health laboratories, Canadian Blood Services blood donor clinics, pharmacies performing immunologic tests for pregnancy and physicians who perform laboratory testing for their own patients are exempt from parts of the Act and its regulations.²⁶

Similarly, Ontario Regulation 683 made under the *LSCCLA* sets out the conditions for the issuance and renewal of a licence to establish, operate or maintain a specimen collection centre. For staff, the regulation specifies that anyone employed by the owner or operator of a specimen collection centre for the purpose of collecting specimens from the human body shall have his or her competence in techniques for specimen collection and handling, ability to care for and manage patients, and standard of personal cleanliness assessed by a legally qualified medical practitioner.²⁷ Specimens are collected in a number of sites that are not necessarily licensed as specimen collection centres, including physicians' offices, long-term care facilities and at the bedside in hospital. In addition, a number of individuals may collect blood and other human specimens, including physicians, nurses, respiratory therapists, MLTs and unregulated staff such as MLA/Ts.

The *LSCCLA* also makes it a condition of a license for a laboratory to submit to a quality management program.²⁸ The Ontario Medical Association (OMA) has been designated as the agency to carry out this quality management program.²⁹ The Quality Management Program - Laboratory Services (QMP-LS), operated by the OMA, designs and delivers external quality assessment, accreditation and education services and related products to meet its regulatory mandate, relevant international standards and client and stakeholder requirements. It has been in operation since 2003. Many laboratories outside Ontario also voluntarily seek accreditation by QMP-LS. All applicant laboratories are issued ISO certificates by the Standards Council of Canada for complying with several international standards and guidelines.³⁰

All Ontario laboratories submit to rigorous monitoring by QMP-LS. They are required to provide evidence of quality goals, sound practices, continual improvement and client satisfaction, among other indicators. There are explicit quality management criteria against which all laboratories are evaluated to ensure the highest quality, safest laboratory operation. Both the accreditation and the external quality assessment are mandatory for all Ontario medical laboratories and are meant to complement the laboratories' own quality control and quality assurance measures. Continued accreditation is dependent on the laboratory demonstrating competence through the external quality assessment visits and surveys that determine the extent to which laboratories conform to requirements for all examinations performed. In particular, the external quality

²⁶ Ibid. ss. 11-13.

²⁷ Ontario Regulation 683, made under the *LSCCLA*, 1990. s.3.

²⁸ *LSCCLA*, 1990. s.9(14).

²⁹ Ontario Regulation 682, made under the *LSCCLA*, 1990. s.14.

³⁰ Quality Management Program – Laboratory Services. About Ontario Laboratory Accreditation. Available at: www.qmpls.org/ola/ola.

assessment encompasses all aspects of laboratory practice with a view to reducing errors, improving quality, developing processes to ensure a failure-resistant system and responding to any adverse events. This comprehensive external quality assessment takes place every four years. QMP-LS also provides educational and other resources to assist laboratories in developing the internal systems and processes required to ensure safe, effective laboratory practice.

Finally, the *MLTA*, and the regulations made under both the *LSCCLA* and the *PHA* specify those professionals who may order laboratory investigations and from whom MLTs and specimen collection centre staff must accept orders for the performance of specimen collection and laboratory investigation.³¹

It is evident that there are multiple layers of public protection afforded by the legislation, regulations, accreditation and quality management of laboratories and specimen collection centres, in addition to the fact that MLTs, who make up a significant portion of the laboratory workforce, are regulated health care professionals.

How the CMLTO Regulates Its Members

Entry to Practice

In order to become registered as a member of the CMLTO, one must:

- Graduate from an MLT educational program accredited by the Canadian Medical Association (CMA), or from a baccalaureate degree program from a Canadian university whose major course content is relevant to medical laboratory technology and has been approved by the CMLTO's registration committee, or provide proof of prior learning assessment conducted by the CSMLS that demonstrates equivalency to a Canadian MLT program;
- Successfully complete the CSMLS national certification exam in the specialties in which registration is being sought;³²
- Show proof of active engagement in medical laboratory technology in the three years preceding the application or show proof of completion of a CMLTO-approved refresher course within the three years preceding the application.

It is currently not a mandatory requirement for registration that MLTs carry professional liability insurance, though this is offered as a benefit of membership of both CSMLS and OSMT.

³¹ *MLTA*, s. 5(1). O. Reg. 207/94 made under the *MLTA*, s. 12. O. Reg. 682 made under the *LSCCLA*, 1990, s. 9. O. Reg. 965 made under the *Public Hospitals Act*, s.24. Ontario Regulation 682 made under the *LSCCLA*, 1990, s.9(1). Ontario Regulation 683 made under the *LSCCLA*, 1990, s.5(d).

³² CSMLS currently offers entry-level medical laboratory technologist certification in three areas: General Medical Laboratory Technology, Diagnostic Cytology and Clinical Genetics. Canadian Society for Medical Laboratory Science. *CSMLS Entry-Level Medical Laboratory Technologist Certification*. November 2005. Available at: www.csmls.org/english/position.htm#book1.

There are several CMA-approved MLT training programs in Ontario. Typically, these are advanced diploma programs but, increasingly, they are moving to a four-year science degree.

The National Medical Laboratory Technologists examination is administered by CSMLS and is competency-based. The CSMLS has developed entry-level competencies for general medical laboratory technologists and these are the basis for the certification examination. Educational programs also use the core competencies as a guide in curriculum development.

The core competencies expected of an entry-level MLT were recently revised and approved by CSMLS and the first examination based on the new competencies is scheduled for June 2010. Advice was obtained from educators, employers, practitioners and others to ensure that the revised competencies reflect needs in the evolving workplace. The core competencies are outcome-based and are categorized as follows: safe work practices, data collection and specimen procurement/receipt, analysis of specimens and validation of results, analytical techniques, interpretation and reporting of results, quality management, critical thinking, applied investigation, resource management, communication and interaction, and professionalism.³³

Quality Assurance

The CMLTO has developed guidelines and other material to help MLTs practise to the CMLTO standard. In addition, it is mandatory for every practicing MLT to maintain a professional practice portfolio documenting evidence of continuous quality improvement. The professional portfolio is intended to include a self-assessment of one's abilities, a description of one's current practice and a career development strategy. The latter must include one of either, a self-directed study plan, a professional enhancement program or a technical assessment survey conducted by peers.

The CMLTO conducts random audits of MLTs' professional practice portfolios. In 2008, 400 members' portfolios were audited. Based on the audit results, the Quality Assurance Committee may direct the MLT to address any deficiencies in the portfolio, submit to a practice review or technical competence assessment or participate in a remedial education program.³⁴ HPRAC was advised that the CMLTO will be piloting a new Practice Review Program in early 2009.

What HPRAC Learned

In addition to carefully reviewing the joint submission of the CMLTO, CSMLS and OSMT, including the supplementary information provided, HPRAC undertook a review of the published literature and a jurisdictional review of the scope of practice of MLTs outside Ontario. The literature and jurisdictional reviews are posted on HPRAC's website. In addition, written

³³ CSMLS. *Competency Profile: General Medical Laboratory Technologist*. May 2005.

³⁴ CMLTO. *Part One: Professional Portfolio Handbook*. June 2006.

submissions were invited and several meetings were held with a number of individuals and organizations. This section summarizes the findings arising from the literature and jurisdictional reviews, as well as the input HPRAC received through its extensive consultations.

Literature Review

There is a shortage of literature related specifically to issues concerning MLTs' scope of practice. The literature, however, does include research on a number of issues related to the field of laboratory technology that can help inform discussions about scope of practice. These issues include growth and other trends in laboratory testing, appropriateness/inappropriateness of testing, laboratory mistakes/errors, and guidelines and performance measures for error reduction. The following is an overview of key themes in the literature.

Scope of Practice

The laboratory is an integrated and complex system involving a wide variety of interactions among different parts and players of the health system.³⁵ Medical laboratory technology is strongly influenced by the developments of new technology and new scientific testing discoveries.³⁶

Evidence-based culture underpins the practice of laboratory medicine. To date, however, evidence-based medicine appears to have had limited actual impact on laboratory medicine. A more evidence-based approach is needed to inform education and training of health professionals and support clinical decision-making and resource allocation.³⁷

The changing role and duties of MLTs are being affected by the availability of real-time laboratory results, more effective tests, enhanced clinical consulting roles, involvement in therapeutic decisions, efforts to prevent rather than cure disease, shift from anecdotal care to evidence-based medicine and the assessment of outcomes for laboratory tests.³⁸

The use of laboratory technicians for routine or automated testing is a current trend that is expected to continue. This development also reinforces the trend toward educating and training multi-skilled laboratory technologists who can respond effectively to changes in their role.³⁹

³⁵ De Capitani, C. Automation of Pre-Analytical Phase: a Performance Evaluation and Alternative Scenarios. *Journal of the Association for Laboratory Automation*. Vol (2): 89– 93. 2002.

³⁶ Health Canada. *An Environmental Scan of the Human Resource Issues Affecting Medical Laboratory Technologists and Medical Radiation Technologists*. Section C: Findings on Medical Laboratory Technologists. Ottawa: Health Canada. 2002.

³⁷ Price, C. Application of the Principles of Evidence-Based Medicine to Laboratory Medicine. *Clinica Chimica Acta*. Vol 333. 147-154. 2003; Price, C. Evidence-Based Laboratory Medicine: Supporting Decision Making. *Clinical Chemistry*. Vol 46:8. 1041-1050. 2000.

³⁸ Plebani, M. Charting the Course of Medical Laboratories in a Changing Environment. *Clinica Chimica Acta*. Vol 319. 87-100. 2002.

³⁹ Health Canada. *An Environmental Scan of the Human Resource Issues Affecting Medical Laboratory Technologists and Medical Radiation Technologists*. Section C: Findings on Medical Laboratory Technologists. Ottawa: Health Canada. 2002.

Health System Changes

In recent decades, dramatic changes have occurred in the organization, number and type of tests, and role of medical laboratories in health care. These changes affect the role of laboratory professionals to require greater analytical accuracy and more stringent test selection and interpretation of results.⁴⁰

Trends in the practice of patient identification and specimen collection include:⁴¹ automated systems that integrate bar-coding of patient identification wristbands with proper specimen collection procedure; computerized physician order entry; standardization of specimen collection procedures within each health care organization; certification of phlebotomists; continued migration from glass to plastic blood tubes; and increased use of blood collection devices that have self-sheathing needles or no needles at all for patients with indwelling catheters or lines.

Patient Safety and Risk of Harm: Laboratory Error

The quality of results provided by the laboratory is dependent on the control of pre-analytical factors such as specimen collection, specimen handling/processing, and specimen integrity.⁴²

Overall, communication between physicians and MLTs on the pre-analytical phase and the implementation of educational programs for defining criteria and procedures needs to be improved. Better education of health professionals is seen as a critical contributor for ultimately improving patient care and outcomes.⁴³

Four institutional factors were significantly associated with higher overall laboratory error rates:⁴⁴ orders verbally communicated to the laboratory; no policy requiring laboratory staff to compare a printout or display of ordered tests with the laboratory requisitions to confirm that orders had been entered correctly; failure to monitor the accuracy of outpatient order entry on a regular basis; and a higher percentage of occupied beds (a busier hospital, for example).

Most laboratory errors occur in the pre- or post-analytical phases, while a minority (13 to 32 percent) occurs in the analytical portion. Evidence suggests that quality programs developed around the analytical phase of the total testing process would only produce limited improvements, since the large majority of errors encountered in clinical laboratories still prevail within “extra-analytical” areas of testing.⁴⁵

⁴⁰ See, for example Plebani, M. Charting the Course of Medical Laboratories in a Changing Environment. *Clinica Chimica Acta*. Vol 319. 87-100. 2002.

⁴¹ Astion, Michael. Future Trends in Patient Identification & Specimen Collection: Automation and Standardization. *Laboratory Errors and Patient Safety*. Vol 1: 2. 2004.

⁴² Ajeneye, Francis. Pre-Analytical Quality Assurance: A Biomedical Perspective. *The Biomedical Scientist*. February 2007.

⁴³ Pansini, N. et al. Total Testing Process: Appropriateness in Laboratory Medicine. *Clinica Chimica Acta*. Vol 333. 141-145. 2003.

⁴⁴ Valenstein, P. and Meier, F. Outpatient Order Accuracy. A College of American Pathologists Q-Probes Study of Requisition Order Entry Accuracy in 660 Institutions. *Archives of Pathology and Laboratory Medicine*. Vol 123. 1145-1150. 1999.

⁴⁵ Lippi, G. et al. Recommendations for Detection and Management of Unsuitable Samples in Clinical Laboratories. *Clinical Chemistry Laboratory Medicine*. Vol 45:6. 728-736. 2007.

Most pre-analytical errors result from system flaws and insufficient audits of the operators involved in specimen collection and handling responsibilities. Lack of standardized procedures for sample collection, including patient preparation, specimen acquisition, handling and storage, account for up to 93 percent of the errors currently encountered within the entire diagnostic process. Standardization of specimen collection procedures reduces errors by simplifying, optimizing and reducing the number of collection procedures followed in a health care organization. There is evidence of personnel cost savings and service quality improvement with pre-analytical phase automation.⁴⁶

Most health care organizations use some combination of centralized specimen collection services that are usually under the laboratory's control and decentralized services provided by nurses, physicians' assistants and medical assistants. Institutions that favour a more centralized approach report that laboratory-based control of the specimen collection process reduces errors significantly.

Among the negative impacts of decentralization, laboratories repeatedly identify five factors that can directly impact errors and adverse events:⁴⁷ reduced error tracking and reporting; less feedback to collection staff; difficult draws being performed by collectors who get less practice; collectors with less awareness of the impact of inadequate samples on laboratory testing; and variations in collection procedures based on equipment, location, and personnel.

However, performance measures have been identified to respond to error reduction strategies, including: customer satisfaction, test turnaround times, patient identification, specimen acceptability, proficiency testing, critical value reporting, blood product wastage and blood culture contamination.⁴⁸

Future Priorities: Challenges and Opportunities

There are several challenges for sustaining changes in the role and contribution of MLTs. These include:⁴⁹ guaranteeing the quality of laboratory tests irrespective of where they are performed, improving the quality of services, improving clinical outcomes, performing joint clinical/laboratory research projects, and developing an awareness of the importance of the knowledge and skills required for the new role of laboratory professionals.

⁴⁶ Lippi, G. et al. Pre-analytical Variability: the Dark Side of the Moon in Laboratory Testing. *Clinical Chemistry Laboratory Medicine*. Vol 44:4. 358-365. March 2006.

⁴⁷ Laboratory Errors and Patient Safety Editorial Staff. Decentralized Specimen Collection and Patient Safety. *Laboratory Errors and Patient Safety*. Vol 1: 2. 2004.

⁴⁸ Howantis, P. Errors in Laboratory Medicine: Practical Lessons to Improve Patient Safety. *Archives of Pathology and Laboratory Medicine*. Vol 129. 2005.

⁴⁹ Plebani, M. Charting the Course of Medical Laboratories in a Changing Environment. *Clinica Chimica Acta*. Vol 319. 87-100. 2002.

Future research efforts to address gaps and shortcomings should focus on: the development of guideline-driven decision support systems to reduce the number of laboratory tests ordered by primary care practitioners; a more rigorous methodology for error detection and classification and the adoption of proper technologies for error reduction; and strategies to decrease computer order entry errors based on regular monitoring of the accuracy of order entry.⁵⁰

Jurisdictional Review

The jurisdictional review provides an overview of regulations concerning MLTs across Canada and selected foreign jurisdictions.

Ontario, Alberta, Saskatchewan, Manitoba, Quebec, New Brunswick and Nova Scotia have self-regulatory bodies that govern the MLT profession. Several of these regulators advised that their provinces are currently reviewing proposals to determine how MLTs should continue to be regulated. The stage of these discussions varies from province to province.

Across Canadian jurisdictions, the scope of practice of MLTs differs little. Provinces either define scope of practice in the legislation or adopt it from the CSMLS competency profile. Most often, it involves the “performance of laboratory investigations” and the “collection and handling of laboratory specimens.” Additionally, the affected provinces reserve the title of “medical laboratory technologist” for licensed professionals.

Of all the provinces, Ontario and Quebec have the most comprehensive regulatory regimes. Both provinces set out the scope of practice and provide for restricted activities or authorized acts for MLTs in provincial legislation.⁵¹ Quebec gives MLTs the broadest scope of practice; it is the only province in which MLTs are permitted to perform Pap tests and allergy testing.

Few jurisdictions permit MLTs to independently decide whether to perform follow-up procedures previously ordered on the basis that these are unnecessary. None of the jurisdictions permit MLTs to independently initiate testing unless the hospital or laboratory has policies or directives in place that give prior permission for follow-up testing where certain test results are present.

Almost every province requires CSMLS certification for provincial licensure, with only one provincial regulatory body, in New Brunswick, requiring CSMLS membership. In addition to providing a competency profile, the CSMLS provides national standards of practice. These are the minimum standards across Canada. Provincial regulatory bodies also have their own standards of practice or code of ethics.

⁵⁰ Price, C. Evidence-Based Laboratory Medicine: Supporting Decision Making. *Clinical Chemistry*. Vol 46:8. 1041-1050. 2000; Bonini, P. et al. Errors in Laboratory Medicine. *Clinical Chemistry*. Vol 48: 5. 691-698. 2002.

⁵¹ Ontario's *MLTA*, S.O. 1991, c.28 and Quebec's Professional Code, R.S.Q. c. C-26.

The foreign jurisdictions surveyed, Australia, New Zealand and Great Britain, take a different approach to regulation of MLTs.

The first marked difference from Ontario can be noted from the titles used. In Australia, MLTs are called medical laboratory scientists. In New Zealand, the regulatory body governs both MLTs and MLA/Ts; and they are called, respectively, medical laboratory scientists and medical laboratory technicians. In Great Britain, MLTs are called biomedical scientists. They were formerly called medical laboratory technicians, but correspond to Ontario's technologists as opposed to technicians/assistants.

A further contrast with Ontario's regulatory regime stems from the absence of specific authorized or restricted activities. No such acts are set out in the Queensland or South Australia jurisdictions. In New Zealand, restricted activities exist but none pertain to MLTs. Likewise, no restricted activities have been set out for MLTs in Great Britain.

The level of regulation also differs in these jurisdictions. There is no statutory registration for medical laboratory scientists in any jurisdiction in Australia. However, some employers do require eligibility for professional membership in the Australian Institute for Medical Scientists (AIMS) for employment.

Perspectives from the Consultations

HPRAC's consultations were designed to gain additional information on the proposed changes to the scope of practice of MLTs as well as stakeholders' perspectives on the benefits and risks associated with the proposed changes.

At the beginning of the consultations, meetings were held with the proponents to review their joint submission, gain a better understanding of the role that MLTs play in the provincial health system and understand the rationale for and implications of the proposals.

HPRAC received comments and information, either through written submissions from individuals and various organizations, or through consultative meetings held with key individuals and organizations.

Six written responses were submitted: from Dietitians of Canada, the Ontario Association of Medical Laboratories, the Ontario Hospital Association, the Ontario Medical Association, the Ontario Society of Clinical Chemists and the College of Respiratory Therapists of Ontario. The submissions indicated support for some of the proposed changes, though most raised significant concerns with some of the proposals. HPRAC has considered these responses in its analysis and recommendations. All of the submissions are available on HPRAC's website.

Meetings were held with representatives of the Laboratories Branch of the Ministry of Health and Long-Term Care, as well as the QMP-LS, to discuss the organization of laboratory services in Ontario and obtain their perspectives on the proposed changes. Sessions also took place with educators on the

implications of the proposed scope enhancements for provincial teaching programs and their capacity to respond to an enhanced scope of practice for MLTs if required. Representatives of Ontario laboratories, including the Ontario Association of Medical Laboratories, the Provincial Public Health Laboratories and a number of directors of hospital-based laboratory services, were consulted, to seek their perspective on proposed changes and how they would affect the provision of laboratory services and meet patient needs. As well, pathologists and other laboratory medicine specialists were consulted on how the changes would impact their role and interactions with MLTs in the provision of diagnostic services to the public. Finally, a roundtable meeting brought together the proponents as well as representatives of professions with an interest in the proposed changes.

HPRAC has considered all these points of view in its analysis and recommendations.

Generally, the feedback from the meetings reflected significant concern with the proposals. With few exceptions, stakeholders indicated limited or no support for the proposed changes to the scope of practice for this profession.

The key points emerging from HPRAC's consultations on the proposed changes to MLTs' scope of practice are summarized under three main categories: System Needs, Scope of Practice and Competency.

System Needs

Participants in consultation meetings argued that there is lack of evidence or rationale to support the changes that have been proposed. While stakeholders acknowledged that MLTs are significant players in the delivery of health care services and play a key role in the collection, analysis of and reporting on specimens, they indicated that the proposed changes appear to be inconsistent with current system needs and critical issues affecting MLTs.

Various participants stressed that the shortage of MLTs has been one of the most significant issues affecting this profession for some time. Concern about the shortage of MLTs in all practice settings was a common theme in the consultations. Participants were not convinced that the proposed changes would make the MLT profession more attractive or result in improved recruitment and retention. They suggested that rather than attempting to expand MLTs' scope of practice to areas outside the laboratory and in direct patient care, the focus of any initiatives should be on strategies that would have a positive impact on MLTs and laboratory system capacity. Some suggested that a specific strategy should be developed to elevate the scope of practice of MLTs and to promote and support specialization of laboratory professionals. HPRAC heard many times about the pending shortages of "master technologists" in many specialty areas of laboratory science.

Concerns were raised by several participants that the proposed changes would exacerbate the present and growing human resources crisis among MLTs since they would be diverted to other functions at the expense of core MLT activities.

Many participants were not convinced that current restrictions on MLTs' ability to make independent testing decisions pose access issues. HPRAC was told that all laboratories have directives, procedures, protocols and algorithms in place that have been approved by their medical laboratory director to facilitate testing follow-up decisions and reduce unnecessary delays. It was also pointed out that it is common practice for MLTs to develop procedures to deal with unexpected or unusual testing situations in consultation with their medical laboratory director or ordering professional.

Our primary concern with expanding the scope of practice as described in the submission is that instead of supporting inter-professional collaboration, it may actually undermine the achievement of this objective.

Ontario Association of Medical Laboratories
Submission to HPRAC
August 2008

Scope of Practice

Some individuals and written submissions expressed limited and qualified support for some of the proposed changes. The clearest indication of support was from dietitians and respiratory therapists, who endorsed the proposed changes that are consistent with their own scope of practice.

By and large, stakeholders expressed significant reservations with and concerns about most of the proposals. They argued that many of the proposed changes go beyond what has been the role of MLTs and are contrary to the direction in which the profession should be evolving. They stated the changes could affect the inherently collaborative relationship that currently exists among all those involved in the provision of diagnostic services—including physicians and other qualified health professionals who order diagnostic tests, medical laboratory physicians, laboratory scientists, clinical chemists and other specialized practitioners. Another significant concern is that the proposed changes would give MLTs independent authority for testing and the ability to perform other diagnostic interventions (e.g., allergy testing, vaccinations) that may conflict with the role of physicians and nurse practitioners as primary care providers with principal responsibility for clinical assessment of their patients.

HPRAC was advised that it would not be appropriate for MLTs to make decisions about adding or removing laboratory tests in the absence of the specific clinical knowledge of the patient. MLTs lack the training and competency in the clinical evaluation of patients to make an appropriate clinical decision. Participants stressed that since MLTs have limited or no contact with patients, they would not be familiar with or have access to a patient's complete medical history and therefore they would not be able to make informed decisions.

Stakeholders raised particular concerns with proposed changes that broaden MLTs' role in obtaining specimens (e.g., Pap tests) or injecting substances for various diagnostic procedures (e.g., allergy testing). HPRAC was advised that Pap and allergy testing should be part of a clinical examination that includes obtaining an appropriate clinical history and performing a thorough examination. They emphasized that only primary health care professionals would have both the competency and the knowledge of the patient, his or her symptoms and clinical history to make such decisions. They conceded that there could be rare and extremely unusual circumstances where an MLT might perform these procedures, but felt that it is more appropriate that they be performed through a specific medical directive or delegation from a physician or other authorized professional who has properly trained and assessed the competency of the individual MLT to perform the task.

Respondents were also concerned that the proposed changes would give MLTs independent authority to do reflex testing or to change testing orders made by qualified health professionals. It was argued that MLTs do not have the necessary training and competency or access to a patient's clinical history. Furthermore, they are provided with limited information about the patient on the test order as a basis for decisions that a test should be added or dropped. Various participants informed HPRAC that the current system of delegation as well as laboratory-specific protocols, algorithms and decision trees clearly define the boundaries within which MLTs can initiate further testing based on initial results. They also pointed out that these "rules" can be adjusted by protocols in each laboratory to reflect particular circumstances and requirements as determined by the medical laboratory director.

We support the...ability of medical laboratory technologists with appropriate training to institute follow-up tests under their own initiatives.

Dietitians of Canada
Submission to HPRAC
August 2008

Competency

One of the key areas explored in the consultations was whether MLTs have the necessary educational preparation to carry out the proposed changes in scope of practice. It was clear that the proposals are beyond the current competencies of MLTs and therefore beyond the current educational programs. HPRAC therefore sought input on the extent to which programs could be amended to reflect an expanded scope, if required.

Educators who participated in the consultations indicated that the current curriculum does not cover a number of the proposed changes. They emphasized that arterial puncture and changes concerning certain

diagnostic procedures would require a significant amount of training, in the classroom and in clinical settings, as well as competency involving a type and level of interaction with patients that is currently outside of the MLT scope of practice.

Educators also indicated that for other proposed changes, such as reflex testing, MLTs do not have the competency to determine what tests should be added or dropped. They stressed that their curriculum does not include the clinical evaluation of patients. Concerns were expressed that if the proposed changes are approved, they could pose significant challenges to education programs, both in the classroom and in clinical settings. An expanded curriculum would be required, particularly concerning patient care, including formalized arrangements with clinical settings outside laboratories. HPRAC was also advised that the core competencies expected of an entry-level MLT that were recently revised and will be introduced in 2010 do not address the training requirements associated with changes in the MLT proposal.

Laboratory physicians and clinical doctoral laboratory scientists undergo three to five years of postgraduate training and are constantly attending clinical CME activities to attain the knowledge and competencies required to interpret laboratory test results. It is our opinion that the majority of MLTs do not have sufficient knowledge required to safely interpret and provide clinical correlation of laboratory tests.

Ontario Clinical Chemists
Submission to HPRAC
August 2008

HPRAC's Observations

Understanding Ontario's laboratory system and the laboratory investigation process is necessary to understand the role of MLTs as well as the systemic barriers to access and quality of care. As noted in the summary of findings from the literature review, and of particular interest to any discussion on patient safety, much attention has been paid to the incidence of errors in the laboratory process. Equally rigorous are the efforts to identify, study and respond to these errors in various ways to improve efficiency, effectiveness and, most importantly, patient outcomes.

HPRAC received considerable input from key stakeholders, either through written submissions or through meetings. HPRAC heard that several stakeholders were not aware of the extent of the proposals being put forward by the proponent, and some indicated that they had only been consulted on specific or limited portions of what was presented to HPRAC. It would appear that there is considerable interest in improving the laboratory system among the various health professions, associations, facilities and individuals involved in delivering laboratory services.

However there is also a need to significantly improve the level of collaboration among key stakeholders, including the CMLTO. It was noted that the scope of practice of MLTs is not top-of-mind when considering the challenges and risks facing laboratory services in Ontario. Rather, systemic issues such as health human resource shortages, the need for specialization and the impact of emerging technological and scientific advances are considered more pressing at this time. HPRAC encourages the CMLTO and other medical laboratory science stakeholders to engage in discussions to identify ways to address these considerable concerns.

HPRAC's Recommendations

The following are HPRAC's recommendations on the scope of practice of MLTs. HPRAC has grouped the requests under the following broad headings:

- Expansion of scope of practice,
- Initiation of laboratory tests,
- Scope of practice statement, and
- Amendments to regulations under the *LSCCLA*.

Expansion of Scope of Practice

The proponents made several requests that would significantly expand and change the nature of the current scope of practice of MLTs.

Taking Blood from Arteries

MLTs currently have the authority to perform a procedure on tissue below the dermis for the purpose of taking blood samples from veins (phlebotomy) or by skin pricking. This is the only controlled act currently authorized to the profession, and one that is increasingly being performed by individuals other than MLTs, such as nurses and MLA/Ts.

While this is a controlled act under the statute, the regulations provide for an exemption from subsection 27(1) of the *RHPA*—which restricts the performance of controlled acts—when the taking of blood from a vein or by skin pricking is performed by a person employed by a laboratory or specimen collection centre licensed under the *LSCCLA*.⁵² As a result, there are relatively few instances where MLTs in practice are currently drawing blood from veins or by skin pricking under the authority of the *MLTA*. The majority of functions performed by MLTs are public domain activities not subject to the controlled act provisions of the *RHPA*.

The proponents' submission requests that the authority to perform a procedure on tissue below the dermis be extended to include the drawing of blood from arteries. The main rationale for the request was to facilitate

⁵² Ontario Regulation 107/96 made under the *Regulated Health Professions Act*, 1991, s.11.

human resources substitution to alleviate the pressure on those health professionals who are currently performing this function, such as nurses and respiratory therapists.

HPRAC consulted extensively with representatives of educational institutions, other professions and key stakeholders. The consensus was that performance of arterial punctures is outside the current knowledge, skill and competencies of MLTs. It was suggested that patient risk increases with arterial blood draws and that these require more skill than venous blood draws.

Educators told HPRAC that it would take a significant amount of additional education and training, both didactic and clinical, to address gaps in the current curriculum. Furthermore, there is no evidence that arterial blood draws are currently being performed by MLTs under delegation; indeed very few even perform phlebotomy. Nor did HPRAC hear of a significant patient need that would be addressed by expanding the scope, education and training of MLTs to perform this function. No other Canadian jurisdiction currently permits MLTs to draw blood from arteries. Finally, HPRAC heard that pulse oxymetry, a less invasive, equally effective method of measuring blood gases, is fast replacing traditional arterial blood draws conducted for that purpose.

Administering a Substance by Injection

The submission proposed that MLTs be authorized to administer substances by injection for diagnostic and prophylactic purposes, such as allergy testing and vaccinations. Again, the rationale for the request was to address wait times for care by patients.

HPRAC heard that this function is not rationally related to the current practice of the profession. There is no evidence that MLTs are currently performing injections under delegation and there were few instances cited where MLTs could possibly be utilized to perform allergy testing or administer vaccinations.

Of particular interest to HPRAC's review was the input relating to patient care and risk of harm. Educators maintain that the knowledge, skill and judgment required to perform injections is not a current competency or part of the curriculum. In general, there is little didactic and clinical education on issues of direct patient care. Performing injections requires knowledge of how to deal with possible adverse reactions beyond basic emergency response. The risk of anaphylaxis is significant and is sometimes life-threatening. There is little evidence to suggest that patients would benefit from the proposed expansion. In no Canadian jurisdiction other than Quebec is allergy testing or administering substances by injection considered to be within the MLT scope of practice.

Instrument, Hand and Finger

The proponents further request that the authority to insert an instrument, hand or finger beyond the urethra and beyond the labia majora be granted to MLTs for the purpose of specimen collection (e.g., Pap tests and urinary

catheterization). In view of the government's emphasis on prevention, screening and disease management initiatives, the proponents suggested that authorizing MLTs to perform these acts will improve access to care, reduce wait times and better support these efforts.

As with the above requests, educators advised HPRAC that the current curriculum lacks the significant patient care component that would be required for MLTs to perform these acts. Educators, other professions and key stakeholders alike were unanimous in their negative comment on Pap testing in particular. The procurement of Pap test specimens is inextricably linked to a comprehensive clinical examination that is only performed by a physician or nurse practitioner. MLTs do not have the competencies to do the specimen collection, and it is not appropriate to separate this from a more thorough physical examination.

The proponents suggest that pre-analytical errors related to improper specimen collection could be alleviated by allowing MLTs to do the procurement and ensure the viability of the specimen. As will be discussed below, there is indeed a role for MLTs to play in addressing pre-analytical errors relating to specimen quality, but the type of specimen collection that would require access to these controlled acts is not an appropriate expansion of MLT practice.

It is conceivable that MLTs with proven competencies could obtain specimens other than blood from veins or by skin pricking when required and where appropriate to the patient, such as throat, eye, wound or cheek swabs. HPRAC feels that, were these situations to arise, delegation and not an expansion of scope would be the appropriate process for authorization where a controlled act is involved. Through delegation, the health professional with the authority would be assured of the knowledge, skills and judgment of the MLT accepting the delegation.

The jurisdictional review conducted by HPRAC revealed that only MLTs in Quebec are permitted to put an instrument, hand or finger beyond the urethra and labia majora for specimen collection. As for other types of specimens, some jurisdictions indicated that MLTs occasionally perform throat swabs, but this depends largely on the employer and is not a typical MLT function.

HPRAC's Conclusions

The proposals for changes to the scope of practice represent a significant departure from MLTs' current scope of practice, and from the recently revised MLT competencies. HPRAC appreciates that demographic and other pressures on the health care system will increase demand for laboratory services to assist in the diagnosis, prevention and treatment of illness and disease. HPRAC is not convinced by the arguments put forward by the proponents and did not find sufficient evidence to support the claims, either in the proponents' material or in its own independent research. HPRAC is firmly convinced that the most appropriate response for Ontario's health care system is to ensure that the right health professionals are providing the right care, at the right time, and in the right place. In other

words, it is by maximizing the potential of health professionals to practise to their maximum competencies that increasing demands for access and quality can be addressed most effectively. Certainly, where practice has evolved to encompass roles outside a profession's scope of practice, it is incumbent upon the government to contemplate legislative changes to facilitate the profession's ability to practise. It is not the case that MLT practice has evolved to encompass the roles contemplated in the proposals submitted to HPRAC. The changes requested would require direct patient interaction, which is currently not occurring in practice.

HPRAC is convinced, however, that MLTs have a significant role to play in addressing the systemic issues that contribute to errors, particularly in the pre-analytical phase of the laboratory investigation process. In fact, numerous examples were provided to HPRAC where MLTs are collaborating in the development of specimen collection and handling protocols and infection control practices and teaching point-of-care testing methods. This is a particular area where further collaboration among professions is warranted.

Recommendation:

1. That MLTs not be authorized to perform the requested controlled acts:
 - Performing a procedure on tissue below the dermis for the purpose of performing arterial puncture,
 - Administering a substance by injection,
 - Putting an instrument, hand or finger
 - Beyond the urethra, or
 - Beyond the labia majora.

Initiation of Laboratory Tests

The proponents requested amendments to the *LSCCLA* and the *PHA* that would add MLTs to the list of individuals authorized to initiate laboratory tests. The proponents reasoned that diagnoses could be expedited if MLTs were able to initiate the follow-up tests they deem necessary based on their initial assessment of a specimen. It was clarified that the request does not pertain to the collection of a new specimen; rather it involves additional investigations on an existing specimen.

Educators informed HPRAC that the MLT curriculum includes the process of test selection using clinical case histories and that MLTs would have the knowledge to determine the need for follow-up testing based on evidence-based management using detailed decision trees. The proponents suggested that often MLTs determine the need for further testing but cannot act on this judgment because they must seek an order from an authorized health care professional to perform additional tests. They argue that in some cases, tests are time-sensitive because a specimen can only be kept for a set period of time. Due to the delay caused in seeking a further order, patients are often inconvenienced by having to give subsequent samples for a follow-up test that could have been conducted on their original specimen.

The proponents also argue that MLTs are in a position to eliminate duplication and unnecessary expense by dropping tests that have been ordered unnecessarily. For instance, anecdotal evidence was provided suggesting that physicians often order a test and a repeat on the same requisition. The submission argued that follow-up tests are often rendered irrelevant by the finding of the original investigation. MLTs suggest that they are obliged to perform the unnecessary tests regardless of their value to patient outcomes.

HPRAC learned that there are technological and setting-specific mechanisms to deal with instances where follow-up testing is required but not ordered. New technology provides for the “flagging” of unusual results and there are “reflex testing” algorithms and protocols that specify when and what type of results warrant automatic follow-up or retesting.

It is important to distinguish initiation of tests for quality management purposes from initiation of tests for clinical purposes. HPRAC learned that MLTs indeed initiate and conduct quality management tests as a matter of course in the laboratory setting. These are done largely to verify the validity of a sample, a result or the patient from whom the sample was taken. The need for these tests is determined at the facility level and they are generally logged only on the laboratory’s records and not on the patients’ charts.

Reflex testing algorithms and protocols are also established at the facility level by the laboratory director, in consultation with other health professionals, including MLTs. Simply put, they determine those instances where, based on the results of an initial test, follow-up testing is warranted and permitted. HPRAC was told that these algorithms and protocols are very detailed and leave little room for independent judgment by an MLT. They are based on clinical best practices, developed collaboratively and approved by medical directors of laboratories and may include medical directives or other such arrangements with ordering professionals. Furthermore, in those instances where an indicator is not covered by an existing protocol or order, the MLT may consult with either the medical director of the laboratory or the ordering health professional to determine the appropriateness of follow-up testing.

One concern raised by stakeholders is that MLTs have little or no information on the patients for whom tests are ordered. They would not be aware of any medical history, other than what is provided on the order for the test. That would not typically include information on symptoms or co-morbidities that might explain unusual results. If MLTs were to act on a finding without a thorough knowledge of the patient or what is already known about his or her condition, the testing could well prove unnecessary.

Another issue is informed consent. Conducting a test for which an order has not been received and for which patient consent has not been obtained presents problems. Physicians in particular commented that it would be difficult for them to report the results of a test for which patient consent was not obtained.

HPRAC has significant concerns with allowing MLTs to initiate tests and the effect this would have on the health system as a whole. HPRAC was impressed by the rigour of the laboratory accreditation, licensing and quality management program. The legislation clearly delineates the rules and responsibilities of all those involved in the laboratory investigation process. HPRAC is satisfied that the current system of protocols and algorithms for follow-up testing, as well as the process of developing these at the facility level, is sufficient to address most situations where additional testing is required. HPRAC is not convinced that patient care is at risk from the protocols and requirements in place for follow-up testing. Rather, facility policies and the ability to consult with either the medical director of the laboratory or the ordering professional can appropriately deal with those cases where MLTs determine, by their own professional judgment, that follow-up testing is required or that a particular test was ordered improperly.

Finally, no other Canadian jurisdiction allows MLTs to initiate laboratory investigations for clinical purposes, though in practice, MLTs in Manitoba and Nova Scotia do not perform tests they deem unnecessary.

HPRAC would encourage the continued involvement of MLTs in the development of facility protocols for the initiation of tests at the laboratory level and the determination of the appropriateness of tests. Health professionals consulted were open to continued communication and collaboration with MLTs in ensuring that the laboratory investigation process is as seamless, effective and efficient as possible so as to maximize the benefit to patient outcomes.

Recommendation:

2. That MLTs not be added to the list of professionals authorized to order laboratory tests under the *LSCCLA* and the *PHA*.

Scope of Practice Statement

The proponents requested that the scope of practice statement be amended to reflect the authorities discussed above, if those were to be granted to MLTs. Though no specific wording was proposed, it was also requested that the competencies of MLTs to correlate tests results to diagnosis, take patient histories and engage in public education be recognized.

As HPRAC is not recommending that the scope of practice for MLTs be expanded as requested, the requisite changes in the scope of practice statement are unnecessary. HPRAC is convinced that MLTs' expertise is indeed in the science required to ensure the validity of specimens and test results to support diagnosis by other health professionals. It is acknowledged that MLTs are relied upon to collaborate with those professionals who diagnose. HPRAC also acknowledges that MLTs are able to take patient histories and often engage in public education. However, these activities do not need to appear in the legislative scope of practice statement.

Recommendation:

3. That no change be made to the scope of practice statement for MLTs in the *MLTA*.

Regulations under the LSCCLA

As discussed briefly, the proponents requested amendments to Ontario Regulations 682 and 683 made under the *LSCCLA* to require all MLTs employed by Ontario laboratories to be members of the CMLTO. The rationale was to recognize the CMLTO as the regulator of the profession and to ensure that competencies are met and maintained, rather than allowing the Director of Laboratory Services, an employee of the Ministry of Health and Long-Term Care, or laboratory directors to employ individuals who may not meet the CMLTO's professional standards and criteria, but who may meet other standards.

HPRAC understands that this issue of overlapping authority over regulation of MLTs and other laboratory employees has been a point of contention for some time. However, in the absence of evidence that unregulated professionals are performing controlled acts that threaten the public's safety, HPRAC is not in a position to recommend a solution.

It was suggested by several individuals and organizations that the qualifications of many individuals currently working in Ontario's laboratories exceed the competencies and qualifications set for entry to practice by the CMLTO and the CSMLS certification process. This is a matter of some concern to HPRAC, and indicates that the CMLTO should consider advancing the scientific, technical and technological competencies for members, rather than moving, as it has suggested in its submission to HPRAC, into direct patient care activity, for which there is limited support or enthusiasm from educators or other health professions who work with members of the profession.

To HPRAC, this profession is composed of scientific workers, whose strengths are in their scientific and technological knowledge. However, there are also other strengths and requirements that accompany the recognition as a profession and that serve the public interest – a code of ethics, assurance that members of the profession are well trained and continue to be competent over their working lives, that quality improvement is continuous, and that breaches of professional responsibilities are examined and disciplined.

There is no question that numerous people working in the laboratory field are not regulated as a profession, but are employed on a basis of a certification process that is little understood by the public. When serious patient safety issues arise, such as inadequacy of pathological examinations and results that rely on work performed by laboratory technologists, it is little wonder that the public loses trust in the system, and people who work in the system also lose trust because they do not believe they have a place to go to report errors and omissions.

HPRAC understands that the licensure, accreditation and quality assessment processes that apply to Ontario laboratories are highly regarded, including those that apply to personnel. It is important to consider that regulated MLTs are one component of a laboratory's personnel complement and that they are considered health professionals.

A more complete review of whether all individuals employed in laboratory services should be part of a regulated profession is one way of arriving at a solution.

Recommendation:

4. That no amendments be made at this time to Ontario Regulations 682 and 683 made under the *LSCCLA* at this time.

The Need for Action

HPRAC is confident in its recommendations on the scope of practice for current MLTs. However, as in previous scope reviews, HPRAC was told of many systemic issues that present barriers to the efficient and effective provision of health care services, but are not suited to scope of practice responses.

HPRAC is aware that a number of initiatives are underway to address some aspects of laboratory services, such as the implementation of a new laboratory information system, the transfer of Ontario's public health laboratories to the Ontario Agency for Health Protection and Promotion, and responses to recent tragedies such as the SARS outbreak and the Walkerton water contamination.

Given the essential role of laboratories in providing information for diagnostic, clinical and public health decision-making, it would be of great value to bring these varied initiatives and investigations together to provide a single, comprehensive inventory of what is needed to improve the quality and viability of Ontario's laboratory services system, and how to achieve it. HPRAC's response to the proposals to expand the scope of practice of MLTs represents but a small piece of the puzzle of improving access to safe, high quality and efficient laboratory services in Ontario.

REVIEW OF THE SCOPE OF PRACTICE OF MEDICAL RADIATION TECHNOLOGY

The College of Medical Radiation Technologists of Ontario (College) and the Ontario Association of Medical Radiation Technologists (Association) submitted a joint response to HPRAC's questionnaire on the review of the scope of practice of medical radiation technology. The College also made a separate response to HPRAC's review of non-physician prescribing and use of drugs under the *Regulated Health Professions Act, 1991 (RHPA)*. While this section of the report concentrates particularly on scope of practice issues, it also takes into account the submission of the profession relating to non-physician prescribing. HPRAC carefully considered the proponents' input, as well as findings from extensive research and consultation, in developing its analysis.

HPRAC's Central Response

HPRAC has concluded that medical radiation technologists (MRTs) are critical members of interprofessional health care teams. They are valuable technical experts in the safe and effective use of rapidly evolving and highly sophisticated diagnostic and therapeutic equipment. MRTs provide crucial information to support diagnosis and monitor the progress of treatments. They are also involved in direct patient care through the delivery of therapeutic interventions. HPRAC's review supports the requests for changes in the scope of practice of medical radiation technology as reasonable since they reflect the daily functions of MRTs in all areas of practice and are supported by their education and training. The proposal also reflects the extent to which the profession has evolved since the inception of the *RHPA* and the *Medical Radiation Technology Act, 1991*.

Background on Medical Radiation Technology in Ontario

The Profession

A MRT is a qualified health professional who uses ionizing radiation¹ or electromagnetism to produce diagnostic images of a patient's body or who administers radiation to treat patients, on the order of a physician.² The joint proposal to HPRAC is not requesting the removal of the requirement for a physician order. Therefore, HPRAC's analysis of this scope of practice review is premised on MRTs having an order from an authorized health

¹ Ionizing radiation ranges from radio waves at the lower end of the electromagnetic spectrum to x-rays, gamma rays given off by radioactive material and cosmic rays at the higher end of the electromagnetic spectrum. The latter, high frequency portion of the spectrum is of concern because of the effect such energy has on atoms and molecules with which it comes into contact. In other words, such energy is dangerous in high, uncontrolled doses and has the potential to cause harm to people. Non-ionizing radiation such as electricity, microwaves and radiofrequency fields are long wavelength/low frequency and do not have the capacity to disrupt molecules. World Health Organization www.who.int/ionizing_radiation/about/what_is_ir/en/index.html.

² College of Medical Radiation Technologists of Ontario. About Medical Radiation Technologists. www.cmрто.org/about/about-mrts.asp.

professional to undertake any activities that they are currently performing or that HPRAC may recommend they should be authorized to perform under a revised scope of practice.

The College regulates the practice of MRTs in the province. According to the joint submission by the College and the Association, there are currently over 6,200 MRTs in Ontario.³ This represents an increase of almost 10% since 2003 when there were just over 5,600 active members. The Association represents the professional interests of MRTs. Membership in the Association is voluntary and several membership categories exist, including those for MRTs who have a limited practice, are retired, are on work leave or are in the commercial field.⁴

MRTs work in hospitals, cancer treatment centres and independent health facilities that provide diagnostic medical imaging services. MRTs practice in one of four specialties within medical radiation technology.^{5, 6}

Four Specialties

Radiological technology is the use of x-rays to produce images of parts of the body on film or on computer screens – such as mammograms, chest x-rays and computerized tomography (CT) scans, which produce detailed cross-sectional images of the body part or system. On the order of an authorized health professional, **radiological technologists** produce images of a body part or system using x-ray equipment. They are responsible for the quality of the x-ray images and for providing the correct view of specific body structures or systems, whether on film or digital images. Some procedures require giving barium and/or a dye called a contrast medium to patients to highlight organs and structures that would not otherwise be seen. Radiological technologists work in hospitals and independent health facilities.

Radiation therapy is the treatment of disease with radiation, which involves the use of radiation to destroy diseased cells in the body – for example, cancer. **Radiation therapists** use focused beams of radiation to destroy tumours while minimizing harm to healthy tissues. Treatment may also involve placing radioactive sources directly into the patient's body. Another part of the radiation therapist's role is to plan the actual course of treatment that has been ordered by a physician, through simulation. This involves taking measurements, determining radiation doses, and performing treatment simulations. Radiation therapists are responsible for precisely targeting these high doses of radiation and carefully monitoring the patients' exposure. Radiation therapists work in hospitals and cancer treatment centres.

³ Submission to HPRAC: Review of Interprofessional Collaboration Under the Regulated Health Professions Act; joint submission by College of Medical Radiation Technologists of Ontario and Ontario Association of Medical Radiation Technologists; June 30, 2008, p. 1.

⁴ Ontario Association of Medical Radiation Technologists. Who we are. www.oamrt.on.ca/whoweare/OAMRT-CMRTOChartp.shtml.

⁵ College of Medical Radiation Technologists of Ontario. About Medical Radiation Technologists. www.cmrtto.org/about/about-mrts.asp.

⁶ Canadian Association of Medical Radiation Technologists. About the Profession. www.camrt.ca/english/career/disciplines.asp.

Nuclear medicine is the use of low-level radioactive substances which are injected, swallowed or inhaled to produce diagnostic images of how the body functions – for example, bone scans, cardiac stress tests and lung scans. A gamma camera collects data that is then processed by computer to produce images of organs from different angles. **Nuclear medicine technologists** work in hospitals or independent health facilities and are involved in all aspects of this imaging modality – from preparing and administering the radioactive substance to positioning and monitoring the patient, performing the test and producing the actual images.

Magnetic resonance is the use of electromagnetism (static magnetic fields and radio frequencies) to produce diagnostic images. Magnetic resonance imaging (MRI) procedures play a significant role in imaging the brain, spine, abdomen, pelvis and the musculoskeletal system. **Magnetic resonance technologists** do not work with ionizing radiation. However, they must carefully screen patients for risks linked with the MRI procedure, such as metal implants or pacemakers, as these objects could be drawn to the magnet, causing serious damage or even death. Patients may suffer emotional distress or claustrophobia from being placed in the machine's tunnel, and the monitoring of the patient throughout the procedure is part of the technologist's role. Magnetic resonance technologists work in hospitals and independent health facilities. Magnetic resonance was added as an MRT specialty in 2003 through amendments to registration regulations under the *Medical Radiation Technology Act, 1991*,⁷ and electromagnetism was added as a prescribed form of energy at the same time.⁸

According to the College's 2007 Annual Report, 70% of the College's membership reports radiology as a primary specialty, 14% report radiation therapy, 11% nuclear medicine and 5% magnetic resonance.⁹

Legislative and Regulatory Framework for the Practice of Medical Radiation Technology

In addition to the *RHPA* and the *Medical Radiation Technology Act, 1991*, which govern members of the profession, the practice of medical radiation technology takes place in a highly regulated environment. Other federal and provincial legislation and regulations govern the forms of energy used by MRTs to ensure public safety and professional accountability. An MRT may not perform any task unless it is in accordance with all applicable legislation and regulations.

The *Healing Arts Radiation Protection Act (HARP)*, which regulates the use of ionizing radiation and restricts the use of x-ray machines in Ontario, is particularly relevant to radiology and radiation therapy. It stipulates that only those who meet specific qualifications can operate an x-ray machine, and that the use of x-ray equipment must be ordered by an authorized health professional. Members of the College meet the qualifications for the use of x-ray equipment.¹⁰

⁷ Ontario Regulation 866/93 s.1(2) under the *Medical Radiation Technology Act, 1991*, S.O. 1991, c. 29.

⁸ Ontario Regulation 266/03 s.1 under the *Medical Radiation Technology Act, 1991*, S.O. 1991, c. 29.

⁹ College of Medical Radiation Technologists of Ontario. 2007 Annual Report. p. 19.

¹⁰ *Healing Arts Radiation Protection Act, R.S.O. 1990, c. H.2, s. 5-7.*

In June 2007, the HARP Commission reported on a comprehensive study conducted on all facets of computed tomography. It recommended enhancements to *HARP Act* and to standards and guidelines on radiation doses and radiation emitting devices in Ontario.¹¹

The *Nuclear Safety and Control Act* came into force in 2000. It established the Canadian Nuclear Safety Commission to protect the health, safety and security of Canadians, as well as the environment, by regulating the proper use of nuclear energy through its licensing authority. A number of regulatory and licensing requirements impact on MRT practice, as they regulate the use of nuclear energy (radiation and radiopharmaceuticals) and stipulate safety requirements that must be in place for the protection of both workers and patients.¹² Radiation protection regulations have been established under the Act, including those that apply specifically to the administration of nuclear substances for medical purposes.¹³

In addition, MRTs are subject to the imaging and patient safety protocols established in the settings where they practise – namely, hospitals, cancer centres and independent health facilities.¹⁴ These will vary by setting and department, or the type of equipment, but are largely developed in conjunction with radiologists.

Medical Radiation Technologists' Current Scope of Practice

In Ontario, the legislative framework for regulated health professions encompasses the *RHPA* and a series of profession-specific Acts, including the *Medical Radiation Technology Act, 1991*. The *RHPA* lists a series of controlled or restricted activities that, if performed by unqualified individuals, pose a substantial risk of harm to patients.

The *Medical Radiation Technology Act, 1991* currently defines the scope of practice for medical radiation technology as follows:

The practice of medical radiation technology is the use of ionizing radiation and other forms of energy prescribed under subsection 12(2) to produce diagnostic images and tests, the evaluation of the technical sufficiency of the images and tests, and the therapeutic application of ionizing radiation.¹⁵

¹¹ Healing Arts Radiation Protection Commission Report. June 2007. p.3.

¹² *Nuclear Safety and Control Act, 1997*. s. 3.

¹³ Radiation Protection Regulations, S.O.R./2000-203 under the *Nuclear Safety and Control Act*.

¹⁴ The *Independent Health Facilities Act, 1990*, sets the requirements for licensure of independent health facilities. The *Public Hospitals Act, 1990*, governs the activities that take place within public hospitals.

¹⁵ *Medical Radiation Technology Act, 1991*, S.O. 1991, c. 29, s.3.

The *Medical Radiation Technology Act, 1991*, also defines the controlled acts authorized to MRTs as follows:

- Taking blood samples from veins,
- Administering substances by injection or inhalation,
- Tattooing,¹⁶ and
- Administering contrast media through or into the rectum or an artificial opening into the body.

Ontario Regulation 226/03 under the *Medical Radiation Technology Act, 1991* prescribes electromagnetism as a form of energy for the purposes of the scope of practice statement. In 2003, when magnetic resonance technologists were added as a specialty within the College, the controlled acts authorized to MRTs in the *Medical Radiation Technology Act, 1991* were not amended to include the application of energy in the form of electromagnetism. Rather, through an amendment to a regulation under the *RHPA*,¹⁷ MRTs were exempted from the restriction on the controlled act of applying a prescribed form of energy, for the purpose of applying electromagnetism for magnetic resonance imaging. As a result, the current legislation lacks transparency on the authority of MRTs to apply electromagnetism for magnetic resonance imaging.

Additional Requirements for Controlled Acts

Under the *Medical Radiation Technology Act, 1991*, MRTs are only permitted to perform a procedure falling within an authorized act if there is an order for performance of the procedure from a physician. Specifically:

- 5(1) A member shall not perform a procedure under the authority of section 4 unless the procedure is ordered by a member of the College of Physicians and Surgeons of Ontario.¹⁸

Delegation and Medical Directives

MRTs currently perform controlled acts not specifically authorized to the profession, through medical directives or delegation.

Medical directives are instructions relating to the care and medical treatment of a specific patient population given by physicians or other health professionals authorized to order the performance of controlled acts.¹⁹ They define the agreement of physicians and other authorized health professionals on best practices for medical interventions and how other health professionals should be involved in carrying out treatment protocols. They contain the delegation and authority for identified health

¹⁶ Tattooing refers to radiation therapy marking on patients undergoing treatment to be able to precisely direct the radiation.

¹⁷ Ontario Regulation 107/96 s.3.1 under the *Regulated Health Professions Act, 1991*.

¹⁸ *Medical Radiation Technology Act, 1991, S.O. 1991, c. 29, s.5(1)*.

¹⁹ Federation of Health Regulatory Colleges of Ontario. *An Interprofessional Guide on the Use of Orders, Directives and Delegation for Regulated Health Professionals in Ontario*. <http://mdguide.regulatedhealthprofessions.on.ca/why/default.asp>.

professionals to carry out treatment protocols when patients meet established criteria. They are written in accordance with evidence-based practice standards. They are usually relevant to a particular practice setting and to specific health professionals who work in that setting.

Delegation, while not specifically defined in the *RHPA*, is understood to be a process whereby a regulated health professional authorized to perform a controlled act under a health profession Act confers that authority to someone – regulated or unregulated – who is not so authorized.²⁰ Any delegation by or to a health professional must be in accordance with any applicable regulations made under the health profession Act governing the member's profession.²¹

Previous HPRAC Recommendations

In February 1999, the Minister of Health requested advice from HPRAC on the following issues:

- The regulation of diagnostic sonographers,
- The regulation of MRI, and
- Expansion of the controlled acts authorized to MRTs.

In its report to the Minister in September 2000,²² HPRAC recommended the regulation of MRI. The government responded by including magnetic resonance technologists in the profession of medical radiation technology in 2003. The regulation of diagnostic sonographers is the subject of a further request for advice to HPRAC, included in the Minister's June 2007 letter. HPRAC expects to report to the Minister on this issue in 2009.

In its September 2000 report, HPRAC supported the expansion of controlled acts authorized to the MRT profession. Since then, the field of diagnostic imaging has evolved rapidly, and the health care system has been challenged to meet the growing and increasingly complex needs of patients in new, collaborative and innovative ways. While cognizant of its previous recommendations throughout the current scope of practice review, HPRAC has concluded that developments since its last report warranted a thorough examination of the issues in question and the proposals put forth by the College and Association. HPRAC has reviewed these matters in the context of the current health care system and in light of the advances in technology that have directly affected the delivery of health care and the role of this profession in particular.

²⁰ Federation of Health Regulatory Colleges of Ontario. *An Interprofessional Guide on the Use of Orders, Directives and Delegation for Regulated Health Professionals in Ontario*. <http://mdguide.regulatedhealthprofessions.on.ca/why/default.asp>.

²¹ *Regulated Health Professions Act, 1991, S.O. 1991, c. 18, ss. 28 and 29*.

²² Health Professions Regulatory Advisory Council. *Advice to the Minister of Health and Long-Term Care: Medical Imaging – Regulation of Diagnostic Sonographers and MRI Technologists, and Expansion of Medical Radiation Technologists' Scope of Practice*. September 2000.

What the College and Association Have Proposed

The College and Association have proposed changes to the scope of practice statement and authorized acts set out in the *Medical Radiation Technology Act, 1991*, as well as a consequential amendment to the regulations under the *RHPA*.

1. Scope of Practice Statement

The proposed scope of practice statement reads:

The practice of medical radiation technology is the use of ionizing radiation, electromagnetism and other forms of energy prescribed under subsection 12(2) for the purposes of diagnostic and therapeutic procedures, the evaluation of images and data relating to the procedures and the assessment of the condition of the individual before, during and after the procedure.

2. Controlled Acts

The proposed controlled acts are:

- Performing a procedure on tissue below the dermis,²³
- Putting an instrument, hand or finger
 - Beyond the larynx
 - Beyond the labia majora
 - Beyond the opening of the urethra
 - Beyond the anal verge, or into an artificial opening into the body, and
- Applying electromagnetism for magnetic resonance imaging.

3. Amendments to Related Legislation

The following ancillary amendments would be required were the above proposals to be accepted:

- Repeal section 3.1 of O.Reg. 107/96 when applying electromagnetism for magnetic resonance imaging becomes an authorized act under the *Medical Radiation Technology Act, 1991*.
- Amend section 1(11) of O.Reg. 855/93 (the Professional Misconduct Regulation made under the *Medical Radiation Technology Act, 1991*) to provide: The following are acts of professional misconduct for the purposes of clause 51(1)(c) of the Health Professions Procedural Code: (11) Carelessly, negligently or unskillfully using ionizing radiation, electromagnetism or a prescribed form of energy.

²³ While MRTs already perform procedures on tissue below the dermis when they take blood from veins or by skin pricking, the proponents are asking that this act be expanded to include performing injections.

It is important to note that the College and Association are proposing to maintain the requirement that MRTs may perform only controlled acts that have been ordered by a physician or other authorized health professional.

How the College Regulates its Members

Educational Preparation

Applicants to the College must complete an approved training program in one of the four MRT specialties. The Canadian Association of Medical Radiation Technologists' Essential Competencies²⁴ are used as the basis for MRT education curricula in Canada. The competency profiles for each of the four MRT specialties are established and validated by the Canadian Association of Medical Radiation Technologists through an extensive consultative process that includes educators, practising MRTs, managers, regulators and governments.

The College assesses the curricula of MRT education programs through the Conjoint Accreditation Process of the Canadian Medical Association. This process determines whether the educational programs sufficiently address required practice competencies – typically through a combination of didactic and clinical learning.²⁵ Several programs, however, have incorporated a simulated learning laboratory to augment the clinical practice component of the curriculum, and to address the shortages of clinical placements for students. There are several approved programs in Ontario for radiological technology and radiation therapy. Only The Michener Institute of Applied Health Sciences offers approved programs in Ontario in nuclear medicine and magnetic resonance, two of the four specialties within medical radiation technology.

Entry to Practice

All applicants to the College, whether trained in Ontario, other Canadian jurisdictions or internationally, must successfully complete the examination set by the Canadian Association of Medical Radiation Technologists. MRTs write exams within their chosen specialty. As with the curricula across Canada, the content of the certification exams is guided by the competency profiles for each specialty. These profiles were recently revised and the new versions will be reflected in examinations beginning in 2011. Programs across Canada have already begun to revise their curricula accordingly and to seek program accreditation under the new competencies.

It is a College registration requirement that applicants show proof of either clinical practice within five years immediately before the application or successful completion of an approved educational program within that period.

²⁴ Canadian Association of Medical Radiation Technology. Professional Practice.Competency Profiles. www.camrt.ca/english/career/competency_profiles.asp.

²⁵ Submission to HPRAC: Review of Interprofessional Collaboration Under the Regulated Health Professions Act; joint submission by College of Medical Radiation Technologists of Ontario and Ontario Association of Medical Radiation Technologists; June 30, 2008, p. 64.

Title Protection

No one may use the title medical radiation technologist or its abbreviations without being a member of the College. The following are the restricted titles, by specialty:

- Medical Radiation Technologist - Radiography, [M.R.T.(R.)],
- Medical Radiation Technologist - Radiation Therapy or Medical Radiation Technologist - Radiation Therapist, [M.R.T.(T.)],
- Medical Radiation Technologist - Nuclear Medicine, [M.R.T.(N.)], and
- Medical Radiation Technologist - Magnetic Resonance, [M.R.T.(M.R.)].

Mandatory Professional Liability Insurance

Professional liability protection for MRTs is mandatory, and is provided through the Canadian Association of Medical Radiation Technologists.²⁶ The insurance program covers all four specialties within the MRT practice. Coverage is \$1 million per member, per occurrence, to an annual aggregate of \$5 million.²⁷

Quality Assurance**Competencies, Standards and Guidelines**

The College has developed an extensive array of materials to support MRTs in their practice. It provides numerous resources to its members about the *RHPA* and the *Medical Radiation Technology Act, 1991*, the controlled acts model and the principles of public protection that underpin these.

The College has developed standards of practice that are comprised of the “Essential Competencies” and “Comprehensive Guidelines for acting in accordance with the RHPA Scope of Practice/Controlled Acts Model”. These key resources are used in conjunction with the Code of Ethics for College members to determine whether an MRT is able to perform at the standards set by the College. They “provide a model for ensuring safe, effective and ethical professional performance to ensure safe, effective and ethical outcomes for patients.”²⁸

The Essential Competencies reflect the knowledge, skills and judgment MRTs need to perform the services and procedures that fall within the scope of practice of the profession.²⁹ The competencies are categorized broadly under six headings: legislation, standards and ethics; equipment and materials; diagnostic examinations and radiation treatment; safe practice; relationship with patients; and records and reporting.

²⁶ Canadian Association of Medical Radiation Technologists. Professional Practice. Professional Liability Insurance. www.camrt.ca/english/career/Insurance_Coverage.asp.

²⁷ Ibid

²⁸ Submission to HPRAC: Review of Interprofessional Collaboration Under the Regulated Health Professions Act; joint submission by College of Medical Radiation Technologists of Ontario and Ontario Association of Medical Radiation Technologists; June 30, 2008, Appendix 1, p. 5.

²⁹ College of Medical Radiation Technologists of Ontario. *Essential Competencies*. 2004. p. 1.

The Comprehensive Guidelines are designed to establish:

- a reference for MRTs in performing authorized acts and in accepting delegation of controlled acts, and
- a decision-making framework for determining the appropriateness of performing services or procedures that are beyond the principal expectations of MRT practice.³⁰

The Quality Assurance Program

Each member of the College is required to participate in the College's Quality Assurance Program annually. This involves:

- Completing the Self-Assessment Profile: evaluating one's practice as measured against the College's Standards of Practice to identify strengths and possible areas for enhancement.
- Maintaining a Continuous Learning Portfolio based on the annual Self-Assessment Profile: identifying and executing continuous learning activities to address areas for enhancement.
- Submitting a Certificate of Competence/Quality Assurance Declaration each year as part of the annual registration process: verifying participation in the self-assessment and achievement of continuous learning goals.

Quality Assurance Monitoring

The College randomly selects members and reviews their Self-Assessment Profile and Continuous Learning Portfolio as the practice assessment component of the Quality Assurance Program. In 2007, the College initiated a multi-source feedback system for the practice assessment component, in which some members undergo a practice assessment conducted by an assessor or program designed to evaluate the members' competence. Designed to assess a member's knowledge, skill and judgment, this component involves input from peers, co-workers and others who complete a survey based on MRT standards of practice.³¹

HPRAC finds that the Quality Assurance Program itself remains largely self-directed, though it has learned that the College's Quality Assurance Committee will be considering revisions that will include a mandatory, formal practice review by the College for a set proportion of the College membership annually.³² The College has submitted a proposed Quality

³⁰ Submission to HPRAC: Review of Interprofessional Collaboration Under the Regulated Health Professions Act; joint submission by College of Medical Radiation Technologists of Ontario and Ontario Association of Medical Radiation Technologists; June 30, 2008, p. 33.

³¹ Submission to HPRAC: Review of Interprofessional Collaboration Under the Regulated Health Professions Act; joint submission by College of Medical Radiation Technologists of Ontario and Ontario Association of Medical Radiation Technologists; June 30, 2008, p. 59.

³² HPRAC interview with Linda Gough, Registrar, College of Medical Radiation Technologists of Ontario.

Assurance regulation that takes into account the changes to the Quality Assurance regulations under the *RHPA* that will take effect in June 2009 as a result of the *Health System Improvements Act, 2007*.³³

What HPRAC Learned

In addition to carefully considering the submission by the College and Association, including supplementary information provided in response to HPRAC's requests for additional material, HPRAC held several consultation meetings, invited written responses to the submission by interested stakeholders and undertook a review of the published literature and a jurisdictional review of the scope of practice of MRTs outside Ontario. The literature and jurisdictional reviews are posted on HPRAC's website.³⁴ This section summarizes the findings from the literature and jurisdictional reviews, as well as the input HPRAC received through written submissions and the consultation meetings.

Literature Review

Generally speaking, literature relating specifically to the scope of practice for MRTs is sparse. However, an abundance of literature is emerging on: the rapid and dramatic technological changes unfolding in the field of diagnostic imaging; barriers to access; health human resources shortages; and escalating costs associated with diagnostic imaging. The following is an overview of key themes in the literature.

Scope of Practice

MRTs practice in radiological technology, radiation therapy, nuclear medicine or magnetic resonance imaging. MRTs make up the majority of the medical imaging workforce in Canada. Approximately three quarters of all MRTs are radiological technologists.³⁵ Basic x-ray and ultrasound account for nearly 80% of all medical imaging examinations in Canadian hospitals.³⁶

Health human resources shortages and increased demand are driving the need to look at how MRT services are delivered and by whom. Shortages of MRTs across Canada are expected to increase in response to a number of health system trends, such as an aging workforce, rapidly changing technology and innovation in the field of diagnostics and a predominately female workforce.³⁷ These anticipated shortages will be particularly pronounced in the face of an aging population with increasingly complex health care needs.

³³ Proposed regulation made under the *Medical Radiation Technology Act, 1991*. Amending Ontario Regulation 545/94.

³⁴ www.hprac.org

³⁵ Canadian Institute for Health Information. *Medical Imaging in Canada*, 2007. Ottawa. 2008.

³⁶ Canadian Institute for Health Information. *Medical Imaging in Canada*, 2007. Ottawa. 2008.

³⁷ Canadian Association of Medical Radiation Technologists. *Supply and Demand Study of Utilization of Medical Radiation Technologists in Canada*. September 2006.

In Great Britain various initiatives have been undertaken to expand roles for MRTs. The radiological technology profession in this jurisdiction has been proactive in challenging the scope of clinical practice.³⁸ Over the past decade, the scope of practice has evolved in response to changing health care needs and rapid innovations emerging in the field. MRTs now undertake new responsibilities in every area of diagnostic imaging and radiotherapy.³⁹

Health System Trends

Lack of access to diagnostic equipment and human resources is impeding early diagnoses and high quality treatment for patients in some parts of the country.⁴⁰ In particular, high MRT vacancy rates are found across Canada, especially for radiological technologists and magnetic resonance technologists. Workforce shortages contribute to increased patient wait times, cancelled procedures, decreased patient satisfaction, and provider plans to stop offering a specific service.⁴¹ A recent report suggested that Canada is below the OECD median for MRI and CT scanners per population, though intensity of operation may vary from country to country. In Canada, the number of diagnostic imaging machines has grown exponentially in the last decade.⁴²

The demand for MRIs and CTs is rapidly increasing. However, there are signs of over-reliance on, and inappropriate use of, diagnostic imaging technology. Inappropriate imaging is a threat to effective diagnosis and effective allocation of resources. The development and dissemination of knowledge-based clinical guidelines (and other decision support systems) is one strategy currently being advocated to reduce inappropriate imaging.^{43,44}

Future advances in computer technology, coupled with an increase in the accuracy and sensitivity of imaging technologies, will make it possible to seamlessly integrate diagnosis and treatment. It is predicted that image-guided interventions will enable health professionals to detect critical

³⁸ See, for example: College of Radiographers [United Kingdom]. Role Development Revisited: The Research Evidence 2003. *Radiography*. 2003. Hardy, M. and Snaith, B. Role Extension and Role Advancement – Is There a Difference? *Radiography*. Vol 12(4):327-331. 2006. Hogg, Peter. Advanced Clinical Practice for Radiographers in Great Britain: Professional Roles, Accountability and the Educational Provision. *The Canadian Journal of Medical Radiation Technology*. Vol 35:4. Winter 2004.

³⁹ College of Radiographers [United Kingdom]. Role Development Revisited: The Research Evidence 2003. *Radiography*. 2003; Hawnaur, Jane. Diagnostic Radiology. *British Medical Journal*. Vol 319:168-171. 1999; Price, R.C. and Le Masurier, S.B. Longitudinal changes in extended roles in radiography: A new perspective. *Radiography*. Vol 13(1):18-29. 2007.

⁴⁰ Canadian Association of Radiologists. Vision 2000: Medical Imaging Services in Canada. In partnership with Organized Radiology – Canadian Heads of Academic Radiology and the Medical Imaging Industry. 2000.

⁴¹ Canadian Association of Medical Radiation Technologists. Supply and Demand Study of Utilization of Medical Radiation Technologists in Canada. September 2006.

⁴² Canadian Institute for Health Information. *Medical imaging in Canada, 2007*. Ottawa. 2008.

⁴³ 2006 Annual Report of the Office of the Auditor General of Ontario: 3.06 Hospitals – Management and Use of Diagnostic Imaging Equipment; Glaves, J. The Use of Radiological Guidelines to achieve a sustained reduction in the number of radiographic examinations of the cervical spine, lumbar spine and knees performed for GPs. *Clinical Radiology*. Vol 60:914-920. 2005.

⁴⁴ Picano, E. Sustainability of medical imaging: doctors and patients should be more aware of the long term risks of radiological investigations. *British Medical Journal*. Vol 328:578-580. 2004.

illnesses at their most curable stage, and that the practice of medicine will shift from one of disease detection and treatment to one of prediction and prevention in asymptomatic, at-risk populations.⁴⁵ While new technologies have significant impacts on clinical practices, their impacts on patient outcomes and productivity need further study.⁴⁶

Radiology has participated in the recent trend towards computerized management in the health system and has responded to the demand for cost-efficient and rapid communication between departments of radiology and their users.⁴⁷

Patient Safety/Risk of Harm

Evidence shows that radiation technologists can successfully undertake high quality diagnostic reporting for some x-rays and simple images (e.g., nuclear medicine, barium enemas), thereby alleviating time pressures and demands on radiologists. However, despite the growing number of studies that evaluate the film-reading performance of different health professionals, there is little evidence tracking and reporting the subsequent effects on the referring clinician's diagnosis, management plans and patient outcomes.⁴⁸ Outcomes-based research is required to properly evaluate the risks and benefits of an increasing use of and reliance on both diagnostic imaging and MRTs.

One or two studies found that physicians and other health professionals are insufficiently aware of the long-term health risks associated with radiological imaging. These risks are often ignored in cost effectiveness analyses of medical imaging. Patients may not be given appropriate information about the risks, benefits and radiation dose for diagnostic imaging tests and CT scans. Patients, emergency physicians and radiologists are unable to provide accurate estimates of CT doses regardless of their experience level.⁴⁹

⁴⁵ National Institutes of Health. *Image Guided Interventions*. Department of Health and Human Services. U.S.A. September 2006.

⁴⁶ Hawnaur, Jane. Diagnostic Radiology. *British Medical Journal*. Vol 319:168-171. 1999.

⁴⁷ Hawnaur, Jane. Diagnostic Radiology. *British Medical Journal*. Vol 319:168-171. 1999; National Institutes of Health. *Image Guided Interventions*. Department of Health and Human Services, USA. September 2006.

⁴⁸ Brealey, S. et al. Radiographers and Radiologists Reporting Plain Radiograph Requests from Accident and Emergency and General Practice. *Clinical Radiology*. Vol 60(6):710-717. 2005; Brealey, S.D. and Scuffham, P.A. The effect of introducing radiographer reporting on the availability of reports for Accident and Emergency and General Practitioner examinations: a time-series analysis. *The British Journal of Radiology*. Vol 78(930):538-542. 2005; Elliot, L. Radiographer reporting in the nuclear medicine department: a learning curve? *Radiography*. Vol 9(3):247-251. 2003; Murphy, M. et al. A Comparison of Radiographer and Radiologist Reports on Radiographer Conducted Barium Enemas. *Radiography*. Vol: 8(4):215-221. 2002; Robinson, P.J.A. et al. Interpretation of Selected Accident and Emergency Radiographic Examinations by Radiographers: A Review of 11000 Cases. *The British Journal of Radiography*. Vol 72(858):546-551. 1999.

⁴⁹ Lee, C. et al. Diagnostic CT Scans: Assessment of Patient, Physician, and Radiologist Awareness in Radiation Dose and Possible Risks. *Radiology*. Vol 231:393-398. 2004; McCollough, C. et al. CT Dose Reduction and Dose Management Tools: Overview of Available Options. *Radiographics*. Vol 26(2):503-512. March 2006.

Awareness of radiation protection issues is generally low, with widespread underestimation of relative doses and risks. A growing body of research is emerging on this issue.⁵⁰

Future Priorities: Challenges and Opportunities

The literature identifies several specific areas where future research is required:

- Training and education to support the changing scope of practice – including establishment of guidelines to ensure MRTs have appropriate skills and knowledge,⁵¹
- Mechanisms to monitor and control the adoption and use of expensive, emerging technology,⁵²
- Web-based and other electronic tools for the management of test results to support clinical decision-making, improve timely access and avoid costly duplication,⁵³
- Collection of regular supply and demand information for MRTs in Canada to inform human resources planning and forecasting,⁵⁴ and
- Awareness of long-term health risks associated with radiological imaging by auditing prescriptions and providing more explicit informed consent forms.⁵⁵

Jurisdictional Review

Among Canadian jurisdictions, Ontario, Alberta and Quebec have the most comprehensive legislation governing MRT practice. There is little or no legislation or regulation governing MRT practice in other jurisdictions, although they do adhere to the scope and standards set by the Canadian Association of Medical Radiation Technologists (CAMRT). CAMRT administers the certification exam for MRTs across Canada and its scope and standards are used as the central guidelines for the profession. Ontario is viewed as a leader in the regulation and utilization of MRTs among Canadian jurisdictions.

Internationally, HPRAC reviewed the regulatory models in Australia, New Zealand and Great Britain.

⁵⁰ Shiralkar, S. et al. Doctor's Knowledge of Radiation Exposure: Questionnaire Study. *British Medical Journal*. Vol 327:371-372. 2003; Thomas, K. et al. Assessment of Radiation Dose Awareness Among Paediatricians. *Paediatric Radiology*. Vol 36(8):823-832. 2006.

⁵¹ Brealey, Stephen. Measuring the Effects of Image Interpretation: An Evaluative Framework. *Clinical Radiology*. Vol 56(5):348. 2001.

⁵² Institute for Clinical and Evaluative Sciences. Diagnostic Services in Ontario: Descriptive Analysis and Jurisdictional Review. April 2007 (revised).

⁵³ Canadian Association of Medical Radiation Technologists. Supply and Demand Study of Utilization of Medical Radiation Technologists in Canada. September 2006.

⁵⁴ Bairstow, P.J. et al. Diagnostic Imaging Pathways: Development, Dissemination, Implementation and Evaluation. *International Journal for Quality in Health Care*. Vol 18(1):51-57. 2006; Institute for Clinical and Evaluative Sciences. Diagnostic Services in Ontario: Descriptive Analysis and Jurisdictional Review. April 2007 (revised).

⁵⁵ Picano, E. Sustainability of medical imaging: doctors and patients should be more aware of the long term risks of radiological investigations. *British Medical Journal*. Vol 328:578-580. 2004.

New Zealand has a “controlled acts” model, which identifies six acts that must be restricted to qualified individuals; however, none of these apply directly to MRTs. The scope of practice of MRTs, as defined by the New Zealand Medical Radiation Technology Board, is very similar to that of Ontario, Alberta and Quebec.

In Australia, there is not a single regulatory model across the country as variations are found in state legislation in definitions of MRT and the disciplines that fall within the practice of the profession.

In Great Britain, medical radiation technology is a self-regulated profession and MRTs fall under the regulatory purview of the Health Professions Council. The Health Professions Council establishes educational and training requirements and standards of conduct and performance. The Society of Radiographers⁵⁶ supports the profession by developing scope of practice documents and other information for the safe practice of radiography.

Perspectives from the Consultations

Consultations were designed to gain additional information, perspectives and understanding of issues, benefits and risks associated with the changes proposed to the scope of practice of medical radiation technology.

HPRAC received comments from various organizations and individuals, either through written submissions or consultation meetings.

Six written responses were submitted – from the Canadian Association of Medical Radiology Technologists, the Ontario Association of Radiology Managers, the College of Respiratory Therapists of Ontario, the Ontario Hospital Association, the Ontario Medical Association and a practising MRT.

In general, the submissions indicated support for the proposed changes. Some submissions offered qualified support pending clarification of some proposals, while others indicated support specific to certain controlled acts that impact on their professions. HPRAC has considered these responses in its analysis and recommendations. All of the written responses are available on HPRAC’s website.

At the beginning of the consultations, a meeting was convened with the College and Association to review their joint submission and gain a better understanding of the role that MRTs play in the provincial health system, as well as the rationale for the request and the consequences of the proposed changes.

Meetings were held with educators on the implications of the proposed scope enhancements for provincial teaching programs and on the teaching institutions’ capacity to address any gaps in the current curriculum. Representatives of hospitals and independent health facilities were consulted to obtain their perspective on how the changes would affect the provision of diagnostic services to their patients. Radiologists and other

⁵⁶ MRTs are referred to as radiographers in Great Britain.

health professions were asked how the changes would affect their role and interactions with MRTs in the provision of diagnostic services to the public. A roundtable meeting was held with representatives of the College and Association and health professions impacted by the proposed changes. A further session took place with MRTs from the four practice areas who work in various settings (hospitals and specialty and community-based clinics) to get their perspectives on the proposed changes. Overall, the feedback received through the consultation meetings points to a high level of support among key stakeholders for the changes proposed.

HPRAC invited input from the Ontario Association of Radiologists⁵⁷ and was advised of concerns about the risk of harm to patients arising from the proposed changes to the MRT scope of practice, as well as the potential impact on the practice of radiologists. HPRAC further explored these issues through a teleconference with representatives from the diagnostic imaging, radiation oncology and nuclear medicine sections of the Ontario Medical Association and found that collaboration and information sharing allowed for a better understanding of the proposals and their potential impact.

The key points emerging from HPRAC's consultations on MRT scope of practice changes are summarized under three main categories: System Needs, Scope of Practice and Competency.

System Needs

A general theme from the consultations was that the proposed changes would improve delivery of health care services to patients in an environment where there is already considerable collaboration among MRTs and other health professions.

Arguments were made that the proposal is about maximizing the use of MRTs' expertise in the utilization of advanced technology that assists diagnosis and treatment. HPRAC also heard from radiologists who suggested that, rather than expanding the direct authority of MRTs, the focus of any changes should be to ensure that MRTs maintain the competencies to meet technological changes in the field, particularly the shift to digital imaging. Radiologists also suggested that technological advancements are making it possible to use different diagnostic approaches that are not reflected in the proposals contained in the submission. For example, the submission cites the need for the controlled act of inserting an instrument, hand or finger beyond the anal verge to facilitate the administration of barium enemas; however, it was suggested that barium enemas might soon be out of use in favour of CT colonography.

Participants in the consultations indicated that the proposed changes would provide a structured regulatory framework for the provision of MRT services and consequently, reduce service gaps, improve access for patients requiring diagnostic or therapeutic interventions and reduce wait times. It was emphasized that provincial and federal legislation contain multiple layers of public protection that impact on the practice of MRTs.

⁵⁷ The Ontario Association of Radiologists did not file a written response to the submission.

Members supported MRTs being authorized to perform the additional acts requested (on the order of a physician) given that they have the competencies and educational requirements to perform these tasks.

Ontario Hospital Association
Submission to HPRAC
August 2008

The OMA is generally supportive of the joint submission of the CMRTO and OAMRT. The OMA's main concern is that any proposed changes to the Medical Radiation Technology Act should be for the purpose of clarification or to better reflect current common delegated practices.

Ontario Medical Association
Submission to HPRAC
August 2008

Scope of Practice

Many participants stressed that the changes would facilitate and maximize the use of MRTs' expertise and capacity to provide health services currently performed under delegation and for which educational preparation and competencies already exist. Arguments were consistently made that the scope changes reflect current practice and are consistent with the level of education and training that MRTs receive.

MRTs emphasized that the changes would not affect the professional relationships that currently exist in their provision of diagnostic and therapeutic services. It was often pointed out that the proposed changes would not result in any changes in the context of practice. The College and Association, and the MRTs who were consulted, stressed that the proposal does not include the ability to initiate tests or perform additional tests based on MRTs' assessment of the patient. MRTs would continue to render services only when these are ordered by an authorized health professional and in accordance with all other existing legislative and regulatory requirements that apply to their practice.

Some radiologists indicated that the proposed changes could lead to MRTs taking on a greater role in the application of various forms of energy (particularly in fluoroscopy imaging techniques) without the direct supervision of a qualified practitioner (e.g., a radiologist). MRTs pointed out that radiologists expect them to take on expanded roles, particularly in radiation treatment. Many of the participants in the consultations

acknowledged that the changes reflect the evolution of diagnostic technology, diagnostic services and public need. For example, the practice of MRTs has evolved to encompass tasks previously reserved for radiation oncologists and to include therapeutic as well as diagnostic application of energy.

Similar observations were made in the written submissions. Some emphasized that the proposed changes will bring the legislated scope of practice of MRTs in line with current practice.

Competency

A key area explored in the consultations was whether MRTs have the necessary educational preparation to carry out the proposed changes in scope of practice and, if not, whether educational programs would be able to address any gaps in knowledge.

The educators consulted indicated that the proposed changes largely reflect current education, training and practice. They said that they develop didactic and clinical models to address system needs and changing technology. In some instances, it was suggested that the clinical practice components would have to be upgraded to address the skills required to perform new controlled acts, but this would be readily accomplished.

Similar support was indicated in written submissions, which stressed that MRTs have been educated to have the required knowledge, skills and judgment based on national competency requirements to perform the proposed controlled acts. It was noted that the procedures associated with these controlled acts are routine and part of MRT practice.

*The changes recommended to the scope of practice of ...
MRTs will permit [MRTs] to practice within the Ontario health
system to the full extent of their competence and capability.*

CAMRT
Submission to HPRAC
August 2008

An Enabling Regulatory Framework

In previous reports to the Minister of Health and Long-Term Care,⁵⁸ HPRAC has made recommendations for an enabling regulatory framework for health professions. It is within this framework that HPRAC is making recommendations for the regulation of MRTs. The proposed enabling regulatory framework will:

⁵⁸ See: HPRAC. *A Report to the Minister of Health and Long-Term Care on the Review of the Scope of Practice for Registered Nurses in the Extended Class (Nurse Practitioners)*. March 2008, and *An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals: Phase II, Part I*. September 2008.

- Maintain a broad professional scope of practice for MRTs under the *Medical Radiation Technology Act, 1991* and regulations,
- Place responsibility for setting appropriate and rigorous standards, limitations and conditions on practice, that could be changed over time, with the College, and
- Require interprofessional collaboration among professions in establishing standards, limitations and conditions on the performance of controlled acts, where professions share the same or similar controlled acts.
- In particular, the Minister has asked HPRAC to take into account, when controlled acts are shared, of public expectations for high quality services no matter which health profession is responsible for delivering care or treatment. HPRAC has done this.
- A key element of HPRAC's approach is the creation of a new Medical Radiation Technology Standards Committee. This mechanism would allow the College to collaborate with other Colleges whose members share the same or similar controlled acts in determining standards, limitations and conditions on the performance of controlled acts by MRTs, based on best practices and with a view to patient safety.

HPRAC's Observations

The submission by the College and Association depicts a highly skilled and knowledgeable health profession whose role has evolved considerably since the inception of the *RHPA*, and even since the regulation of magnetic resonance technologists in 2003. MRTs' expertise is increasingly relied upon by other members of interprofessional health care teams through all stages of care, from prevention and screening to diagnosis, treatment and monitoring. MRTs have established valuable relationships with physicians, radiologists, nurses, respiratory therapists and others in the delivery of quality patient care. They have also established important relationships with patients, many of whom are in the midst of difficult diagnostic investigations or therapeutic interventions. With reasonable changes to the scope of practice of MRTs, the interaction between MRTs and their health professional colleagues can be made more efficient and effective, improving their ability to contribute to interprofessional health care teams to the maximum of their competence and to the benefit of patients.

The evolution of the profession has been driven to a great extent by the rapid and dramatic changes in the technology used by MRTs. The imaging equipment has become more sophisticated and complex and it is used for both diagnostic and therapeutic purposes. Specifically, imaging equipment and modalities are used to plan the radiation treatment area for patients undergoing radiation therapy, and hybrid imaging equipment has emerged to address patients' diagnostic and treatment needs in innovative ways. In the last decade, hybrid imaging modalities – such as positron emission tomography/ computed tomography (PET/CT) and single photon emission computed tomography/computed tomography (SPECT/CT) – combine nuclear medicine and CT imaging equipment to provide superior images of body systems and how they function. The potential to significantly improve patient outcomes through the use of such sophisticated

equipment by highly knowledgeable health professionals, under the direction of physicians, has generated much interest in the health care community.

Individuals and organizations that participated in the review of the proposals by the College and Association, whether through meetings or written submissions, were largely supportive. They also verified that the national competency profiles define the knowledge, skill and judgment required for entry to practise and support the requested scope changes.⁵⁹ The Minister's question sought input on the health professions regulatory mechanisms that protect the public interest. HPRAC also took into consideration the numerous layers of legislative and regulatory requirements and facility-based protocols that also influence the practice of MRTs in the public interest.

HPRAC's Approach

Based on its research and consultations, HPRAC developed recommendations on the scope of practice of MRTs. Recommendations on access to controlled acts are followed by recommendations on the scope of practice statement for MRTs and then on the administration of drugs by MRTs, flowing from HPRAC's review of non-physician prescribing and use of drugs.

Access to Controlled Acts

Performing a procedure on tissue below the dermis

MRTs currently are authorised to take blood samples from veins and perform tattooing. MRTs take blood samples from patients as part of their practice, for example, to assess effective renal plasma flow. They also routinely perform radiation therapy marking – that is, tattooing – of patients undergoing treatment so radiation can be directed precisely.⁶⁰

MRTs also perform intravenous, subcutaneous or intramuscular injections as part of the process of administering a substance by injection, a controlled act that is already authorized to the profession. The College has interpreted the controlled act of administering a substance by injection as *including* the act of piercing the skin and/or vein. In the practice setting, however, MRTs routinely perform injections under delegation because other health professions have defined the single MRT authorized act of administering a substance by injection as encompassing two separate controlled acts: both as a procedure on tissue below the dermis and as the administration of a substance by injection. A review of the manner in which the controlled act of performing a procedure on tissue below the dermis is authorized to other health professions did not produce any legal or clinical

⁵⁹ Submission to HPRAC: Review of Interprofessional Collaboration Under the Regulated Health Professions Act – Respecting the Scope of Practice of Medical Radiation Technologists; submission by the Canadian Association of Medical Radiation Technologists, August 15, 2008.

⁶⁰ Submission to HPRAC: Review of Interprofessional Collaboration Under the Regulated Health Professions Act; joint submission by College of Medical Radiation Technologists of Ontario and Ontario Association of Medical Radiation Technologists; June 30, 2008, p. 34-35.

rationale for either interpretation. HPRAC finds it is reasonable that the College seeks authorization for the controlled act of performing venipuncture in order to administer a substance by injection.

It is inherent in the practice of medical radiation technology that contrast media, radiopharmaceuticals or drugs be injected into patients as part of diagnostic imaging or therapeutic procedures. Requiring a medical directive or physician order for a function inherent to a health profession's practice is neither efficient nor necessary. Moreover, having to practice under a medical directive rather than one's own professional authority because of discrepancies in the interpretation of the same controlled act is a barrier that needs to be addressed more broadly. This request provides clarity to other professions with whom MRTs work, and avoids interprofessional conflict.

This scope review is being undertaken in the context of a broader initiative that seeks to identify mechanisms to facilitate interprofessional collaboration among Colleges. It is therefore strongly suggested that Colleges collaborate to streamline the interpretation and application of the controlled acts model across professions in order to contribute to greater clarity and understanding of roles in the practice setting.

There was no disagreement from stakeholders that MRTs have the knowledge, skill and judgment to administer substances by injection. Educators confirmed that performing injections, establishing saline locks and starting peripheral lines for the purpose of administering radiopharmaceuticals or contrast media is integrated into both the curriculum and the certification exam. A review of Canadian jurisdictions also found that the act of piercing the skin to establish a mechanism for the injection of substances is common to MRT practice.

General Recommendations

1. That MRTs be authorized to perform a procedure on tissue below the dermis.

That the purposes for which this act would be performed be specified in the regulations.

That the purposes be:

- taking blood samples from veins,
- administering substances by injection, and
- tattooing.

That the regulations made under the *Medical Radiation Technology Act, 1991* require the College to develop the standards, limitations and conditions for the performance of this controlled act through a process of interprofessional collaboration with other Colleges, individuals and entities.

Instrument, Hand or Finger

Beyond the Larynx

MRTs administer radiation treatment to patients with head and neck cancers who often have tracheostomies and trachea tubes. A tracheostomy is a surgical procedure on the neck to open a direct airway through an incision in the trachea (windpipe). The opening is created below the larynx. Tracheal suctioning is performed to clean and remove secretions from the airway and to more effectively deliver oxygen to the lungs. As these patients must lie flat and remain immobile for the duration of treatment, they are unable to clear their own secretions.

HPRAC heard that it is not always possible, realistic or efficient to have a nurse, respiratory therapist or other authorized professional present during treatment in order to suction patients. MRTs are trained and certified to perform this procedure and are currently performing it under delegation. The College and Association assert that MRTs often relieve airway obstructions caused by tracheobronchial secretions during radiation treatment of patients with tracheostomies.

MRT educators confirmed that students learn about such situations and the didactic curriculum covers the indications for suctioning. The submission by the College and Association included course outlines and other excerpts from various program curricula that clearly indicate that knowledge of the indications for and performance of tracheal suctioning is available in the educational program. While the actual clinical practice of the skill of suctioning is not covered adequately at present, educators assure HPRAC that this could readily be accommodated.

In the consultations there was considerable discussion on whether “beyond the larynx” is the appropriate controlled act for tracheal suctioning. No other jurisdiction authorizes MRTs to insert an instrument, hand or finger beyond the larynx, though most authorize access beyond the pharynx, which is not as far down the respiratory tract. The College and Association confirmed that the sole purpose for which they would insert an instrument beyond the larynx is to access a tracheostomy and not to access the larynx through the mouth. Respiratory therapists currently have access to the controlled act of putting an instrument, hand or finger beyond the larynx. Physiotherapists also have the authority to perform tracheal suctioning under the controlled act of putting an instrument, hand or finger beyond the larynx. Nurses have access to the controlled act of putting an instrument, hand or finger both beyond the larynx and into an artificial opening into the body, but define the act of tracheal suctioning as a procedure into an artificial opening into the body. Both respiratory therapists and nurses are supportive of MRTs having the authority to perform tracheal suctioning through a tracheostomy.

HPRAC is satisfied that MRTs should be performing the act of tracheal suctioning of patients with tracheostomies under their own authority rather than under delegation. HPRAC suggests that the controlled act that most appropriately describes the suctioning of patients with tracheostomies, the sole purpose for which authorization is being sought, is the act of inserting an instrument into an artificial opening into the body.

2. That MRTs be authorized to insert an instrument, hand or finger into an artificial opening into the body for the purpose of tracheal suctioning of patients with tracheostomies.

That the regulations under the *Medical Radiation Technology Act, 1991* require the College to develop the standards, limitations and conditions for the performance of this controlled act through a process of interprofessional collaboration with other Colleges, individuals and entities.

Beyond the Labia Majora

Due to the evolution of imaging technology and procedures, MRTs routinely perform imaging and therapeutic procedures that involve putting an instrument, hand or finger beyond the anal verge but do not involve the administration of contrast media. For this reason, the College and Association request that authority to put an instrument, hand or finger beyond the anal verge not be restricted solely for the purpose of administering a substance into the rectum.

MRTs routinely insert vaginal markers to demonstrate the position of the cervix and vagina for patients undergoing radiation therapy for cervical or endometrial cancer. As discussed above, radiation treatment planning is a key function of MRTs. This role demonstrates the evolution in medical radiation technology because it uses diagnostic imaging equipment to facilitate therapeutic interventions, blurring the line between diagnosis and therapy. The College and Association provided evidence of at least one program's curriculum relating to the insertion of vaginal markers.⁶¹

In addition, MRTs have taken on additional roles due to technological advances in radiation therapy, the strain on radiation oncologists caused by health human resources shortages and increasing demands on the latter's time. For example, in the treatment of patients with cervical or endometrial cancer, MRTs perform brachytherapy, which involves inserting radiation directly into the body to attack the tumour.

The rationale for the request, therefore, is two-fold: not only to address the fact that MRTs have been delegated the authority to insert instruments, hand or fingers beyond the labia majora for radiation treatment planning for some time; but also to respond to the increasing need for them to do so in order to implement new and emerging techniques in radiation therapy. The College and Association argue that the process of requiring delegation and medical directives is cumbersome and time consuming. These barriers could be alleviated by providing direct authority to MRTs for this aspect of their routine practice.

HPRAC strongly emphasizes that as the profession continues to evolve through new applications of controlled acts, the College must ensure that standards, limitations and conditions for the performance of those acts are

⁶¹ Submission to HPRAC: Review of Interprofessional Collaboration Under the Regulated Health Professions Act; joint submission by College of Medical Radiation Technologists of Ontario and Ontario Association of Medical Radiation Technologists; June 30, 2008, Appendix 2, Section II, Tabs 1&2.

updated to reflect the competencies required and to ensure transparency for other health professionals and the public. This is a central tenet of HPRAC's enabling regulatory framework.

A review of Canadian jurisdictions found that MRTs in Quebec and Alberta are authorized to perform this controlled act, and it is considered common in MRT practice in New Brunswick.

3. That MRTs be authorized to insert an instrument, hand or finger beyond the labia majora.

That the regulations made under the *Medical Radiation Technology Act, 1991* require the College to develop the standards, limitations and conditions for the performance of this controlled act through a process of interprofessional collaboration with other Colleges, individuals and entities.

Beyond the Urethra

MRTs in the specialties of radiological technology, nuclear medicine and radiation therapy currently perform the controlled act of putting an instrument beyond the urethra under delegation. It is part of the routine practice of these MRTs to insert urinary catheters to either visualize the location of the urethra in the course of radiation treatment planning or to inject contrast media for x-ray simulation in the treatment planning process for prostate and bladder cancer. There are also diagnostic imaging modalities that require the bladder to be empty to better visualize the pelvic area.⁶²

Educators confirmed that these tasks are commonly taught and tested as part of the MRT curriculum and fall within the essential competencies of the profession.⁶³ In addition, this act is authorized in Quebec and Alberta and common in MRT practice in New Brunswick.

HPRAC maintains that, since it is a routine part of MRT practice, performing this function under one's own professional authority and accountability is preferable to delegation from another authorized health professional. It is also more transparent to the public and to other members of a collaborative health team providing patient care.

4. That MRTs be authorized to insert an instrument, hand or finger beyond the urethra.

That the regulations made under the *Medical Radiation Technology Act, 1991* require the College to develop the standards, limitations and conditions for the performance of this controlled act through a process of interprofessional collaboration with other Colleges, individuals and entities.

⁶² Submission to HPRAC: Review of Interprofessional Collaboration Under the Regulated Health Professions Act; joint submission by College of Medical Radiation Technologists of Ontario and Ontario Association of Medical Radiation Technologists; June 30, 2008, p. 37.

⁶³ Submission to HPRAC: Review of Interprofessional Collaboration Under the Regulated Health Professions Act; joint submission by College of Medical Radiation Technologists of Ontario and Ontario Association of Medical Radiation Technologists; June 30, 2008, Appendix 2, Section III, Tabs 1&2.

Beyond the Anal Verge or into an Artificial Opening into the Body

The College and Association seek authority to perform this controlled act to clarify MRTs' role in the administration of contrast media through or into the rectum or an artificial opening into the body, a controlled act already authorized to the profession. This issue is similar to the question of whether administering a substance by injection includes the act of performing a procedure below the dermis. In this case, MRTs seek confirmation that the authority to administer contrast media through or into the rectum or into an artificial opening into the body includes the authority to insert an enema tip or catheter to enable the administration of these substances.

The College has interpreted the act of administering contrast media through or into the rectum or an artificial opening into the body to include the insertion of the enema tip or catheter beyond the anal verge or into an artificial opening into the body,⁶⁴ that is, to include establishing the means of delivering the substance. In some settings, these are seen as two separate acts and MRTs must therefore be delegated the act of putting an instrument, hand or finger beyond the anal verge or into an artificial opening into the body. The College and Association view this approach as unnecessarily splitting hairs in defining the components of administering barium or another substance into the rectum. Again, it is time consuming and inefficient to require delegation or medical directives to be developed for one component of a function MRTs have been routinely fulfilling.

In addition, due to the evolution of imaging technology and procedures, MRTs are routinely performing imaging and therapeutic procedures that involve putting an instrument, hand or finger beyond the anal verge but do not call for the administration of contrast media. For this reason, the College and Association request that authority to put an instrument, hand or finger beyond the anal verge not be restricted solely to the purpose of administering a substance into the rectum.

Examples of such innovations include MRTs in magnetic resonance imaging inserting an endorectal coil into the patient's rectum for high resolution MRI of the prostate gland or cervix. Similar to the treatment of cervical and endometrial cancer, in the treatment of prostate cancer, radiation can be implanted directly into the prostate through brachytherapy. In addition, the planning of such treatment requires the insertion of a trans-rectal ultrasound probe into the patient's rectum to obtain images that will assist the proper placement of the radiation.

It is clear that access to this controlled act will facilitate efficient and timely diagnostic imaging and treatment by MRTs by eliminating the need for delegation or medical directives. MRTs in Quebec and Alberta perform this act under their own professional authority and New Brunswick recognizes this as inherent to the practice of MRTs. HPRAC found that the MRT curriculum currently includes the knowledge required for the safe

⁶⁴ Access would be through an artificial opening if portions of the patient's anatomy (rectum, bowel) had already been removed or are being bypassed.

performance of these procedures, as well as for appropriate assessment. Competence in the performance of these procedures can be demonstrated at the facility level.

HPRAC is convinced that for the purpose of confirming the role of MRTs in some settings, as well as recognizing the evolution of MRT practice, authorization to perform this act is in the public interest and would optimize the skills of MRTs and other health professionals.

5. That MRTs be authorized to put an instrument, hand or finger beyond the anal verge.

That MRTs be authorized to put an instrument, hand or finger into an artificial opening into the body for the purpose of administering contrast media.

That the regulations under the *Medical Radiation Technology Act, 1991* require the College to develop the standards, limitations and conditions for the performance of this controlled act through a process of interprofessional collaboration with other Colleges, individuals and entities.

Applying electromagnetism for magnetic resonance imaging

The College and Association are requesting that application of electromagnetism be a controlled act authorized to MRTs. Paragraph 7 of subsection 27(2) of the *RHPA* establishes the controlled act of applying or ordering the application of a form of energy prescribed by the regulations under the Act. Electromagnetism is a form of energy prescribed by a regulation under the *RHPA* for the purpose of this paragraph.

Ontario Regulation 226/03 under the *Medical Radiation Technology Act, 1991* prescribes electromagnetism as a form of energy for the purposes of the scope of practice statement. However, in 2003, when magnetic resonance technologists were added as a specialty within the College, the controlled acts authorized to MRTs in the *Medical Radiation Technology Act, 1991* were not amended to include the application of energy in the form of electromagnetism. Rather, through an amendment to a regulation under the *RHPA*, MRTs were exempted from the restriction on the controlled act of applying a prescribed form of energy, for the purpose of applying electromagnetism for magnetic resonance imaging.⁶⁵ As a result, the current legislation lacks transparency on the authority of MRTs to apply electromagnetism for magnetic resonance imaging.

The application of electromagnetism is integral to the practice of MRTs who specialize in magnetic resonance imaging. Authorizing the application of electromagnetism, rather than simply exempting MRTs from the restrictions on the performance of this controlled act, would bring the legislation in line with the regulated status of MRTs in magnetic resonance. It would also be more transparent to the public and other health professionals.

⁶⁵ Ontario Regulation 107/96 s. 3.1 under the *Regulated Health Professions Act, 1991*.

The application of electromagnetism by MRTs is authorized in Quebec and Alberta, and common to MRT practice in Saskatchewan and New Brunswick though not a controlled act.

HPRAC agrees that there should be greater clarity in the legislation as to the forms of energy used by MRTs. HPRAC notes that any legislative framework must remain flexible to address the future evolution of the practice of a profession and the technology or modalities used by health professionals. It is therefore preferable to prescribe the forms of energy in the regulations rather than in the legislation, to allow for future developments in the field.

6. That MRTs be authorized to apply a prescribed form of energy.

That the prescribed forms of energy be specified in the regulations.

That section 3.1 of Ontario Regulation 107/96 under the *Regulated Health Professions Act, 1991* be repealed.

Scope of Practice Statement

The College and Association have requested that the scope of practice statement for MRTs be amended to more accurately reflect the current practice of MRTs, as follows:

The practice of medical radiation technology is the use of ionizing radiation, electromagnetism and other forms of energy prescribed under subsection 12(2) for the purposes of diagnostic and therapeutic procedures, the evaluation of images and data related to the procedures and the assessment of the condition of an individual before, during and after the procedure.

First, the College and Association seek to add a reference to the use of electromagnetism to include MRTs who practise in magnetic resonance imaging, for the reasons described in the discussion on the controlled act request.

They also seek recognition in the scope of practice statement that radiation and energy are now being used by MRTs for both diagnostic and therapeutic purposes. In other words, the evolution of the technology, patient needs and the profession itself has blurred the lines between the use of radiation and energy for diagnostic purposes and for therapeutic purposes. The College and Association have provided evidence that MRTs are participating in procedures that are both diagnostic and therapeutic, and hybrid technologies are being developed to facilitate interventions that blend both purposes.

Another significant departure from the current scope of practice statement is the assertion that MRTs evaluate more than just the *technical* sufficiency of the images they produce, leading to the request for removal of the word “technical”. This proposal implies that MRTs can evaluate images and data to identify abnormalities, implement changes to the procedure, perform

additional or different procedures and consult other health professionals to ensure the best possible care of the patient. As well, inclusion of the word “data” is suggested to acknowledge the move to digital imaging and computerized reporting.

Finally, the proposed scope of practice statement recognizes that MRTs performing either diagnostic or therapeutic interventions are responsible for monitoring the condition of the patient before, during and after the procedure. For example, MRTs in magnetic resonance perform safety screening for metal implants and other contraindications before proceeding with a scan, and are trained to recognize and address signs of emotional distress in patients undergoing scans. MRTs in radiological technology or nuclear medicine might assess blood test results prior to injecting contrast media or other substances. MRTs in radiation therapy monitor the physical, mental and emotional state of patients undergoing a course of radiation for cancer.

HPRAC is of the view that scope of practice statements should describe the broad practice of the profession, so as to provide the parameters within which controlled acts authorized in the profession-specific Acts can be performed. It is not the purpose of a scope of practice statement to itemize the various tasks involved in the practice of any particular profession. Rather, standards of practice and professional practice guidelines should elaborate on the detailed aspects of a profession’s role, whether or not they are controlled acts. The broad scope of practice statement in the legislation is one part of the scope of practice of a profession.

Generally, the proposed scope of practice statement is more detailed than in other Canadian jurisdictions and other regulated health professions. For example, assessment of patients is generally not included and forms of energy are not explicitly cited in scope of practice statements.

HPRAC agrees that the scope of practice statement should reflect the practice reality that radiation and forms of energy are used for both diagnostic and therapeutic interventions. While HPRAC understands that the assessment and monitoring of a patient’s condition before, during and after a diagnostic or therapeutic intervention is central to the practice of the profession and critical to optimal outcomes and patient safety, it is beyond the purpose of a scope of practice statement. Finally, suggesting that MRTs assess images and data rather than assess the technical sufficiency of images and data causes some concern for HPRAC. It risks an interpretation of the knowledge, skill and judgment of MRTs that is beyond their current competencies. Assessment is not a controlled act though it is inherent to the practice of virtually all regulated health professions. Using the term “assess” in the way proposed by the College and Association would appear to closely resemble the concept of “diagnose”. For example, what is the difference between “assessing” an abnormality on an image and “diagnosing” a disease? HPRAC believes the expertise of MRTs lies in providing quality images that facilitate diagnosis by a health professional who has the authority to communicate that diagnosis, as well as in participating in image-guided therapy and administering radiation therapy.

Finally, as stated in the discussion on the controlled act of applying electromagnetism, it is preferable to prescribe the forms of energy used by MRTs in the regulations to facilitate amendments should new forms of energy emerge as part of their practice.

7. That the scope of practice of medical radiation technologists read:

The practice of medical radiation technology is the use of ionizing radiation, electromagnetism and other prescribed forms of energy to produce diagnostic images and data and to perform therapeutic procedures as prescribed in the regulations, and the evaluation of the technical sufficiency of the diagnostic images and data.

Non-Physician Prescribing and Administration of Drugs

The College's submission on HPRAC's review of non-physician prescribing and administration of drugs under the *RHPA* does not propose any changes to the current regulatory framework governing the practice of medical radiation technology.

MRTs are currently authorized to administer any substance by injection or inhalation, when the substance is ordered by a physician. The College submits that restrictions on the substances that MRTs may administer in practice are unnecessary. In fact, the College is concerned that any attempt to specifically list in regulation the substances or classes of substances that could be administered by MRTs would create a barrier to collaborative practice and could also negatively impact access to services and system efficiencies.

HPRAC is persuaded by this argument, specifically because MRTs cannot self-initiate the administration of a substance. To ensure a consistent approach to the regulatory framework for drug authorities across all regulated health professions, however, HPRAC makes the following recommendations.

8. That MRTs continue to be authorized to administer substances by injection or inhalation but that this authorization be expanded to cover orders by physicians as well as other authorized prescribers.

That section 1(1) of O.Reg 855/93 (Professional Misconduct) be repealed and the following substituted:

Contravening a term, condition or limitation imposed on the member's certificate of registration.

That section 1(5) of O.Reg 855/93 (Professional Misconduct) be repealed and the following substituted:

Practicing the profession while the member is in a conflict of interest.

Implementation Proposals

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That section 3 of the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

Scope of practice

3. The practice of medical radiation technology is the use of ionizing radiation, electromagnetism and other prescribed forms of energy to produce diagnostic images and data and to perform therapeutic procedures as prescribed in the regulations, and the evaluation of the technical sufficiency of the diagnostic images and data.
2. That section 4 of the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

Authorized acts

4. In the course of engaging in the practice of medical radiation technology, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:
 1. Administering substances by injection or inhalation.
 2. Performing a prescribed procedure on tissue below the dermis.
 3. Putting an instrument, hand or finger:
 - (a) into an artificial opening of the body for the purpose of tracheal suctioning or for the purpose of administering contrast media;
 - (b) beyond the labia majora;
 - (c) beyond the urethra;
 - (d) beyond the anal verge.
 4. Applying a prescribed form of energy.
3. That section 5 of the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

Additional requirements for authorized acts

- 5.(1) A member shall not perform a procedure under the authority of section 4 unless the procedure is ordered by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the order.

- (2) A member shall perform a procedure under the authority of section 4 in accordance with any requirements prescribed in the regulations.

Grounds for misconduct

- (3) In addition to the grounds set out in subsection 51(1) of the Health Professions Procedural Code, a panel of the Discipline Committee shall find that a member has committed an act of professional misconduct if the member contravenes subsection (1) or (2).

Individual scope of practice for medical radiation technologists

- 5.1 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

4. That section 12 (2) of the *Medical Radiation Technology Act, 1991* be repealed, and that a new section 12(2.1) be added to the *Medical Radiation Technology Act, 1991* as follows:

Regulations

- 12 (2.1) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,

- (a) designating the procedures that a member may perform on tissue below the dermis; and
- (b) specifying requirements for the performance of procedures under the authority of paragraph 3 of section 4.

- (2.2) Subject to the approval of the Lieutenant Governor in Council, the Minister may make regulations prescribing forms of energy, other than ionizing radiation, for the purposes of paragraph 4 of section 4.

5. That a new section 7.1 be added to Ontario Regulation 866/93 under the *Medical Radiation Technology Act, 1991* as follows:

- 7.1(1) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 3 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

- (2) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 3 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.
6. That Ontario Regulation 866/93 under the *Medical Radiation Technology Act, 1991* be amended by adding the following:

STANDARDS OF PRACTICE

- 7.2. The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 3 of section 4 of the Act.
- 7.3. The standards of practice referred to in section 7.2 shall be developed on the recommendation of the Medical Radiation Technology Standards Committee.
- 7.4. For the purposes of section 7.3, the College shall establish the Medical Radiation Technology Standards Committee referred to in section 10 and shall appoint the membership of the Medical Radiation Technology Standards Committee, which shall include, at a minimum, one or more:
- a) members of the Council;
 - b) members of the College (including practitioners and educators);
 - c) persons who are not and have not been members of the College or of the Council; and
 - d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario.
- 7.5. The College shall post the following on its website:
- a) the standards of practice referred to in section 7.2; and
 - b) a list of those members who are authorized to perform a procedure under the authority of paragraph 3 of section 4 of the Act.
7. That the title of Ontario Regulation 226/03 under the *Medical Radiation Technology Act, 1991* be changed to **PRESCRIBED FORMS OF ENERGY AND PRESCRIBED PROCEDURES**
8. That section 1 of Ontario Regulation 226/03 under the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

Prescribed Forms of Energy

1. Electromagnetism is a prescribed form of energy for the purposes of paragraph 4 of section 4 of the Act.
9. That section 2 be added to Ontario Regulation 226/03 under the *Medical Radiation Technology Act, 1991* as follows:

Prescribed Procedures

2. The following are prescribed procedures below the dermis for the purposes of paragraph 3 of section 4 of the Act:
 - a) Taking blood samples from veins.
 - b) Tattooing.
 - c) Administering a substance by injection.
10. That section 3.1 of Ontario Regulation 107/96 under the *Regulated Health Professions Act, 1991* be repealed.
11. That section 1. 1. of Ontario Regulation 855/93 under the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:
 - 1 (a) Contravening a term, condition or limitation imposed on the member's certificate of registration.
12. That a new section 1. 1. (b) of Ontario Regulation 855/93 under the *Medical Radiation Technology Act, 1991* be added as follows:
 1. (b) Exceeding the scope of practice of the profession.
13. That section 1. 5. of Ontario Regulation 855/93 under the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:
 5. Practicing the profession while the member is in a conflict of interest.
14. That section 1. 11. of Ontario Regulation 855/93 under the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:
 11. Carelessly, negligently or unskillfully using ionizing radiation, electromagnetism or a prescribed form of energy.
15. That section 1. 12. of Ontario Regulation 855/93 under the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:
 12. Contravening or failing to maintain a standard of practice of the profession.

THE PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF CHIROPODY AND PODIATRY

The College of Chiropodists of Ontario (CCO), the Ontario Podiatric Medicine Association (OPMA) and the Ontario Society of Chiropodists (OSC) made a joint submission to HPRAC requesting that additions be made to their current controlled acts to enable them to administer substances by inhalation and to dispense drugs for their patients to use in-office and at home. The profession is also requesting an expansion of its current designated drug list and the authority to order laboratory tests.

HPRAC's Central Response

In addition to the current review of the prescribing and use of drugs by non-physicians, the Minister has asked HPRAC to “review issues relating to the regulation of chiropody and podiatry and provide advice as to whether and how there should be changes to existing legislation regarding these related professions”. The Minister asked that HPRAC include “an analysis of the current model of foot care in Ontario, issues regarding restricted titles, and whether the existing limitations on the podiatrist class of members should continue.”

This current review of the prescribing and use of drugs by podiatrists and chiropodists in Ontario will therefore be preliminary to the more extensive examination that HPRAC will be undertaking relating to these professions. For this report, HPRAC has assessed the requests made by the professions for new authorities relating to drugs, keeping in mind that further revisions may be necessary following the outcomes of the upcoming review. It has also taken into account that a new drug regulation was approved for the profession in September 2008, containing authorities for injections, prescriptions and standards of practice, along with drug schedules.¹

In this report, HPRAC recommends to the Minister that the professions of chiropody and podiatry be granted the authority to administer substances by inhalation, and to dispense drugs with terms, limitations and conditions placed on that authority. In addition, HPRAC recommends that one new therapeutic class of drugs be authorized to the profession.

Background on the Professions of Chiropody and Podiatry in Ontario

The Profession

Chiropodists and podiatrists are primary care professionals regulated by

¹ Ontario Regulation 203/94 ss.1-4 (General) made under the *Chiropody Act, 1991, S.O. 1991, c. 20*.

the CCO. Chiropodists and podiatrists deliver patient care within the chiropody scope of practice, that is, the “assessment of the foot and the treatment and prevention of diseases, disorders or dysfunctions of the foot by therapeutic, orthotic or palliative means”.² Active membership with the CCO includes 424 chiropodists and 78 podiatrists, for a total of 502 members.³

The OMPA is a voluntary association representing podiatrists in Ontario, all of whom are registered with the CCO. The OSC is the professional association for chiropodists in Ontario. Membership in the OSC is voluntary and includes approximately 120 members.

The history of chiropody in Ontario is unique. In 1980, the Ontario government adopted a chiropody model of foot care that was adapted from Great Britain. Podiatrists who practised in the province at that time continued to practise under the 1944 statute, but the Board of Regents (the regulatory body of the time) discouraged new podiatrist applicants. When the *Regulated Health Professions Act, 1991 (RHPA)* and *Chiropody Act, 1991* came into force, podiatrists who were registered under the previous Act were “grandfathered” into a new class in the chiropody profession. No new podiatrists could be registered with the CCO after 1993. This came to be known in the profession as the “podiatry cap”.

Foot Care in Ontario

The incidence of foot problems in the population is increasing due to factors such as an aging population, lifestyle issues such as obesity, sports or recreation-related injuries, and growth in immigrant populations who received little or no foot care during formative years.

The increase in incidence of chronic disease is also making new demands on the need for foot care in Ontario. Diabetes is approaching epidemic proportions and has been identified as a priority by the Ministry of Health and Long-Term Care. Many studies confirm the importance and efficacy of foot care for diabetic patients.⁴ Proper podiatric care may help seniors remain in their homes and possibly avoid further medical complications. Podiatrists play an important role in treating patients with osteoporosis and obesity, including children. Studies also show that melanoma is a common foot malignancy and it is more likely to be missed or misdiagnosed than a melanoma located elsewhere.⁵

There have been a number of changes in the practice of foot care in Ontario in recent years. Health human resource shortages mean that there is a growing decline in health professionals, including physicians and orthopaedic surgeons, who are available to provide foot care. According to the profession, many hospitals have closed or downsized their chiropody

² *Chiropody Act, 1991, S.O. 1991, c. 20, s.4.*

³ College of Chiropodists of Ontario. Fall 2008 Bulletin. V.19 (1): 12.

⁴ CCO, Ontario Podiatric Medical Association and Ontario Society of Chiropodists Association. Joint submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 14, 2008: 30.

⁵ Ibid.

clinics to save costs or because they see a more effective role in community delivery for foot care. This has meant that foot care in Ontario has moved from a predominantly hospital-based setting to a community-based setting, where most chiropodists and podiatrists now practise. Some chiropodists are now part of family health teams or work with collaborative professional networks.

Review of Foot Care in Ontario

In response to the request for advice from the Minister in his letter of June 28, 2007, HPRAC is about to undertake a comprehensive review of the foot care model in Ontario, including the scope of practice of the chiropody and podiatry professions. This review will consider the legislative and regulatory framework governing podiatry and chiropody, including whether the podiatric cap should remain in place. It will look at the trend to community-based foot care services, and the effect of foot care models on government priorities, such as chronic disease management, health human resource issues and reduction in wait times. It will include a scope of practice review of both podiatry and chiropody and the qualifications and foundational education of each.

This report on the prescribing and use of drugs in the profession of chiropody is therefore a first step. In the course of this review, HPRAC has decided that it will not consider the request for the ordering of laboratory tests. It will examine that request in the next phase of the review of the profession.

Authorized Acts

While chiropodists and podiatrists share the same scope of practice, the authorized acts under the *Chiropody Act, 1991* reflect the two classes of registrants, with different clinical practice and educational qualifications.

Chiropody

In the course of engaging in the practice of chiropody, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Cutting into subcutaneous tissues of the foot.
2. Administering, by injection into feet, a substance designated in the regulations.
3. Prescribing drugs designated in the regulations.⁶

⁶ *Chiropody Act, 1991, S.O. 1991, c.20, s.5 (1).*

Podiatry

In the course of engaging in the practice of chiropody, a member who is a podiatrist is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Communicating a diagnosis identifying a disease or disorder of the foot as the cause of a person's symptoms.
2. Cutting into subcutaneous tissues of the foot and bony tissues of the forefoot.
3. Administering, by injection into feet, a substance designated in the regulations.
4. Prescribing drugs designated in the regulations.⁷

Regulations

The CCO Council may make regulations, subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, designating the substances that may be administered by injection and the drugs that may be prescribed by members in the course of engaging in the practice of chiropody.⁸

A regulation may designate individual drugs or categories of drugs.⁹

Federal Legislation

Podiatrists, but not chiropodists, in British Columbia, Alberta, Ontario and Quebec are exempt from the prohibitions of trafficking and possessing certain controlled substances under the *Controlled Drugs and Substances Act (CDSA)*¹⁰ with respect to benzodiazepines by virtue of a 2003 Health Canada exemption. Podiatrists in these provinces are permitted to prescribe, administer, sell, provide, send, deliver or transport benzodiazepines as long as they satisfy the Targeted Substances Regulation of the *CDSA* and the provincial regulatory authorities have appropriate mechanisms in place to ensure podiatrists comply with this exemption.¹¹ Podiatrists will be brought under the definition of practitioner under the *CDSA* if and when the New Classes of Practitioners regulations under the *CDSA* comes into force.

⁷ Ibid. c. 20, s.5 (2).

⁸ Ibid. c. 20, s.13(1).

⁹ Ibid. c. 20, s.13 (2).

¹⁰ S.C. 1996, c. 19.

¹¹ Health Canada. "Issuance of a class exemption under section 56 of the Controlled Drugs and Substances Act to reinstate prescribing privileges of benzodiazepines to podiatrists (Effective October 15, 2003)." Available: <http://www.hc-sc.gc.ca/dhp-mps/substancontrol/pol/pol-docs/section-article-eng.php>.

Education and Continuing Competency

Podiatry

Since 1993, graduates of Doctor of Podiatric Medicine (DPM) programs, meeting other registration requirements, are eligible to register with the CCO as chiropractors. No new podiatric class members have been registered since 1993, but ten new DPMs have registered under the title of chiropractor and practise the authorized acts of a chiropractor.

Podiatrists who registered prior to 1993 completed a four-year DPM degree from a college of podiatric medicine in the United States accredited by the Council of Podiatric Medical Education (CPME) in Bethesda, Maryland.¹² The Board of Regents administered a registration examination for podiatrists that included a non-exemptible pharmacotherapy component.

There are currently eight DPM programs in the United States. The Université de Québec at Trois-Rivières offers the only educational program for podiatry in Canada. This four-year program has been in place since 2004. It is primarily based on the U.S. podiatry education model and the CPME standards, and includes didactic and clinical components. The program has a collaborative relationship with the New York College of Podiatric Medicine.

The curriculum at U.S. podiatry schools is similar in the first years to that of medical schools. Pharmacology is taught separately in most programs in the third year, as two half-courses or a full-year course. Podiatrists who are graduates of DPM programs are authorized to prescribe a wide range of pharmaceuticals in other jurisdictions, including narcotics in most U.S. states, as they are in Canada.

Chiropractic

Chiropractic education in Ontario has evolved from a two-year post-secondary program at George Brown College (discontinued in the early 1990s) to the current graduate advanced program in chiropractic offered by The Michener Institute for Applied Health Sciences. Graduates of this three-year, seven-semester full-time program are awarded a Graduate Diploma of Health Sciences (Chiropractic). All applicants must have completed an undergraduate degree from a recognized university and registration is given to those applicants who have completed undergraduate studies in two or more of the following areas: biochemistry, human physiology, psychology, statistics, research methodology, kinesiology and/or physical education.¹³

The Michener Institute's curriculum ensures the minimum qualifications for the prescribing or administration of drugs by chiropractors in Ontario. Course competencies include knowledge of pharmacy and pharmacology; pharmacokinetics and pharmacokinetic principles relating to drug delivery,

¹² CCO, OPMA, OSC. Presentation to HPRAC: *Non-Physician Prescriber Review*. November 24, 2008: 6.

¹³ The Michener Institute. Admission Requirements. Available: <http://www.michener.ca/ft/chiropractic.php#admission>.

absorption, distribution, biotransformation, excretion and relevance to clinical situations; principles of quantification of drug actions, including dose-response studies, drug efficacy, potency and intrinsic activity; pharmacodynamic principles, including action of drugs at the molecular, cellular, organ and system levels and relevance to clinical situations; and systems pharmacology. Other course elements deal specifically with treatments of various foot conditions and anaesthesia and injectables.

Design of a Bridging Program with The Michener Institute

The CCO stated in its submission to HPRAC that until September 26, 2008 it did not have an authorized list for drugs or substances and, therefore, did not have any requirements in place with respect to continuing education and training to ensure competency in prescribing or administering drugs, whether by injection or inhalation. In anticipation of proclamation of the regulation, the CCO initiated discussions with The Michener Institute to develop a relevant “bridging course” for those who do not have the requisite competencies but would like to prescribe or administer drugs in their practices as proposed in their submission. The program will be launched as early as possible in 2009.¹⁴

The part-time bridging program includes three modules: pain management and analgaesic agents, and antibiotics. It will be an independent study program of approximately 39 to 65 hours, and will include both didactic (available online) and clinical components and an examination upon completion.¹⁵

The CCO also stated that if the expanded scope of practice and authorized acts that will be proposed through the chiropody/podiatry review are implemented, there will be wholesale revisions to the educational programs, including moving to a university-level degree in podiatry, plus continuing education and bridging programs for those who wish to practise to the full scope but require additional competencies to do so. The bridging courses relating to prescribing or administering drugs would be incorporated in that wider reconfiguration of the educational component.

What the Profession Has Proposed

The CCO, the OPMA and the OSC made a joint submission to HPRAC requesting additional authorized acts and changes to regulations under the *Chiropody Act, 1991* to enable them to:

1. Administer substances by inhalation, mainly to handle emergency situations and to manage pain;
2. Dispense drugs for their patients to use in-office and at home;

¹⁴ CCO, OPMA and OSC. Joint submission to HPRAC: *Review of Non-Physician Prescribing*: 22. Joint submission to HPRAC: *Chiropody/Podiatry*. November 14, 2008: 27.

¹⁵ HPRAC discussion with Sydney Redpath, Chair, Primary and Critical Care, The Michener Institute for Applied Health Sciences. January 2009.

3. Include new drugs in current drug regulation; and
4. Order laboratory tests.

Preparing for New Authorities

The CCO and the professions recognize the risk of harm associated with administering substances by inhalation. That risk of harm would be mitigated by authorizing only those registrants who demonstrate the requisite competencies to perform that component of the controlled act safely and effectively. A standard of practice would specify clearly the circumstances and conditions under which inhalation could be used and how the substances would be maintained and secured, backed up by the CCO's quality assurance program.

The risk of harm associated with inhalation, in the view of the CCO and the professions, is more than offset by the risk of harm in not being able to use inhalants when responding to emergencies that may occur when performing surgical procedures in non-institutional settings and by the enhanced ability to manage patient pain and stress. A CCO standard of practice and quality assurance program will ensure that registrants are able to perform such procedures safely and effectively and that the substances involved are safely and securely stored and maintained.¹⁶

The profession received approval of its drug regulation in September 2008, and as a result the CCO is currently developing standards of practice, guidelines, continuing education and quality assurance requirements for the prescribing and administration of drugs, and expects to have them completed and in force by late 2009.¹⁷

In its written submission to HPRAC, the CCO explained that in order to ensure that each chiropractor is competent to prescribe the drugs listed in the new regulation safely and effectively, it is presently undertaking a registrant-by-registrant investigation of competencies. The CCO's investigation relies heavily on the pharmacotherapy education received as part of each registrant's diploma program and any subsequent post-graduate or continuing education programs successfully completed thereafter. Terms, conditions and limitations applying to prescribing will be attached to each registration, unless and until that registrant demonstrates full competencies to the CCO's satisfaction. The same process will be applied to any expanded authorities awarded to the profession.¹⁸

Until the assessment is completed, the CCO is uncertain of the number of chiropractic-trained members who may need a bridging program to become ready for the authority to prescribe or administer drugs.

The CCO stated in its written submission that those relatively recent graduates of DPM programs who are practising in Ontario as chiropractors,

¹⁶ CCO, OPMA and OSC. Joint submission to HPRAC: *Review of Non-Physician Prescribing*: 21.

¹⁷ Ibid 22, 26-27.

¹⁸ Ibid. 23

because of the podiatric cap, are deemed by the CCO to be competent to prescribe the current and proposed substances and drugs safely and effectively.

1. Administration of Substances by Inhalation

The proponents are requesting the authority to administer substances by inhalation. Specifically, podiatrists and chiropodists are seeking the authority to administer medical gases such as oxygen and nitrous oxide. The authority would be used to administer nitrous oxide for pain management and to respond to patient duress and oxygen to respond to emergencies.

Proponents' Rationale

Responding to Emergencies

Most chiropodists and nearly all podiatrists provide their services in community-based clinics where there is little or no institutional support. They perform surgical procedures on subcutaneous tissues of the foot, and in the case of podiatrists, into the bony structures as well. These procedures entail risk of harm that could give rise to emergencies to which, for patient safety reasons, chiropodists and podiatrists should be able to respond.¹⁹

The CCO is concerned that since oxygen is classified as a drug, chiropodists and podiatrists will not be able to administer oxygen in an emergency. Proponents said that an oxygen tank would normally be kept in the operatory. It would be used to respond to patients who exhibit anxiety, or have circulatory or respiratory distress in the course of a procedure. Protocols for equipment maintenance and staff training would be put into place in each care setting.

According to the CCO, the number of patients expected to require emergency interventions is relatively small, but the benefits to those patients is significant.

Managing Pain or Distress

Proponents said that podiatrists and some chiropodists are trained to use nitrous oxide and oxygen in conscious sedation to manage pain or distress during surgical procedures. Administering these substances by inhalation represents best practices in other Canadian and foreign jurisdictions. Chiropodists and podiatrists in Ontario are not authorized to administer substances by inhalation, and pain management may not be sufficient for patients. The majority of members do not work in settings that include anaesthesiologists and access to the administration of nitrous oxide by other practitioners is unavailable. Professionals and patients in Ontario are disadvantaged by having to limit pain management techniques to non-inhalants.

¹⁹ Ibid. 15.

The Michener Institute redesigned its chiropractic program in 2006/07, and it is now identified as the “graduate advanced program in chiropractic.” Graduates of this redesigned program have the competencies to administer oxygen by inhalation but course content does not include the administration by inhalation of nitrous oxide.²⁰ Graduates of discontinued programs, including programs offered by George Brown College and The Michener Institute for Applied Health Sciences prior to September 2006, have the competencies to administer oxygen only. The proponents stated in its written submission that those relatively recent graduates of DPM programs who are practising in Ontario as chiropractors because of the podiatric cap are deemed by the CCO to be competent to prescribe the current and proposed substances and drugs safely and effectively.

Along with the educational bridging program at The Michener Institute, the CCO is developing a quality assurance program to ensure that registrants are able to perform the procedures safely and effectively and that the substances involved are safely and securely stored and maintained.²¹

The CCO would restrict the authority to administer a substance by inhalation to those registrants who demonstrate the requisite competencies to perform the procedure safely and effectively and would develop a standard of practice with respect to the use of inhalants for purposes of pain management and emergencies.²²

What HPRAC Found

What Other Jurisdictions Do

In Manitoba, legislation allows podiatrists to inject medications. There is no reference to administration of drugs or substances by inhalation, however, the authority is inferred, since podiatrists must maintain an emergency kit and oxygen in good order in the clinical suite and be trained in its use.²³ In British Columbia, podiatrists are limited to administering local anaesthesia.²⁴ Neither British Columbia nor Quebec authorize podiatrists to administer nitrous oxide.

The use of local anaesthesia by podiatrists is authorized by statute in Alabama, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, West Virginia and Wyoming.

The use of general anaesthesia is more limited. It is authorized, with certain limitations, by statute in Georgia (under direction of a physician) and in Maine (under supervision of a medical or osteopathic physician).²⁵

²⁰ HPRAC discussion with Sydney Redpath, Chair, Primary and Critical Care, The Michener Institute for Applied Health Sciences. January 2009

²¹ CCO, OPMA, OSC. Submission to HPRAC: *Review of Non-Physician Prescribing*. 21.

²² Ibid. 18.

²³ HPRAC. *Prescribing and Use of Drugs by Non-Physician Health Professionals: A Jurisdictional Review of the Professions of Chiropractic & Podiatry*. November 2008.

²⁴ Ibid.

²⁵ American Podiatric Medical Association, Inc. *Scope of Practice Statutory Compilation, APMA State Reference Manual*. November 2007.

Podiatrists would be able to use nitrous oxide without supervision in Vermont and New York to support the use of general anaesthesia.

Managing the Risk of Harm

Nitrous Oxide

HPRAC's consultations indicated that there is broad support among medical specialists for the authority to administer conscious sedation when surgeries are being performed. Among others, a leading orthopaedic surgeon told HPRAC that, "Access to nitrous oxide is a must for anyone doing in-office surgery or treatments".²⁶

The College of Respiratory Therapists of Ontario has recommended additional training and strict standards for the safe use of oxygen and nitrous oxide by other professionals in their offices. Respiratory therapists say there is minimal risk in administration of oxygen for emergency purposes, and that other emergency protocols must also be observed.²⁷

HPRAC is satisfied that with the additional training that the CCO is proposing along with the development of appropriate standards of practice, guidelines and quality assurance programs, members of the CCO will be competent to safely administer oxygen and nitrous oxide to their patients.

An Emergency Kit and Oxygen

HPRAC considered the need for an emergency medications kit, or "crash cart" as it is generally described, for chiropodists and podiatrists, and heard during the consultations with colleges and other stakeholders that since minor surgery is being performed on site, chiropodists and podiatrists should have the knowledge and necessary tools to handle an emergency situation.

The standard emergency medications are as follows:

- **Oxygen:** 100 percent for most medical emergencies (same concentration for both adults and children).
- **Epinephrine:** Used for anaphylactic shock, severe asthmatic attack not responsive to inhaled salbutamol and cardiac arrest. Injected into the muscle (0.3-0.5 mg) or IV (0.1 mg).
- **Nitroglycerin:** Used to treat angina (chest pains). Administered under the tongue (sublingual) at 0.3 to 0.4 mg.
- **Diphenhydramine or chlorpheniramine:** Used for moderate to severe allergic reactions. Administered in the muscle or IV at 10-50 mg, or 1.0 mg/kg in children.

²⁶ Summary notes from meeting between HPRAC and key interveners.

²⁷ HPRAC and College of Respiratory Therapists of Ontario Meeting Notes. December 2, 2008.

- **Salbutamol:** Bronchodilator for asthmatic bronchospasm. Two puffs (100 micrograms/puff) or one puff for children.
- **ASA:** Administered if acute heart attack suspected. 160-325 mg in adults.²⁸

HPRAC concludes that an emergency kit should be available for in-office chiropractic and podiatry procedures. The CCO will need to establish standards, protocols and practice guidelines for emergency situations, including a requirement that members maintain current certification in basic cardiopulmonary resuscitation.

As a standard of practice, emergency care equipment and drugs should be required in the clinics with protocols established respecting the maintenance, storage and use of the emergency kit and training required for the professionals who might use the equipment or drugs or perform the emergency activity.

2. Dispensing

The proponents have requested that dispensing drugs be included in the profession's authorized acts to enable chiropractors and podiatrists to provide oral and topical medications that are classified as "drugs" for self-care and emergency purposes and to use topical and oral medications in their clinics. This would eliminate excessive reliance and ambiguity related to using the emergency provisions in section 29 of the *RHPA*.

Proponents' Rationale

The proponents said that the lack of a clear definition of dispensing in the *RHPA* means that members are uncertain about their authority to use topical and oral medicines in their clinics, and to dispense medicines to patients for self-care. Members said they need the authority to dispense a drug they are authorized to prescribe (such as topical medications and drug samples) for use by the patient at home for self-care purposes.²⁹

This authority will remove any ambiguity in the current practice of podiatrists and chiropractors who provide their patients with oral or topical drugs or drug samples in their clinics and allow the CCO to more effectively regulate the practice. The CCO notes that practitioners currently do so safely and effectively and the lack of complaints to the CCO from patients or providers supports this conclusion.

In its written submission to HPRAC, the profession states that the CCO would restrict access to "administering a substance by inhalation" to those registrants who demonstrate the requisite current competencies to perform the procedure safely and effectively and would promulgate a standard of practice with respect to the use of inhalants for purposes of pain

²⁸ Royal College of Dental Surgeons of Ontario. *Guidelines, Use of Sedation and General Anesthesia in Dental Practice*. For distribution, February 2009. In press and referenced with permission.

²⁹ CCO, OPMA, OSC. Submission to HPRAC: *Review of Non-Physician Prescribing*: 10.

management and emergencies.³⁰ The CCO indicates that limitations on dispensing should be expressed in regulation and specify those classes of drugs that could be dispensed by members. Conditions would be placed on the purposes for which a drug could be dispensed, and a professional misconduct regulation would require that drugs could only be dispensed without mark-up or profit to the member.³¹

The CCO said that there is no need for additional education or training for the dispensing function.

Members said that without the authority to dispense, in communities where access to a pharmacist may be limited or where the patient is not able to get to a pharmacy easily, delays in treatment may occur and the condition may worsen. This is particularly the case in foot care, where elderly or diabetes patients may have difficulty obtaining the drug needed to support their treatment.

What HPRAC Found

Transparency

HPRAC recognizes that while the act of dispensing has been interpreted for many years by the CCO as authorized through section 29 of the *RHPA*, these emergency provisions were not intended to authorize the routine practice of a profession, or to provide a back-door entry to controlled acts. Rather, it is important that the authority to perform a controlled act is clear to members, their patients and other professionals. The statutory authority also provides clear accountability for the CCO to regulate the profession to the highest standard, with practice standards, quality assurance programs and professional misconduct rules in place and implemented.

Readiness for Change

The profession's written submission to HPRAC suggests that most members of the chiropractic profession who wish to administer substances by inhalation are expected to need an educational bridging program. The submission further states that some members of the podiatry class who have not maintained their currency with respect to inhalation may also take the bridging program. The submission also emphasized that only those registrants who wish to self-initiate the administration of substances by inhalation will be required to successfully complete the bridging program. No additional education or training was envisaged for the dispensing function as proposed

What other jurisdictions do

There are no specific authorities for dispensing in Canadian jurisdictions that regulate chiropractic. In Alberta, authorized by the Lieutenant Governor in Council and subject to the *CDSA*, a podiatrist may purchase and supply drugs, chemicals and compounds to patients. They may prescribe those

³⁰ Ibid. 18.

³¹ Ibid. 18.

authorized drugs, chemicals or compounds for compounding under the direction of a pharmacist or restricted practitioner under the *Pharmaceutical Profession Act*.

In British Columbia, a podiatrist is permitted to “prescribe, compound, or administer a drug listed in Schedules 1 or 2 of the Act, including Schedule F of the Food and Drugs Act.” In Quebec, every podiatrist is authorized to use the medications which may be needed in the practice of the profession, and to administer and prescribe medications to patients, provided that they are medications contemplated by the regulations made under the Act. He or she may also issue attestations relating to the supplying of such medications.

Conditions and Limitations on Dispensing

The Ontario College of Pharmacists (OCP) said that much of what has been described as “dispensing” appears to be distributing drugs, rather than performing the full act of dispensing as required for pharmacists under the *Drug and Pharmacies Regulation Act (DPRA)*. OCP feels that other professions that dispense drugs should be held to the same high standards as pharmacists under the *DPRA*.³²

In order to dispense as the proponents describe the act (i.e., providing patients with a supply of medication to use at home), the OCP suggested that chiropody/podiatry could be authorized the controlled act of dispensing with comparable authority to pharmacy technicians, who have terms, limitations and conditions set in the standards of practice that narrowly define their dispensing authority. This way, the requirements remain stringent, and reasonable limits and standards could be developed for other professions who dispense drugs.³³

There is a distinct difference in the accountabilities of pharmacists under the *DPRA* and what is requested by other professionals to allow them to distribute drugs, including samples. Appropriate standards, limitations and conditions should be in place, as recommended by the OCP to restrict dispensing activities to specific ranges of knowledge and classes of drugs that are within the scope of practice of chiropody and podiatry.

Regarding dispensing samples, HPRAC has concluded that providing a drug sample constitutes dispensing, and that the same standards that apply to dispensing should apply to providing samples.

3. Classes versus Lists

The CCO is requesting the use of classes of drugs in the drug regulation rather than lists of individual drugs.

³² Notes from meeting between HPRAC and OCP and OPA. November 25, 2008.

³³ Ibid.

Proponents' Rationale

The current regulation lists individual drugs that may be prescribed by chiropractors and podiatrists. Proponents told HPRAC that the requirement to list each substance or drug available to podiatrists and chiropractors was a cause of a delay of many years in obtaining Lieutenant Governor in Council approval of the drug regulation. Adopting categories or classes would avoid lengthy delays in obtaining approval or amendment to regulations. These delays have meant that chiropractors and podiatrists have been unable to use the latest and most effective drugs and substances, and patients may not receive the most appropriate medication or the best care. Categories or classes would allow chiropractors and podiatrists to have access to the latest and most effective proven drugs and substances in their treatment regimens.

The CCO said that problems also occur when patients exhibit multiple allergies or sensitivities that mean first-line drugs are contraindicated. There are also issues of cross reactivity that require flexibility in the prescription of drugs.³⁴

What HPRAC Found

HPRAC notes that the current regulatory approvals process is being addressed with its recommendation for a new drug approvals framework for Ontario, which includes the regulation of therapeutic classes of drugs and a separate transparent process for identifying specific agents and the terms, limitations and conditions that would apply to a class of drug designated in the regulation.

4. Additions to CCO's Drug Regulations

The CCO is requesting that six additional classes of drugs be added to its drug regulation, which came into force on September 26, 2008, including medical gases (oxygen and nitrous oxide), emergency medications, viscosupplementation agents, oral antifungals, gout therapy cytoprotective agents and corticosteroids.

Administration of Oxygen and Nitrous Oxide by Inhalation

Chiropractors and podiatrists are seeking to administer oxygen and nitrous oxide for pain management and in emergency situations. Nitrous oxide and oxygen are important components of the chiropractors' and podiatrists' emergency kit, and are important for pain management. With proper training it is appropriate for chiropractors and podiatrists to be able to administer these substances.

HPRAC recommends that the profession be authorized to administer substances by inhalation in limited circumstances.

³⁴ CCO, OPMA, OSC. Submission to HPRAC: *Review of Non-Physician Prescribing*: 12.

Oral Antifungals

The proponents state that topical antifungals may not penetrate far enough into deep toenail infections to eradicate the infection and that oral antifungals are necessary to effectively treat this type of infection. The prescribing of oral antifungals reflects best practices of the profession, provides better outcomes for patients and can avoid a referral to a physician for a needed prescription.

HPRAC agrees that chiropodists and podiatrists should have access to oral antifungals to treat infections of the foot. This will enable practitioners to treat infections more effectively, will benefit the patient, and possibly limit complications and unnecessary visits to physicians.

Cytoprotective Agents and Corticosteroids to Treat Gout

Proponents are also seeking cytoprotective agents and corticosteroids to treat gout.

Cytoprotective agents can carry serious toxicities. HPRAC is also concerned that gout that does not respond to diet, NSAIDs and/or corticosteroids should be referred to a rheumatologist. Further discussion of this issue is required, and may be revisited as part of the upcoming scope of practice review.

Viscosupplementation

Chiropodists are seeking viscosupplementation to treat the smaller joints of the foot.

HPRAC feels that further consideration is required regarding the use of viscosupplementation agents. HPRAC learned during its pharmacological review that viscosupplementation is a new type of treatment that is usually used in larger joints such as the knee or shoulder. More information is needed on the effectiveness of this treatment and further study is required to determine if this practice is within the scope of practice of the profession. This issue will therefore be revisited as part of the upcoming scope of practice review.

5. Authority to Order Laboratory Tests

The CCO is asking that chiropodists and podiatrists be granted the authority to order laboratory tests that are consistent with standards of practice and authorized acts. HPRAC will be considering this request as part of the scope of practice review.

Conclusions

HPRAC recognizes the importance of foot care in Ontario, and the important role that chiropodists and podiatrists play in foot care. Providing chiropodists and podiatrists with the authority to administer substances by inhalation, with appropriate competencies, education and standards of

practice in place will enable professionals to manage pain and to respond to emergency situations that may occur in the course of their practice.

HPRAC supports the authority for the profession to dispense drugs following clear standards of practice and in accordance with terms, limitations and conditions.

HPRAC is about to undertake a major review of the scope of practice of the professions of chiropody and podiatry in Ontario. While minor changes to the current drug regulation are recommended in this report, others that may involve a change in scope of practice will be examined in the context of the broader ministerial referral.

The current regulation 203/94 made under the *Chiropody Act, 1991* prescribes standards of practice for chiropodists who administer substances by injection and prescribe drugs through schedules containing drug lists. HPRAC is recommending that these provisions be repealed in favour of interprofessional collaborative standards of practice for administering a substance, either by injection or inhalation, and for prescribing or dispensing drugs.

Recommendations

- 1:** That chiropodists and podiatrists be authorized to administer a substance by inhalation. Standards of practice should be determined by an interprofessional process. Terms, limitations and conditions should be placed on each member's registration respecting the administration of substances by inhalation.
- 2:** That standard emergency care equipment and drugs be required onsite in chiropody/podiatry clinics, with protocols established respecting the maintenance, storage and use of the emergency kit, and training required for regulated professionals and unregulated personnel who may be required to utilize the equipment or perform emergency activity.
- 3:** That chiropodists and podiatrists be authorized to dispense drugs. That standards of practice for the dispensing of drugs be developed by an interprofessional committee, taking into account the proficiencies of the profession, that describes standards, limitations and conditions that are appropriate for the dispensing requirements of the profession.
- 4:** That oral antifungals be added to the classes of drugs for podiatrists and chiropodists, and that anti-gout agents and the issue of visco-supplementation be considered as part of the scope of practice review.
- 5:** That the following classes of drugs be included in a designated drugs regulation under the *Chiropody Act, 1991*. The specific agents and any terms, limitations or conditions attached to the authority to prescribe drugs would be developed through a new drug approvals framework.

Class	Specific Agents
Class: Antihistamines	Hydroxyzine
Class: Anti-infective Agents Sub-class: Antibacterials	Amoxicillin trihydrate Amoxicillin trihydrate/clavulanate potassium Azithromycin dihydrate Cefadroxil Cephalexin monohydrate Ciprofloxacin hydrochloride Clindamycin hydrochloride Cloxacillin sodium Sulfamethoxazole/trimethoprim Erythromycin Tetracycline hydrochloride Bacitracin Framycetin sulfate Fusidic acid Gentamicin sulfate Mupirocin Silver sulfadiazine Erythromycin Bacitracin/neomycin sulphate Neomycin sulphate/polymyxin B sulphate/bacitracin Neomycin sulphate/polymyxin B sulphate/gramicidin
Class: Anti-infective Agents Sub-class: Antifungals	Ciclopirox olamine Clotrimazole Ketoconazole Miconazole nitrate Nystatin Terbinafine HCl Tolnaftate cream Undecylenic acid
Class: Anti-infective Agents Sub-class: Antivirals	
Class: Cardiovascular Drugs Sub-class: Sclerosing Agents	Alcohol Bleomycin OK-432/Picibanil Ethibloc Percent sodium tetradecyl sulfate Others
Class: CNS Agents Sub-class: General Anesthetics Sub-sub-class: Inhalation Anesthetics	Nitrous Oxide
Class: CNS Agents Sub-class: Analgesics and Antipyretics Sub-sub-class: NSAIDs	Diclofenac potassium Diclofenac sodium Diclofenac sodium/misoprostol Diflunisal Ibuprofen Indomethacin Meloxicam Ketorolac tromethamine Naproxen Naproxen sodium Tiaprofenic acid

Class	Specific Agents
Class: CNS Agents Sub-class: Anxiolytics, Sedatives and Hypnotics Sub-sub-class: Benzodiazepines	Diazepam Lorazepam
Class: Hormones and Synthetic Substitutes Sub-class: Adrenals	Betamethasone sodium phosphate beta-acetate Dexamethasone sodium phosphate Hydrocortisone sodium succinate Methylprednisolone acetate Triamcinolone acetonide Amcinonide Betamethasone dipropionate Betamethasone valerate Clioquinol/hydrocortisone Desoximetasone Flumethasone/clioquinol Fluocinonide Halcinonide Hydrocortisone Hydrocortisone 17 valerate Mometasone furoate Triamcinolone acetonide
Class: Local Anesthetics	Bupivacaine Lidocaine hydrochloride (with or without epinephrine) Mepivacaine hydrochloride
Class: Skin and Mucous Membrane Agents	Imiquimod Cantharidin Podophyllin Salicylic acid combination (one percent or less Cantharidin with two percent or less Podophyllin with 30 percent or less Salicylic acid) Salicylic acid (70 percent or less) Silver Nitrate (95 percent or less) 5-Fluorouracil (five percent or less) Salicylic acid/lactic acid combination (Salicylic acid 16.7 percent and Lactic acid 16.7 percent in flexible collodion) Salicylic acid/lactic acid/formalin combination (Salicylic acid 25 percent, Lactic acid 10 percent, Formalin 5 percent) Aluminum Chloride hexahydrate Cantharidin Podophyllin Topical benzocaine Capsacin Diethylamine salicylate Lidocaine/prilocaine Becaplermin Santyl collagenase
Class: Vitamins	B12-cyanocobalamin
Class: Emergency Medications	Oxygen Epinephrine (IV or IM), Antihistamines (IM) Salbutamol ASA

Implementation Proposals

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That paragraph 2 and 3 of subsection 5(1) of the *Chiropody Act, 1991* be repealed and the following substituted:

Authorized acts

5(1) In the course of engaging in the practice of chiropody, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

2. Administering by inhalation, or injection into feet, a substance designated in the regulations.
3. Prescribing, dispensing and selling a drug that the member may prescribe, dispense and sell under the regulations.

2. That paragraph 3 and 4 of subsection 5(2) of the *Chiropody Act, 1991* be repealed and the following substituted:

5(2) In the course of engaging in the practice of chiropody, a member who is a podiatrist is authorized, subject to the terms, conditions and limitation imposed on his or her certificate of registration, to perform the following:

3. Administering by inhalation, or injection into feet, a substance designated in the regulations.
4. Prescribing, dispensing and selling a drug that the member may prescribe, dispense and sell under the regulations.

3. That the *Chiropody Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts for chiropodists

5.1 A member shall perform a procedure under the authority of paragraph 2 or 3 of subsection 5(1) in accordance with any requirements prescribed in the regulations.

Additional requirements for authorized acts for podiatrists

5.2 A member who is a podiatrist shall perform a procedure under the authority of paragraph 3 or 4 of subsection 5(2) in accordance with any requirements prescribed in the regulations.

Individual scope of practice for podiatrists

5.3 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health professionals.

4. That section 13 of the *Chiropractic Act, 1991* be repealed and the following substituted:

Regulations

13. Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations regulating the prescribing, dispensing and sale of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing, dispensing and sale of drugs.

5. That sections 1 through 4 of Ontario Regulation 203/94 under the *Chiropractic Act, 1991* (General) be repealed and replaced by the following:

PART I

CONTROLLED ACTS AND STANDARDS OF PRACTICE

1.(1) The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 2 and 3 of subsection 5(1) and paragraph 3 and 4 of subsection 5(2) of the Act.

(2) The standards of practice referred to in subsection (1) shall be developed on the recommendation of the Chiropractic Standards Committee.

(3) The College shall establish the Chiropractic Standards Committee referred to in subsection (2) and shall appoint the membership of the Chiropractic Standards Committee, which shall include, at a minimum, one or more:

(a) members of the Council;

(b) members of the College (including practitioners and educators);

(c) persons who are not and have not been members of the College or of the Council;

(d) members of the College of Physicians and

Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario;

(e) members of the College of Respiratory Therapists of Ontario, approved by the College of Respiratory Therapists of Ontario; and

(f) members of the Ontario College of Pharmacists, approved by the Ontario College of Pharmacists.

(4) The College shall post the following on its website:

(a) the standards of practice referred to in subsection (1); and

(b) a list of those members, who are authorized to perform a procedure under the authority of paragraph 2 and 3 of subsection 5(1) and paragraph 3 and 4 of subsection 5(2).

6. That Schedule 1, Schedule 2, Schedule 3 and Schedule 4 of Ontario Regulation 203/94 under the *Chiropody Act, 1991* (General) be repealed.

7. That section 7 of Ontario Regulation 830/93 under the *Chiropody Act, 1991* (Registration) be amended by adding the following paragraph:

GENERAL TERMS, LIMITATIONS AND CONDITIONS

4. (1) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of either paragraph 2 or 3 of subsection section 5(1) or paragraph 3 or 4 of subsection 5(2) of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

(2) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of either paragraph 2 of subsection 5(1) or paragraph 3 of subsection 5(2) of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

(3) For the purposes of this section, “Drug List” has the meaning given to it in the *Regulated Health Professions Act, 1991*.

(4) A member holding a general or academic class certificate may prescribe, dispense, or sell the following classes of drugs:

- (a) antihistamines
- (b) anti-infective agents: antibacterials, antifungals, antivirals
- (c) CNS agents: general anaesthetics, analgesics and antipyretics, anxiolytics, sedatives, and hypnotics
- (d) emergency medications
- (e) hormones and synthetic substitutes: adrenals
- (f) local anaesthetics
- (g) sclerosing agents
- (h) skin and mucous membrane agents
- (i) vitamins

(5) A member may only prescribe, dispense or sell those drugs within the classes designated in subsection that are listed in the Drug List and must prescribe, dispense or use those listed drugs in accordance with the terms, limitations and conditions contained in the Drug List.

8. That section 1(4) of Ontario Regulation 750/93 under the *Chiropody Act, 1991* (Professional Misconduct) be repealed and the following substituted:

4. Delegating an act set out in paragraph 1 or 2 of subsection 5(1) of the Act or paragraph 1, 2 or 3 of subsection 5(2) of the Act except as permitted by the *Regulated Health Professions Act, 1991* or the regulations made thereunder or under the Act, or delegating an act set out in paragraph 3 of subsection 5(1) or paragraph 1 or 4 of subsection 5(2) of the Act.

9. That section 1(7) of Ontario Regulation 750/93 under the *Chiropody Act, 1991* (Professional Misconduct) be repealed and the following substituted:

7. Prescribing, dispensing, selling or administering a drug or substance for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell or administer drugs or substances.

10. That Ontario Regulation 750/93 under the *Chiropody Act, 1991* (Professional Misconduct) be amended by adding the following sections:

1.1 Exceeding the scope of practice of the profession.

8.1 Recommending or providing unnecessary services.

- 15.1** Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.
- 31.1** Contravening, while engaged in the practice of chiropody, any federal or provincial law or municipal by-law with respect to the prescribing or dispensing of any drug or substance or mixture of drugs and substances.

THE PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF DENTAL HYGIENE

The College of Dental Hygienists of Ontario (CDHO), the Canadian Dental Hygienists Association (CDHA) and the Ontario Dental Hygienists Association (ODHA) made a joint submission to HPRAC requesting the authority to administer substances by injection or inhalation, including anaesthesia and anxiolytics, and for the controlled act of “prescribing, dispensing or compounding a drug,” including antibiotics, smoking cessation agents and drugs for oral preventive care.

HPRAC’s Central Response

HPRAC is recommending that the dental hygienists be authorized to prescribe, dispense, sell and compound drugs. Within that authority, HPRAC is recommending that the designated drug regulation made under the *Dental Hygiene Act, 1991* specify classes of drugs, and that the classes of drugs include anti-infectives and the sub-class of cariostatic agents in the class of miscellaneous therapeutic agents. The specific agents that could be prescribed, dispensed, sold and compounded would include fluoride treatments and preventive oral rinses (chlorhexidine). HPRAC also recommends an interprofessional standards committee to collaborate in developing standards of practice for these authorized acts.

Dental Hygiene and How Dental Hygienists are Regulated Today

A dental hygienist is an oral health professional who performs a variety of roles including clinical therapy, health promotion, education, administration and research in a variety of practice environments, including in dental offices, independent practices and settings such as long-term care homes.¹ Dental hygiene focuses on preventive oral health services and helping clients maintain optimal oral health. The *Dental Hygiene Act, 1991* describes the scope of practice of dental hygiene as, “the assessment of teeth and adjacent tissues and treatment by preventive and therapeutic means and the provision of restorative and orthodontic procedures and services.”²

The majority of dental hygienists work with general practitioner or specialist dentists and dental assistants in stand-alone dental practices. Until recently, there has been little opportunity for collaboration with other health care providers in, for example, family health teams or nurse-led clinics.

Amendments to the *Dental Hygiene Act, 1991* made in 2007 authorized qualified dental hygienists to self-initiate some procedures that previously had been performed under delegation or supervision by a member of the Royal College of Dental Surgeons of Ontario (RCDSO). As a result, a number

¹ College of Dental Hygienists of Ontario. *CDHO Definition of a Dental Hygienist*. Available: http://www.cdho.org/About_Definition.htm.

² *Dental Hygiene Act, 1991*, S.O. 1991, c. 22, s.3.

of dental hygienists are exploring options to work in new practice settings including independent practice, multidisciplinary venues, with homebound clients, or in various forms of non-traditional practice including long-term care facilities, schools and mobile clinics. Some are also opening practices in rural and remote areas.³

The CDHO regulates the profession of 10,464 members, 2,109 of whom are qualified to self-initiate some procedures. The CDHA is the national organization that represents more than 14,000 dental hygienists who work across Canada. The ODHA represents the interests of member dental hygienists in Ontario and works to advance the profession.

Before December 31, 1993, the profession of dental hygiene was regulated by the RCDSO. With the proclamation of the *Regulated Health Professions Act, 1991(RHPA)*, dental hygiene became a self-regulating profession. Under this structure, dental hygienists were required to obtain an order from a dentist to perform the authorized act of scaling teeth and root planing, including curetting surrounding tissue.

With the passage of the *Health System Improvements Act, 2007*, dental hygienists gained the authority to self-initiate the authorized act based on their own clinical assessment and the absence of complicating factors, without need of a prior dentist's order. Self-initiation authority is designed to give clients greater access to preventive oral care in a variety of environments and the right to choose among alternate health professionals. To date, some 60 dental hygienists in Ontario have established independent practices, including some storefront and some mobile operations.

The CDHO has developed a Standard of Practice for Self-Initiation and reviews applications from registrants to determine if they meet criteria for self-initiation.⁴

Dental hygienists are beginning to service those populations who, for whatever reason, couldn't or wouldn't access the oral preventive and treatment services they need through the traditional dental office. The ability to self-initiate has changed the paradigm of dental hygiene care.

Elaine Powell
Practice Advisor, Patient Relations
College of Dental Hygienists of Ontario

³ CDHO. Submission to HPRAC: Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act. November 12, 2008: 2.

⁴ CDHO. College of Dental Hygienists of Ontario 2007. Annual Report. 3.

Authorized Acts

In the course of engaging in the practice of dental hygiene, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Scaling teeth and root planing including curetting surrounding tissue.
2. Orthodontic and restorative procedures.⁵

The act of scaling teeth and root planing, including curetting surrounding tissue, must be performed in accordance with any requirements prescribed in the regulations, and may be performed either:

- (a) on the member's own initiative, if none of the contraindications prescribed in the regulations to performing the procedure are present, and if the member ceases the procedure if any of the prescribed contraindications to continuing the procedure are present, or
- (b) if the procedure is ordered by a member of the RCDSO.⁶

For orthodontic and restorative procedures, the procedure must be ordered by a member of the RCDSO.

Regulations

The CDHO Council may make regulations, subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, as follows:

- (a) specifying drugs that a member may use in the course of engaging in the practice of dental hygiene;
- (b) prescribing requirements for performing scaling teeth and root planing, including curetting surrounding tissue, which requirements may include the educational and experiential qualifications that must be obtained in order for a member to undertake those procedures on the member's own initiative;
- (c) prescribing contraindications to a member performing or continuing to perform on the member's own initiative the procedures of scaling teeth and root planing, including curetting surrounding tissue.⁷

A regulation made under clause (a) may specify individual drugs or categories of drugs.⁸

⁵ Dental Hygiene Act, 1991, S.O. 1991, c. 22, s.4.

⁶ Ibid: c. 22, s.5(1).

⁷ Ibid: c. 22, s.12(1).

⁸ Ibid: c. 22, s.12(2).

If a patient has not received clearance from a physician or dentist, a dental hygienist may not independently proceed with scaling teeth and root planing, including curetting surrounding tissue, if contraindications exist. The contraindications are:

1. Any cardiac condition for which antibiotic prophylaxis is recommended in the guidelines set by the American Heart Association (AHA), as those guidelines are amended from time to time, unless the member has consulted with either the patient's physician, dentist or registered nurse in the extended class (RN(EC)) and determined that it is appropriate to proceed if the patient has taken the prescribed medication per the AHA guidelines.
2. Any other condition for which antibiotic prophylaxis is recommended or required.
3. An unstable medical or oral health condition, where the condition may affect the appropriateness or safety of scaling and root planing, including curetting surrounding tissue.
4. Active chemotherapy or radiation therapy.
5. Significant immunosuppression caused by disease, medications or treatment modalities.
6. Any blood disorders.
7. Active tuberculosis.
8. Drug or alcohol dependency of a type or extent that it may affect the appropriateness or safety of scaling and root planing, including curetting surrounding tissue.
9. High-risk of infective endocarditis.
10. A medical or oral health condition with which the member is unfamiliar or that could affect the appropriateness, efficacy of or safety of the procedure.
11. A drug or combination of drugs with which the member is unfamiliar or which could affect the appropriateness, efficacy or safety of the procedure.⁹

In addition, a member may not perform the procedure of scaling teeth and root planing, including curetting surrounding tissue, if the member is in doubt as to the status or accuracy of the medical or oral history of the patient.¹⁰

⁹ Ontario Regulation 218/94, s.7(1) made under the Dental Hygiene Act, 1991, S.O. 1991, c. 22.

¹⁰ Ontario Regulation 218/94, s.7(2) made under the Dental Hygiene Act, 1991, S.O. 1991, c. 22.

Under the Dentistry Regulation of the *Drug and Pharmacies Regulation Act (DPRA)*, dental hygienists may perform a number of specified acts in the practice of dentistry under the supervision or direction of a dentist, including three that involve the use of drugs. These are:

- Topical application of anticariogenic agents, and other materials designed to assist in the prevention of caries.
- Application of topical anaesthetics.
- Topical application of desensitizing agents.¹¹

As well, the *DPRA* authorizes pharmacists to sell drugs to dental hygienists for use in the course of engaging in the practice of their profession.¹²

Education and Continuing Competency

To practise in Ontario, dental hygienists must be registered with the CDHO. Registration criteria differ depending on where the applicant was trained. Graduates from a program accredited by the Commission on Dental Accreditation of Canada (CDAC) or by the American Dental Association Commission on Dental Accreditation (ADACDA) must successfully pass the National Dental Hygiene Competency Examination to be certified by the National Dental Hygiene Certification Board (NDHCB).

A graduate from a non-accredited program must have completed a two-year course of study that the CDHO Registration Committee considers equivalent to an accredited program. The graduate must have a certificate issued by NDHCB, or have successfully completed a provincial written certification examination approved by the Registration Committee of the CDHO as well as a provincial clinical competency assessment approved by the Registration Committee.

In Ontario, accredited dental hygiene education programs are offered in community or private colleges, for which high school graduates are eligible to apply. The Ontario training programs take 18 to 24 months to complete.

Competencies assessed by the NDHCB

Five of the 151 competencies assessed by the NDHCB examination relate to the ability of dental hygienists to assess pharmacological actions and interactions and the oral manifestations of pharmaceuticals.¹³ Three competencies deal with implementation: the dental hygienist is examined on the actions, interactions and oral manifestations of pharmaceuticals, and demonstrates the application of dentinal desensitizing agents and pharmacotherapeutics, excluding fluoride. No competencies are tested relating to administering a drug or substance by injection or inhalation.

¹¹ Ontario Regulation 547, s.50.

¹² Drug and Pharmacies Regulation Act, R.S.O. 1990, c.H4, s.118(3).

¹³ National Dental Hygiene Certification Board. Blueprint for the National Dental Hygiene Certification Examination. 2005. Available: http://www.ndhcb.ca/files/blueprint_en.pdf.

A set of the 2008 National Competencies were developed by the CDAC, the NDHCB and the Federation of Dental Hygiene Regulatory Authorities, Dental Hygiene Education of Canada (DHEC) and the CDHA.¹⁴ Although they have not yet been adopted, the CDHO is currently promoting the adoption of these competencies in order to homogenize the practice of dental hygiene across Canada and to facilitate the teaching of a core or basic curriculum. The competency framework consists of eight domains and an associated list of abilities within each domain.¹⁵

Overview of the Requests for Change

The CDHO and the ODHA are asking for two additional authorized acts that they state are important in realizing the potential of self-initiation. They are asking for the authority to provide “short term administration of a limited group of anaesthetics and anxiolytics”

- to manage pain that patients may anticipate or experience in the course of treatment,
- to deal with anxiety of individuals with dental phobia, and
- to be able to respond to emergency situations.¹⁶

Administration of these drugs would include a requirement for the authorized act of administering a substance by injection or inhalation.

Dental hygienists are also asking for the authorized acts of prescribing, dispensing or compounding a drug, including antibiotics, smoking cessation agents and higher than over-the-counter (OTC) concentrations of substances for home care such as fluoride.

Request for Change: Administration of Drugs by Injection or Inhalation

Dental hygienists seek the authority to administer certain substances by injection or inhalation so they can “manage client pain or anxiety during performance of dental hygiene interventions” and be able to respond to emergency situations.

A proposed regulation under the *Dental Hygiene Act, 1991* would enable dental hygienists with the requisite training to administer the following:

By injection:

1. Local anaesthetics, and
2. EpiPen.

¹⁴ CDHO. *Milestones*. November 2008. Available: http://www.cdho.org/Publications/Milestones/Milestones_Nov08.pdf.

¹⁵ HPRAC meeting with CDHO and ODHA. November 27, 2008.

¹⁶ CDHO. Submission to HPRAC. 6.

By inhalation:

1. Oxygen, and
2. Nitrous oxide.

HPRAC received further clarification from the CDHO indicating that this proposal also presumes that the dental hygienist has the authority to prescribe these same drugs, as set out in the second request for prescribing.

Proponents' Rationale

Proponents argue that the authority to administer drugs and substances by injection or inhalation is consistent with the profession's evolution to self-initiation. Having the ability to manage pain and anxiety that may be associated with teeth cleaning would allow dental hygienists to cease their reliance on dentists or other health professionals being present to perform services they feel are a natural corollary to their scope of practice. Proponents also argue that this supports the client's desire for access to services and choice of provider.

Proponents told HPRAC that while dental hygienists need no longer practise exclusively with dentists, they must still rely substantially on dentists or other health professionals to provide or authorize the performance of controlled acts that support their work. For example, to administer or monitor nitrous oxide/oxygen for the purpose of conscious sedation to patients, the dental hygienist must have a dentist, physician, nurse or respiratory therapist present in the room during the procedure. This requirement curtails the ability of dental hygienists who would like to offer these services in an independent practice from doing so.

The CDHO and the ODHA said that access to the authorized act of injection or inhalation of a substance would allow dental hygienists to better manage client pain and anxiety. Proponents said that dental hygienists are currently able to use topical anaesthetics during treatment, but this is not always sufficient to manage sensitivity and pain. According to the CDHO, in some cases, the administration of a limited group of anaesthetics and anxiolytics is required. Proponents also state that overall client access to care would improve, because clients could obtain the full spectrum of care and preventive therapies without the necessity of a referral to a dentist or family physician.

Periodontal or deep scaling is often very traumatic for patients and some will not even come in for treatment if they cannot be assured of nitrous oxide. I often have people say, "If I can't have nitrous, I'm not coming."

Kim Ivan, Vice President and Regional Director
Ontario Dental Hygienists' Association

The authority to administer oxygen and EpiPen auto-injectors would enhance dental hygienists' ability to respond to emergencies, according to the CDHO and ODHA. This authority would be particularly important for practitioners who work in remote or rural areas. It would allow them to offer comprehensive and timely care in the absence of other health professionals.

Proponents said that these changes would enable dental hygienists to participate more fully in interprofessional health care delivery venues where physicians or dentists are unavailable, such as in long-term care settings.

The ODHA said the profession feels that the risks associated with administering drugs would be “ameliorated by appropriate education and skill development”. Only registrants who meet the requirements set by the CDHO would be authorized to perform the controlled acts of prescribing or administering drugs, including post-graduate training that would be developed according to the established models of other jurisdictions.¹⁷

Request for Change: Prescribing, Dispensing and Compounding

To provide comprehensive service to clients who may not have ready access to other health professionals, such as in remote and some rural communities, dental hygienists are requesting the authority to prescribe, dispense or compound a drug.

Proponents explain that this authority would allow dental hygienists to prescribe:

- Chlorhexidine,
- Fluoride,
- Smoking cessation therapies classed as “drugs”, and
- Antibiotics (after consultation with a family physician).

These authorities would enable them to dispense certain self-treatment therapies and to compound and dispense fluoride rinses and gels in concentrations higher than OTC products.

The CDHO has indicated that it plans to adapt the Alberta qualification requirements for registered dental hygienists to meet certification requirements in Ontario.

Lists or Classes

The ODHA, in its submission to HPRAC, supported the ability of the CDHO to regulate the profession to protect the public interest and said that it is unnecessary to stipulate lists or classes of drugs in the designated drug

¹⁷ HPRAC meeting with CDHO and ODHA. November 27, 2008.

regulation under the *Dental Hygiene Act, 1991*. The CDHO and the ODHA agree that one of the main reasons for objecting to a list of drugs in the regulation is the regulation-making process itself. They said that having a list of individual drugs in regulations under the Act would impede the implementation of best practices. However, if classes are deemed necessary, the CDHO proposes that the classes should include, but not be limited to:

- Fluorides,
- Oral rinses,
- Topical agents,
- Anaesthetics,
- Smoking cessation drugs,
- Antibiotics,
- Antifungals,
- Anti-infectives,
- Antivirals,
- Epinephrine,
- Bronchodilators,
- Topical corticosteroids,
- Nitrous oxide/oxygen conscious sedation,
- Contents of emergency kit, and
- Pain control, such as ASA, ibuprofen and acetaminophen.
- The ODHA recommended that the class of drugs also include:
 - Anti-inflammatories,
 - Anti-allergics including antihistaminics,
 - Sedative-hypnotics, and
 - Salivary stimulants.

Proponents' Rationale

Currently in Ontario, dental hygienists do not have the authority to prescribe, dispense or compound drugs. Proponents said this authority would be consistent with the evolution of dental hygienists as independent practitioners who can, under prescribed conditions, self-initiate oral care treatment to their clients.

To maximize client convenience and health outcomes, the ability to prescribe is an important adjunct to independent practice.

Margaret Carter, Executive Director
Ontario Dental Hygienists' Association

A few dental hygienists are establishing independent or collaborative practices in remote and rural communities and among populations who either do not or will not access a traditional dental office. Although dental hygienists need no longer work exclusively with dentists, they still rely heavily on dentists or other health professionals to provide or authorize the performance of controlled acts that support their work.

The whole premise behind self-initiation was about accessibility, affordability and choice. Of the dental hygienists who have gone into independent practice, most of them are offering some degree of mobile practice because of their ability to go where their client is. Having the drugs authorized to the profession will only improve the care they can provide to these clients.

Margaret Detlor, President
Ontario Dental Hygienists' Association

Proponents state that certain medications, integral to dental hygiene practice, are related to periodontal disease and smoking cessation. Not being able to prescribe, dispense or compound these drugs or substances is having an impact on the quality, effectiveness, timeliness and cost of services for clients.

The ability to prescribe drugs to manage pain and anxiety related to dental hygiene services is an adjunct to the request for authority to administer such drugs, which is needed particularly in areas where other health professionals are not available.

The CDHO and the ODHA state that the inability of members of the profession to prescribe affects patient access to care and quality of care. HPRAC was told that during the process of teeth cleaning, bacteria might be released that might require antibiotics to control a resulting infection. Currently, the dental hygienist must refer the patient to a dentist or physician for the prescription. The dental hygienist cannot be certain that the recommendation for antibiotics is being followed or the patient may face delays in obtaining a required antibiotic.

The inability to administer, prescribe and dispense even a limited group of substances and drugs presents a significant barrier to the delivery of the full range of dental hygiene services and to timely, effective and convenient client care.

CDHO submission to HPRAC
November 12, 2008

Dispensing

Dental hygienists are requesting the controlled act of dispensing drugs for those members who work in communities where a pharmacy is not readily available. It is not expected that dental hygienists will stock medications in most other circumstances, including in remote locations. For example, in most remote communities, drugs could be dispensed by a local nursing station.

Compounding

The CDHO is requesting the authority to compound drugs for the purposes of mixing certain substances, such as fluoride, chlorhexidine and mouth rinses.

What HPRAC Found

Administration of drugs by injection and inhalation

A number of stakeholders have raised significant concerns about authorizing the controlled act of administering a substance by injection or inhalation to dental hygienists. Both the RCDSO and the College of Physicians and Surgeons of Ontario (CPSO) have expressed reservations about the dental hygiene curricula and the requisite training to ensure competency in the administration of drugs by injection or inhalation, and about the adequacy of training in anatomy required to administer drugs by injection without damaging major vessels in the mouth. The College of Respiratory Therapists of Ontario has raised concerns about the training and safeguards required for the use of oxygen and for the administration of nitrous oxide.

Other Jurisdictions

Dental hygienists in jurisdictions such as British Columbia, Alberta, Saskatchewan and Manitoba have the authority to administer anaesthetics.^{18,19,20,21} However, limitations have been placed on these authorities. In British Columbia, a dental hygienist may administer oral local anaesthetic only when a dentist is on-site and immediately available, or in a facility where the anaesthetic has been authorized by a medical practitioner or a dentist and a person qualified to act in a medical emergency is immediately available.²² In Alberta, the route of administration of drugs is not a restricted activity; however, the College of Registered Dental Hygienists of Alberta (CRDHA) has made it a requirement for its members to complete continuing education courses in order to receive a certification to administer local anaesthetic.²³

¹⁸ Dental Hygienist Regulation, B.C. Reg. 276/2008, s. 5.

¹⁹ Dental Hygienists Profession Regulation, Alta. Reg. 255/2006, s.13.

²⁰ Dental Disciplines Act, c.D-4.1. 23(5), Sask.. Available: <http://www.qp.gov.sk.ca/documents/English/Statutes/Statutes/D4-1.pdf>.

²¹ Dental Hygienists Act, s. 2(2), Man. Available: <http://web2.gov.mb.ca/laws/statutes/ccsm/d034e.php>.

²² Dental Hygienist Regulation, B.C. Reg. 276/2008, s. 4.

²³ Government Organization Act, Schedule 7.1.

The CRDHA *Practice Guidelines for the Utilization of Nitrous Oxide/Oxygen Conscious Sedation* stipulate that a dental hygienist can only administer nitrous oxide/oxygen conscious sedation for the purposes of providing combination inhalation-enteral (oral) nitrous oxide/oxygen conscious sedation if an appropriately trained physician or dentist is prescribing the enteral (oral) sedation agent.²⁴ The prescribing physician or dentist must be on-site and immediately available.

In Saskatchewan, dental hygienists do not have the authority to practise independently.²⁵ Dental hygienists have the authority to administer local anaesthesia but the dental hygienist may only perform authorized practices when employed by or practising under contract with: (a) an employer that employs or has established a formal referral or consultation process with a dentist; or (b) a dentist.

In order to fulfill this legislative requirement, dental hygienists in Saskatchewan must have a contractual relationship established with the institution or a dentist directly. However, this does not mean the patient needs to be seen by the dentist prior to the initiation of treatment by a dental hygienist.²⁶

Manitoba's *Dental Hygiene Act* came into force April 15, 2008. Dental hygienists are able to practise as a collaborative health professional in a dentist's office, in a facility, as part of an oral health program or in a setting approved by the patient's dentist. These include public health care settings, such as long-term care homes, hospitals and designated oral health programs.

Dental hygienists are authorized to administer oral anaesthetics if they are registered on an "oral anaesthetic roster". They may use a restricted list of oral therapeutic agents, including anticariogenic agents, desensitizing agents, periodontal chemotherapeutic agents and other categories of oral therapeutic agents approved by the council.

Dental hygienists in Manitoba must be supervised by a dentist except in prescribed circumstances, including consultation with a dentist, a physician, an extended class nurse or a clinical assistant, in the case of an oral health or other medical condition, or consultation with a dentist, physician or pharmacist in the case of a drug or combination of drugs. The procedure may proceed if a dental hygienist is satisfied, after consultation, that it is safe and appropriate to perform the treatment without the supervision of a dentist.²⁷

²⁴ Alberta Practice Guidelines for the Utilization of Nitrous Oxide/Oxygen Conscious Sedation. April 2008.

²⁵ The Canadian Dental Hygienists Association. News Release, April 18, 2008. Available: <http://www.cdha.ca/pdf/CDHA%20congratulates%20Manitoba%20Dental%20Hygienists%20April%2018%202008.pdf>.

²⁶ Saskatchewan Dental Hygienists' Association. Scope of Practice Document.

²⁷ College of Dental Hygienists of Manitoba. Dental Hygienists Regulation. Available: http://cdhm.info/legislation/CDHM_Regulations.pdf.

The proponents indicated that changes in legislation to allow dental hygienists the authority to administer anaesthetics is being considered in Nova Scotia and Newfoundland and Labrador. On further investigation, HPRAC found that dental hygienists in both jurisdictions are currently regulated under a *Dental Act*, rather than a profession specific Act.^{28,29}

In Nova Scotia, Bill 24, 2007, *An Act Respecting Dental Hygienists* (the *Dental Hygienists Act*), was passed on December 13, 2007, but is not yet in force.³⁰ A draft regulation under the Act has been submitted to the Department of Health by the Nova Scotia Dental Hygienists Association to authorize dental hygienists to administer oral anaesthetic with the written order of the client's dentist or physician.³¹ In Nova Scotia, only dentists, physicians and nurses acting under the direct control and supervision of a dentist or physician may administer any sedative agent in the dental setting.³²

In Newfoundland and Labrador, Regulation 47/01 under Section 21 of the *Dental Act* authorizes dental hygienists to provide a topical application of anticariogenic agents, and to apply pit and fissure sealants, desensitizing solutions and topical medicaments.³³ HPRAC has been unable to confirm that there are any Bills respecting dental hygienists on the legislative order paper in Newfoundland and Labrador.

The New Brunswick legislature approved first reading on December 17, 2008 to a Bill that includes self-regulation for dental hygienists and will authorize dental hygienists to provide services in long-term care residences, community health centres and remote areas in addition to dental offices.

Dental hygienists can administer anaesthetics in 40 U.S. states; however, in most of these states the physical presence and direct supervision of a dentist is required. In most states, dental hygienists are required to successfully complete accredited or approved courses with clinical and didactic content and pass an examination to be certified for the administration of anaesthetics.³⁴

²⁸ Dental Hygienists Regulations, N.S. Reg. 208/94. Available:

<http://www.canlii.org/eliisa/highlight.do?language=en&searchTitle=Nova+Scotia&path=/ns/laws/regu/1994r.208/20080818/whole.html>.

²⁹ Dental Auxiliaries' Regulations, C.N.L.R. 1013/96. Available:

<http://www.canlii.org/eliisa/highlight.do?language=en&searchTitle=Newfoundland+and+Labrador&path=/nl/laws/regu/1996r.1013/20080818/whole.html>.

³⁰ Government of Nova Scotia. An Act Respecting Dental Hygienists. Available:

<http://www.gov.ns.ca/legislature/legc/PDFs/annual%20statutes/2007%20Fall/c029.pdf>.

³¹ College of Dental Hygienists of Nova Scotia. Draft Regulations. October 2008. Available:

<http://www.nsdha.ns.ca/Draft%20Regulations%20sent%20to%20Department%20of%20Health-October,%202008.pdf>.

³² Provincial Dental Board of Nova Scotia. Use of Sedation in Dental Practice. Available:

<http://www.pdbns.ca/useofsedationindentalpractic.aspx>.

³³ Consolidated Newfoundland Regulation 1013/96. Dental Auxiliaries' Regulations under the Dental Act. Available: <http://www.assembly.nl.ca/legislation/sr/annualregs/CNR1996/Cr961013.htm>.

³⁴ American Dental Hygienists' Association. Local Anesthesia Administration by Dental Hygienists State Chart. Available: http://www.adha.org/governmental_affairs/downloads/localanesthesia.pdf.

Alberta dental hygienists have the authority to administer nitrous oxide for the purposes of conscious sedation. This is considered to be an advanced practice requiring training from a CRDHA-approved nitrous oxide/oxygen conscious sedation course, such as the continuing education course offered by the University of Alberta on administering local anaesthetic.³⁵ Eligible members must have their name listed in the CRDHA's roster as being authorized to perform this restricted activity.³⁶

Foundational Education

HPRAC's review of education indicated that pharmacology courses in dental hygienists' studies provide an overview of pharmacological actions and interactions; however, there is less exposure in the areas of anatomy, biochemistry and physiology. These courses are fundamental to understanding pharmacotherapeutics. Stakeholders have also identified issues with consistency of pharmacological education across community colleges and career colleges in Ontario.

Proponents have indicated that post-community or career college training would be required for dental hygienists to become competent to administer local anaesthesia and other drugs. In its submission, the CDHO states "to the best of the College's current information, approximately 300 dental hygienists have provided the College with certificates indicating that they have successfully completed a course in pain management that includes the administration of local anaesthetics."³⁷ HPRAC heard from the CDHO that these individuals all received their training outside Ontario. Pain management courses are available in British Columbia, Alberta, the University of Manitoba, Detroit Mercy Hospital and other locations in the United States and Great Britain.

A review of some of these course outlines and study guides show they are continuing education courses, typically structured with a component of self-study followed by lectures and hands-on training where the participants can practice effective administration of local anaesthetics.^{38,39} The in-person part of the course can range in duration from two to four days. A review of the University of Manitoba's *Pain Management for Dental Hygienists* study guide indicates participants who attend this three-day training session are taught to understand the physiological origin of pain as well as the mechanism of pain.⁴⁰ Students are also taught various methods of pain control, head and neck anatomy as it relates to administration of local anaesthetics, pharmacology of dental anaesthesia, local and systemic complications with use of anaesthesia and armamentarium for local anaesthesia. As a part of the training students are expected to practise application of local anaesthetics on each other.

³⁵ College of Registered Dental Hygienists of Alberta. Restricted Activities Authorization. August 2007. Available: <http://crdha.ca/LinkClick.aspx?fileticket=wZumKWBSiYU%3D&tabid=56&mid=416>.

³⁶ Ibid.

³⁷ CDHO. Submission to HPRAC: 10.

³⁸ University of British Columbia. Continuing Dental Education, Winter/Spring 2009 Calendar. Available: http://www.dentistry.ubc.ca/continuing_education/programs/2008-09/UBC_CDE.pdf.

³⁹ University of Detroit Mercy. School of Dentistry, Continuing Education. Available: <http://www.dental.udmercy.edu/ce/calendar.php>.

⁴⁰ Lavigne, Salme E. Pain management for dental hygienists, study guide and lab manual. University of Manitoba.

The CDAC is a national program that accredits educational programs for most dental professions from dentistry to dental assistants. HPRAC reviewed the CDAC accreditation requirements for dental hygiene programs, which now include eleven programs at community colleges and nine programs at career colleges in Ontario. Potential students at two of the career colleges have been warned that the offered programs might not meet accreditation standards as of November 2009. Educational programs must be a minimum of two academic years or equivalent at the post-secondary level. Foundational knowledge, including professional behaviour, biomedical and oral health sciences, along with dental hygiene theory and practice, must be integrated through training programs. Elements of dental hygiene practice must include the process of care, including dental hygiene assessment, diagnosis, planning, implementation and evaluation at an entry-to-practice standard. Biomedical science content to provide background for practice decisions includes content in anatomy, physiology, chemistry, biochemistry, microbiology, general pathology, nutrition and pharmacology. The biomedical knowledge must emphasize the orofacial complex and information on abnormal biological conditions must be provided to support oral and oral-related disorders and pathologies.⁴¹

To HPRAC, it is not evident that there is extensive emphasis on pharmacological or pharmacotherapeutic studies, although curriculum content must include pain and anxiety management in sufficient scope and depth to permit graduates to develop client-centred approaches to oral health and wellness. HPRAC concludes from the accreditation requirements and academic course curriculum review that graduates of a two-year post-secondary program would have high technical competence in dental hygiene, and that there would be only introductory exposure to pharmacotherapeutics.

Nitrous Oxide and Oxygen

The CDHO has requested the authority to administer substances by injection and inhalation for the purpose of pain management and to deal with emergency situations. The use of oxygen/nitrous oxide for conscious sedation has been specified as one of the purposes for the authority. HPRAC understands that nitrous oxide is a valuable agent for the control of pain and anxiety in dentistry, but also carries risks due to variables related to its delivery, including the type of dental procedure, patient movement, mask fit, quality of high-speed evacuation and mouth breathing.⁴²

The RCDSO has issued extensive guidelines for the dental profession on the *Use of Sedation and General Anaesthesia in Dental Practice*. The guidelines defining conscious sedation are:

⁴¹ Commission on Dental Accreditation of Canada. Accreditation Requirements for Dental Hygiene Programs. November 2008. Available: http://www.cda-adc.ca/cdacweb/_files/dental_hygiene_2008_en.pdf.

⁴² Whitcer, C. Control of occupational exposure to [N.sub.2]O in the dental operator. Cincinnati: National Institute of Occupational Safety and Health, 1975.

Conscious sedation is a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command. It is produced by a pharmacological or non-pharmacological method or a combination thereof. In dentistry, it is used to reinforce positive suggestion and reassurance in a way which allows dental treatment to be performed with minimal physiological and psychological stress, and enhanced physical comfort. The technique must carry a margin of safety wide enough to render loss of consciousness highly unlikely.

Conscious sedation may be induced by any one of the following modalities:

1. Oral administration of a single sedative drug;
2. Nitrous oxide and oxygen;
3. Combination of oral sedative drugs or nitrous oxide and oxygen with an oral sedative drug;
4. Parenteral administration of sedative drugs (intravenous, intramuscular, subcutaneous, submucosal or intranasal).⁴³

Under the RCDSO guidelines for the profession of dentistry, only the following persons may administer any sedative or general anaesthetic agent in the dental setting:

- A dentist currently registered in Ontario;
- A physician currently registered in Ontario;
- A nurse currently registered with the College of Nurses of Ontario in the Registered Nurse Class acting under the required order and the direct control and supervision of a dentist or a physician, currently registered in Ontario;
- A respiratory therapist currently registered in Ontario acting under the required order and the direct control and supervision of a dentist or a physician, currently registered in Ontario.

Nitrous oxide and oxygen conscious sedation must be administered by:

- a. An appropriately trained dentist or
- b. An appropriately trained registered nurse or registered respiratory therapist, under the order of an appropriately trained dentist, provided that:
 - An appropriately trained dentist is present at all times in the office suite and immediately available in the event of an emergency;
 - Nitrous oxide and oxygen conscious sedation has been previously administered for the patient by the dentist;
 - Appropriate dosage levels have been previously determined and recorded by the dentist in the patient record.⁴⁴

⁴³ Royal College of Dental Surgeons of Ontario. Guidelines on the Use of Sedation and General Anaesthesia in Dental Practice.3. Available: http://www.rcdso.org/pdf/guidelines/Guidelines_sedation_01_05.pdf.

⁴⁴ Ibid. 5.

The College of Nurses of Ontario has an extensive medication standards reference list on conscious sedation and analgesia, in addition to its medication standards of practice.⁴⁵

HPRAC has been told that the CDHO would establish one or more standards of practice for conscious sedation in consultation with the CPSO, the RCDSO and the Ontario College of Pharmacists. The expectation is that the CDHO would adapt the CRDHA qualification requirements for registered dental hygienists to meet certification requirements in Ontario. The proponents have indicated they have had discussions with the Ontario Ministry of Training, Colleges and Universities for support to any changes needed in the Ontario dental hygienist curriculum in order to comply with the National Competencies.⁴⁶ These changes could be ready within 18 months to two years.

Injection of Anaesthetics

Local anaesthetic, with almost no resulting side-effects, is commonly used in dentistry, and patients refer to the procedure as “freezing”. The injection of the local anaesthetic is sometimes preceded by a numbing gel, so patients do not feel the needle slide into their gums.

Anxiety-induced events are the most common adverse reaction associated with local anaesthetics in dentistry, the most common of which is syncope. In addition, other symptoms, including hyperventilation, nausea, vomiting and alterations in heart rate or blood pressure may be noted.⁴⁷ Allergic reactions may also be common, including signs such as urticaria, edema and bronchospasm.

The training required for the injection of local anaesthetics includes not only expertise in the drugs that may be injected, but also the site of administration, the speed of injection and maximum dose calculations that are appropriate to the patient. The patient’s medication history and possible drug interactions must be taken into account.

During the process of dental anaesthesia, including infiltration anaesthesia as well as mandibular anaesthesia, oral bacteria can enter the tissue following perforation of the mucous membrane by the needle injection.⁴⁸ Dental local anaesthesia may therefore lead to suppurative local infections or odontogenic bacteraemia, as has been shown to occur in other dental surgery interventions. These circumstances have raised the issue of routine antibiotic prophylaxis in oral surgery.⁴⁹

⁴⁵ College of Nurses of Ontario. Practice Standard: Medication. Revised 2008. Available: http://www.cno.org/docs/prac/41007_Medication.pdf.

⁴⁶ HPRAC meeting with proponents.

⁴⁷ Haas, Daniel A. An Update on Local Anaesthetics in Dentistry. Journal de l’Association dentaire canadienne, October 2002. Vol. 68.9. Available: <http://www.cda-adc.ca/jadc/vol-68/issue-9/546.pdf>.

⁴⁸ Gräff, 1965; Streitfeld & Zinner, 1958; Winther & Praphailony, 1969.

⁴⁹ Rahn, 1989; Roberts et al., 1998.

Extensive education, including knowledge of drugs and their interactions, potential responses to interventions, the need for antibiotic prophylaxis and clinical practice training is essential to the administration of oral local anaesthetics.

Conclusions

Administration of Drugs by Injection and Inhalation

As a result of its review, including an examination of current competencies of the profession, a jurisdictional review, examination of accreditation criteria, educational programs and the depth of knowledge of pharmacotherapeutics within the profession of dental hygiene, HPRAC is not prepared to recommend that dental hygienists be authorized to independently administer substances by injection or inhalation. Current dental hygiene education programs in Ontario do not have the course content needed to prepare new practitioners to perform these activities; no related standards of practice have been developed, and no continuing competence or bridging programs to train existing practitioners are in place today.

HPRAC sees value in the expansion of dental hygienists' independent practice into urban and rural communities. HPRAC has heard from providers in long-term care homes and home care that on-site oral hygiene services provide value for their residents, patients and clients. Nonetheless, when people who can benefit from oral hygiene care need pain management, it should be provided in a context of total physical care and not as an isolated intervention.

Request for Prescribing, Dispensing and Compounding

Several organizations and individuals have raised concerns about the competencies of dental hygienists to prescribe drugs.

HPRAC heard particular concerns from members of the dentistry profession about inconsistencies in dental hygiene training programs and deficiencies in quality assurance programs that have been put in place by the CDHO to require educational bridging programs and “gap training” for internationally-trained graduates. Others voiced concerns about CDHO's quality assurance programs and their exactitude in defining and measuring prescribing competencies.⁵⁰ The Ontario Dental Association told HPRAC that dental hygienists at present do not have the comprehensive training and education needed to prescribe prescription drugs.

HPRAC heard from numerous professionals, regulators and professional associations of concerns about dental hygiene education in the areas of anatomy, biochemistry and physiology that would qualify members of the profession to prescribe drugs for patients. A number of stakeholders

⁵⁰ HPRAC meetings and interviews with key stakeholders. November and December 2008.

asserted that the educational standards are insufficient to support the request; however, some were unwilling to do so for the record.⁵¹ HPRAC's own research found sufficient indications to support those assertions. Accreditation requirements do not require pharmacotherapeutic coursework as a central part of educational programs, as HPRAC discovered in its review of dental hygiene accreditation standards.

Dental hygienists in Alberta are authorized to prescribe a limited number of classes of Schedule 1 drugs for the purpose of treating oral health conditions, providing prophylaxis and treating emergencies. They are also authorized to compound, provide for selling or sell, incidentally to the practice of dental hygiene, a Schedule 1 drug or Schedule 2 drug.⁵² The classes include:

- (i) antibiotics,
- (ii) antifungal agents,
- (iii) anti-infective agents,
- (iv) antiviral agents,
- (v) bronchodilators,
- (vi) epinephrine,
- (vii) fluoride,
- (viii) pilocarpine, and
- (ix) topical corticosteroids.

The CRDHA has developed a bridging course for its members wishing to perform this new authority. The CRDHA course, *Elements of Prescribing: A Pharmacy Refresher Course for Dental Hygienists*, is a non-accredited post-graduate course that took three years to develop.⁵³ The course content was developed in collaboration with the Alberta College of Pharmacists and a licensed dentist. The CRDHA also consulted with educators from the University of Alberta and other educators in the United States in finalizing the curriculum.

This refresher course is a self-study program with the use of an online tool. Students enrolled in this course have up to six months to complete the program and take the exam.⁵⁴ Upon successful completion of this course, the individual then applies to the CRDHA for a prescriber identification number. To date, 40 students have enrolled and are expected to finish the course in January 2009.

The CDHO has stated that only those dental hygienists who have taken the necessary pharmacological training to perform the authorized acts safely and effectively would be authorized to do so. The CDHO also said that it would need to establish one or more standards of practice for the performance of the authorized act in consultation with the CPSO, the RCDSO and the Ontario College of Pharmacists. As well, the CDHO expects

⁵¹ Ibid.

⁵² Dental Hygienists Profession Regulation, Alta. Reg. 255/2006, s. 13(1).

⁵³ Personal communication with CRDHA Deputy Registrar Stacie Mackie. December 17, 2008.

⁵⁴ Personal communication with CRDHA Registrar Brenda Walker. December 16, 2008.

that it would be working with the CRDHA to use curriculum created in Alberta to develop appropriate certification processes and standards for Ontario. The CDHO does not anticipate that all members will be certified for prescribing authorities.

The CDHO has made the following specific requests for prescription drugs:

Oral Rinses

Dental hygienists use chlorhexidine (CHX) in the normal course of practice. It has been clinically proven that the effectiveness of this antimicrobial agent is prolonged when it is used during therapy and on a daily basis by clients who are trying to manage periodontal disease. HPRAC agrees that CHX is an important drug for dental hygienists to be able to prescribe to ensure effective treatment and promote long-term oral health.

Fluoride

Fluoride has long been established as the main agent used for the prevention of dental caries and is used for treatment of early stages of coronal and root caries. The CDHO argues that dental hygienists need to be able to independently prescribe, compound and dispense fluoride rinses and gels of higher concentration than those typically found in OTC rinses and gels to manage these risks. This is a particular need for clients from youth, senior, immigrant and low-income demographic groups. HPRAC agrees that fluoride is an important drug for dental hygienists to be able to prescribe, compound and dispense to ensure effective treatment and promote long-term oral health.

Antibiotics

The CDHO proposes that dental hygienists should be authorized to prescribe and dispense a limited number of antibiotics for the treatment of periodontal disease, in consultation with the client's family physician. HPRAC remains concerned about the risk of over-prescribing antibiotics and the lack of consistent protocols for antibiotic prophylaxis. The CDHO has referenced only one of several health professions who have prescriptive authorities (physicians) and who might be involved in continuing patient care with dental hygienists. HPRAC has concluded that the prescribing of antibiotics should be done by an authorized prescriber, such as a physician, dentist or nurse practitioner, who can take into account a full physical and medical profile. HPRAC does not see a compelling argument for the independent prescribing by dental hygienists of antibiotic prophylaxis.

Antifungals and Antivirals

Dental hygienists are asking to prescribe antivirals and antifungals to deal with conditions they observe during clinical assessment of the patient. HPRAC is not convinced that dental hygienists have appropriate education and training to make an appropriate differential diagnosis of a fungal or viral infection of the mouth. In this situation, a dental hygienist should make an assessment and follow-up with a referral to another health professional for a diagnosis.

Nitrous Oxide and Oxygen

Protocols and guidelines have been well established for the administration of nitrous oxide and oxygen for conscious sedation and HPRAC does not think that these protocols should be treated lightly. They encompass not only requirements for the maintenance of equipment, but for the participation of health professionals and emergency preparation. HPRAC recommends that dental hygienists should not be authorized to independently administer nitrous oxide/oxygen conscious sedation.

Local Anaesthetics

HPRAC heard significant concerns about the proposed administration by injection of local anaesthetics performed by dental hygienists. At the best of times, this is a delicate task, requiring significant training and skill. Pain management courses of limited duration do not prepare dental hygienists to perform this task. The dental hygienist is well qualified to identify the need for an anaesthetic and to make a referral to an appropriate health professional to perform the procedure.

Salivary Stimulants

Pilocarpine, a cholinergic agonist, can be used to stimulate salivation. However, this drug may also have serious cardiovascular effects, for example, slowing of the heart rate. HPRAC is of the opinion that there are a number of OTC medications that can safely address this issue and this drug need not be authorized for prescription by dental hygienists.

Smoking Cessation

HPRAC acknowledges that dental hygienists, along with a number of other health professionals who are committed to health promotion, play an important role in smoking cessation and that they should be encouraged to continue in this role. HPRAC is also of the opinion that there are sufficient OTC medications, such as gums, patches, sprays, and lozenges, to assist with smoking cessation and that access to antidepressants (bupropion) is not necessary and poses significant risks to the patient.

Sedative-hypnotics

Sedative-hypnotics include benzodiazepines such as diazepam (Valium). They can be used to relieve anxiety and to cause mild sedation prior to medical procedures. In this case, HPRAC is concerned about the risk of sedation, overdose and abuse. In addition to the risk of using benzodiazepines themselves, there is also a risk of significant drug interactions, particularly with other CNS-active agents.

Adrenals

Similar to the concerns about the use of antivirals and antifungals, HPRAC does not recommend that topical corticosteroids such as triamcinolone should be authorized at this time. Although prudent use of topical corticosteroids can relieve temporary pain and inflammation, these agents

can also impair the function of the immune system and worsen infections. HPRAC is not convinced that dental hygienists have appropriate education and training to make an appropriate differential diagnosis of infections, therefore HPRAC is not convinced that topical corticosteroids would only be used on inflamed tissue and not on undiagnosed infections.

Dental Emergencies

A recent study indicates that medical emergencies in a dental office are most likely to occur during and after local anaesthesia, primarily during tooth extraction and endodontics. Over 60 percent of the emergencies are syncope (temporary loss of consciousness), with hyperventilation the next most frequent at seven percent. Other dental emergencies seen are allergic reactions, angina pectoris/myocardial infarction, cardiac arrest, postural hypotension, seizures, bronchospasm and diabetic emergencies. There are two categories of drugs considered for a dentist's emergency kit. The first category is essential drugs to manage potentially life-threatening situations and the second category is supplemental and might be included depending on the type of dental practice. Essential drugs include: oxygen for almost any medical emergency; epinephrine for treatment of anaphylaxis or asthma unresponsive to bronchodilator; nitroglycerin for angina pain; antihistamine for allergic reactions; albuterol/salbutamol for asthmatic bronchospasm; and aspirin for myocardial infarction (heart attack).⁵⁵

HPRAC has reviewed carefully the request of the dental hygiene profession for an emergency kit. The evidence is that most dental emergencies occur in dental care that is out of the scope of practice of dental hygienists. HPRAC is not recommending changes to the scope of practice and has concluded that an emergency kit is not necessary in routine dental hygiene practice, even when that practice is not co-located with dentistry or another health profession. However, knowledge of emergency procedures is an important function for dental hygienists.

HPRAC has noted that the CDHO has a requirement in its quality assurance program and practice guideline that dental hygienists must ensure the provision of services/programs in emergency situations by:

- knowing the practice environment's emergency protocols;
- knowing the location of emergency supplies and oxygen; and
- maintaining current certification in basic cardiopulmonary resuscitation.

This requirement applies to all practice settings, and HPRAC recommends that the CDHO consider whether additional emergency protocols should be developed for dental hygienists in independent practice who practise in non-traditional settings.

⁵⁵ Haas, D.A. "Management of Medical Emergencies in the Dental Office: Conditions in Each Country, the Extent of Treatment by the Dentist," *Journal of Japanese Dental Society of Anesthesiology*. 2005; Vol. 33:153–157.

Conclusions

This profession is dedicated, performs highly-skilled technical work and is a mainstay of oral health care in most communities in the province. Some members of the profession are in transition from working under delegation to being independent providers of oral health care and are establishing dental hygiene clinics and mobile services outside of traditional practice settings. Long-term care homes and home care agencies see these new models of dental hygiene services as valuable tools in providing patient and client health services. Community health centres in urban areas can benefit from the new services that dental hygienists can offer. HPRAC applauds these efforts on the part of the dental hygiene profession.

In 2007, the profession gained authority to perform oral hygiene procedures independent of dentistry, with some strict protocols attached to this authority. In 2008, the leadership of the profession is again seeking new authorities to prescribe and administer drugs. While it admits that these rights to controlled acts would not be used broadly within the profession, it continues to strive for new authorities for members of the profession to provide patient care.

While HPRAC appreciates this approach, it also has some reservations. Dental hygienists study for two years at the post-secondary level. Their work is highly technical, and everything that HPRAC has learned about the evolution of the profession indicates that its members are working to a high standard and providing exemplary patient care. Dental hygienists are not dentists, and they are not physicians. They are primary care health providers, and they are a central part of a patient's circle of care. For patients, the dental hygienist is a highly skilled health professional, who works with others to ensure coordinated care. At this time of increasing demand for interprofessional collaboration, dental hygienists must be a central part of primary health care delivery, working collaboratively with other health professions.

Recommendations

1. That the *Dental Hygiene Act, 1991* be amended to authorize dental hygienists to prescribe, dispense, sell and compound drugs.
2. That the following therapeutic classes of drugs be included in a designated drugs regulation under the *Dental Hygiene Act, 1991*. The specific agents and any terms, limitations or conditions attached to the authority to prescribe drugs would be developed through a new drug approvals framework. At the outset, the specific agents that could be prescribed, dispensed, sold and compounded would include fluoride treatments and preventative oral rinses (chlorhexidine).

Class	Specific Agents
Anti-infectives Sub-class: miscellaneous	Chlorhexidine
Miscellaneous therapeutic agents Sub-class: cariostatic agents	Fluoride

3. That the CDHO should establish an interprofessional standards committee to develop standards of practice for the prescribing, dispensing, selling and compounding of drugs designated in regulations under the *Dental Hygiene Act, 1991*.

Implementation Proposals

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That the *Dental Hygiene Act, 1991* be amended by adding the following sections:

Authorized acts

- 4.3 Prescribing, dispensing, selling or compounding a drug that the member may prescribe, dispense, sell or compound under the regulations.

Additional requirements for authorized acts

- 5(2.1) A member shall perform a procedure under the authority of paragraph 3 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.

Individual scope of practice for dental hygienists

- 5(4) A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

2. That section 5(3) of the *Dental Hygiene Act, 1991* be repealed and the following substituted:

Grounds for misconduct

- (3) In addition to the grounds set out in subsection 51(1) of the Health Professions Procedural Code, a panel of the Discipline Committee shall find that a member has committed an act of professional misconduct if the member contravenes subsection (1), (2) or (2.1).
3. That section 12 of the *Dental Hygiene Act, 1991* be repealed and the following substituted:

Regulations

12. Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,
- (a) regulating the prescribing, dispensing, selling or compounding of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing, dispensing, selling or compounding of drugs;
 - (b) prescribing requirements for performing scaling teeth and root planing, including curetting surrounding tissue, which requirements may include the educational and experiential qualifications that must be obtained in order for a member to undertake those procedures on the member's own initiative; and
 - (c) prescribing contraindications to a member performing or continuing to perform on the member's own initiative the procedures of scaling teeth and root planing, including curetting surrounding tissue.
4. That Ontario Regulation 218/94 under the *Dental Hygiene Act, 1991*(General) be amended by adding the following sections:
- 12.1(k.1)** any drug prescribed, dispensed, sold or compounded for the client.
- 39. (a)** For the purposes of this section, "Drug List" has the meaning given to it in the *Regulated Health Professions Act, 1991*.
- (b)** A member may prescribe, dispense, sell or compound the following classes of drugs:
- i Anti-infectives— miscellaneous
 - ii Miscellaneous therapeutic agents – cariostatic agents.

- (c) A member may only prescribe, dispense, sell, compound or use those drugs within the classes designated in subsection 39(b) that are listed in the Drug List and must prescribe, dispense, sell, compound or use those listed drugs in accordance with the terms, limitations and conditions contained in the Drug List.
40. (1) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 3 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.
- (2) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 3 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.
41. The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 3 of section 4 of the Act.
42. The standards of practice referred to in section 41 shall be developed on the recommendation of the Dental Hygiene Standards Committee.
43. For the purposes of section 42, the College shall establish the Dental Hygiene Standards Committee referred to in section 42 and shall appoint the membership of the Dental Hygiene Standards Committee, which shall include, at a minimum, one or more:
- a) members of the Council;
 - b) members of the College (including practitioners and educators);
 - c) persons who are not and have not been members of the College or of the Council;
 - d) members of the Royal College of Dental Surgeons of Ontario, approved by the Royal College of Dental Surgeons of Ontario; and
 - e) members of the Ontario College of Pharmacists, approved by the Ontario College of Pharmacists.

- 44.** The College shall post the following on its website:
- a) the standards of practice referred to in section 41; and
 - b) a list of those members, who are authorized to perform a procedure under the authority of paragraph 3 of section 4 of the Act.
- 5.** That section 15 of Ontario Regulation 218/94 under the *Dental Hygiene Act, 1991* (General) be amended by adding the following paragraphs:
- 1.1** Exceeding the scope of practice of the profession.
- 48.** Prescribing, dispensing, selling, compounding or using a drug or substance for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell, compound or use drugs or substances.
- 49.** Contravening, while engaged in the practice of dental hygiene, any federal or provincial law or municipal by-law with respect to the distribution, sale, prescribing or dispensing of any drug or mixture of drugs.
- 51.** Delegating an act set out in paragraph 1 or 2 of section 4 of the Act except as permitted by the *Regulated Health Professions Act, 1991* or the regulations made thereunder or under the Act, or delegating an act set out in paragraph 3 of section 4 of the Act.
- 6.** That section 50 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act* (Dentistry) be repealed and made a regulation under Ontario Regulation 218/94 under the *Dental Hygiene Act, 1991* (General).

THE PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF DENTISTRY

The Royal College of Dental Surgeons of Ontario (RCDSO) and the Ontario Dental Association (ODA) are not seeking any change to the current authorities for the prescribing, administration or use of drugs in the practice of the profession.

In response to the Minister’s question on “whether lists, categories or classes of drugs should be prescribed by regulation for the profession,” the RCDSO and the ODA submitted a joint response opposing the development of lists or classes of drugs that might limit the existing prescribing authority of dentists.

“The College is satisfied that the current authorized acts and regulations for the prescribing and administration of drugs in dental practice are working well for both members and the public. We are not proposing any changes to the current framework at this time.”¹

HPRAC’s Central Response

HPRAC has concluded that dentists have a long history of safely and effectively prescribing medications to their patients working under broad prescribing authority. This history, combined with the addition of comprehensive standards of practice developed in a collaborative framework with other health professions, supports the continuation of current prescribing authorities for dentists.

Background on Dentistry in Ontario

The RCDSO, the governing body for dentists in Ontario, has been regulating the profession since 1868, the year prior to the opening of the first dental school in Canada at what is now the Faculty of Dentistry at the University of Toronto.

The scope of practice of dentistry is “the assessment of the physical condition of the oral-facial complex and the diagnosis, treatment and prevention of any disease, disorder or dysfunction of the oral-facial complex”.²

The practice of dentistry in Ontario is regulated under the *Regulated Health Professions Act, 1991 (RHPA)* and the *Dentistry Act, 1991*. There are more than 8,000 dentists in Ontario in general and specialty practices that include orthodontics, paediatric dentistry, periodontology, endodontics,

¹ Royal College of Dental Surgeons of Ontario. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 14, 2008: 2.

² *Dentistry Act, 1991. S.O. 1991,c.24, s.3.*

prosthodontics, oral and maxillofacial surgery and anaesthesia, dental anaesthesia, oral pathology and medicine, oral radiology, and dental public health.

There are two dental schools in Ontario, one at the University of Toronto and one at the University of Western Ontario.

Authorized Acts

In the course of engaging in the practice of dentistry, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Communicating a diagnosis identifying a disease or disorder of the oral-facial complex as a cause of a person's symptoms.
2. Performing a procedure on tissue of the oral-facial complex below the dermis, below the surface of a mucous membrane or in or below the surfaces of the teeth, including the scaling of teeth.
3. Harvesting tissue for the purpose of surgery on the oral-facial complex.
4. Setting a fracture of a bone of the oral-facial complex or setting a dislocation of a joint of the oral-facial complex.
5. Administering a substance by injection or inhalation.
6. Applying or ordering the application of a prescribed form of energy.
7. Prescribing or dispensing drugs.
8. Fitting or dispensing a dental prosthesis, an orthodontic or periodontal appliance or a device used inside the mouth to protect teeth from abnormal functioning.³

Regulations

The RCDSO Council may make regulations, subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, regulating the dispensing of drugs by members. These regulations require members to keep prescribed records and to provide the Minister with reports containing prescribed information respecting the dispensing of drugs.⁴

Dentists also have a detailed professional misconduct regulation. It includes “prescribing, dispensing or selling a drug for an improper purpose, or otherwise using improperly the authority to prescribe, dispense or sell drugs” as grounds for disciplinary action.⁵

³ *Dentistry Act, 1991*. S.O. 1991.c.24.s.4.

⁴ *Dentistry Act, 1991*. S.O. 1991.c.24.s.12.

⁵ For the purposes of clause 51 (1) (c) of the Health Professions Procedural Code.

Education and Continuing Competency

Dentistry education in Ontario and across Canada ensures that entry-to-practice dentistry graduates are competent to safely and effectively use and prescribe drugs.

Although dentistry curricula vary slightly across Canadian universities, in general, dentistry students take courses in general microbiology, anatomy, histology, pathology, pharmacotherapeutics and pharmacokinetics alongside medical students or at a similar level to courses offered to medical students. Most programs offer two courses in anaesthesia and all programs offer extensive general pharmacology courses at a similar level to medical students, as well as a dentistry-specific pharmacology course. All programs offer courses in general medicine focusing on how common illnesses impact dental care.

Applicants to studies in a faculty of dentistry must have successfully completed three years of university education that included courses in biochemistry, physiology and life sciences. Graduates of four-year undergraduate studies in dentistry are conferred the degree of Doctor of Dental Surgery (D.D.S.).

Competency Evaluation

In order to practise dentistry in Ontario, an applicant must be a graduate of an accredited four-year university dentistry program, have successfully completed the National Dental Examining Board of Canada examinations and be certified by the RCDSO.

Request for Change

The RCDSO and the ODA are not seeking any change to the current authorization for the prescribing, administration or use of drugs for the profession.

Proponents' Rationale

The RCDSO notes that dentists are limited to treating patients with conditions that fall within the scope of practice of dentistry. Further, regulations require that each dentist maintain the standards of practice of the profession, and not attempt to treat beyond his or her expertise or competence.⁶

The RCDSO feels that the current framework reflects best practices for the prescribing and administration of drugs in the course of practice for its members. Specifically it provides flexibility to enable dentists to practise across a wide range of practices, from generalist to specialist. It also provides important safeguards to protect the public. The proponents

⁶ RCDSO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 14, 2008: 1.

conclude that this framework serves the public well, and they do not see a risk of harm to the public in retaining the current authorities to prescribe drugs.

The ODA supports the need for flexibility in prescribing. They say that the broad authority to prescribe drugs “recognizes the varying needs of dental patients to have access to a comprehensive range of drugs to manage their oral health and overall health needs as it relates to their dental treatment”. Like the RCDSO, the ODA agrees that dentists have worked within a framework that enables them to match individual patient needs with the most appropriate pharmacotherapy.⁷

The proponents also note that pharmacotherapy is an essential component of the modern practice of dentistry and practitioners safely and effectively prescribe and administer drugs to their patients every day. As well, pharmacotherapy is a core component of the education curriculum and forms a substantial portion of dentists’ continuing education.⁸ The ODA notes that local, national and international speakers provide continuing education courses on a broad range of topics, including those specific to prescribing drugs and patient safety.⁹

The RCDSO also states that the College regularly addresses contemporary issues including advancements in pharmacotherapy with its members through a variety of means of communication, including its quarterly magazine, *Dispatch*.

What HPRAC Found

Educational Background

HPRAC’s review of dentistry education in Ontario found that it is provided at a high level, and that graduates are competent to safely and effectively use and prescribe drugs in practice. Dental programs have extensive general pharmacology courses at levels comparable to medical students. All programs offer courses in general medicine relating to how common illnesses impact dental care. Most programs offer two courses in anaesthesia.

HPRAC heard from proponents that dentists use a wide variety of drugs in their practices, and from virtually all therapeutic classes, with the exception perhaps of hormones. HPRAC was told that dentists practicing in

⁷ Ontario Dental Association. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 12, 2008: 2.

⁸ Ibid: 1.

⁹ Ibid: 2.

particular specialties would require the authority to prescribe drugs that might be thought of as being outside the scope of practice of primary care dentists, (e.g., chemotherapeutic drugs) but would nonetheless be required in the course of practice of some specialist members of the profession. HPRAC agrees that moving to designated classes of drugs in regulation would serve no practical purpose and would not provide substantial benefit to the public.

Ensuring on-going Competencies

HPRAC found that the RCDSO provides information to its members on appropriate use of drugs on an ongoing basis as part of continuing education. Dentists participate in continuing education programming to remain current in the prescription and administration of drugs. In 2008, RCDSO circulated the proposed draft Quality Assurance Regulation to members and external stakeholders. The proposal included requirements for continuing education, practice enhancement, peer consultation, and an annual declaration.¹⁰

Managing the Risk of Harm

The RCDSO has recently updated guidelines on the Use of Sedation and General Anaesthesia in Dental Practice, based on the work of the College's Quality Assurance Committee. The guidelines state that:

Sedation or general anaesthesia may be indicated to treat patient anxiety associated with dental treatment, to enable treatment for patients who have cognitive impairment or motor dysfunction which prevents adequate dental treatment, to treat patients below the age of reason, or for traumatic or extensive dental procedures. These techniques are to be used only when indicated, as an adjunct to appropriate non-pharmacological means of patient management.¹¹

Members who use sedation or general anaesthesia in practice must have successfully completed a training program in the specific modality, and the dental facility must be suitably staffed. Clearly recorded patient medical histories, including information concerning illnesses, hospital admissions, current medications, allergies and an appropriate physical examination must be completed for each patient prior to the administration of any form of sedation or general anaesthesia. Dentists and staff must be prepared to recognize and treat adverse responses using appropriate equipment and drugs as necessary.

¹⁰ RCDSO. *Proposed Draft Quality Assurance Regulation to be made under the Dentistry Act, 1991 S.O. 1991, c.24*. www.rcdso.org/pdf/con_ed/Proposed-Draft-Quality-Assurance-Regulation-June2008.pdf. 2008.

¹¹ RCDSO. *Guidelines on the Use of Sedation and General Anaesthesia in Dental Practice*. January 2005. www.rcdso.org/pdf/guidelines/Guidelines_sedation_01_05.pdf.

Under the RCDSO Guidelines, only dentists, physicians, or nurses or respiratory therapists acting under the order and direct control of the dentist or physician may administer any sedative or general anaesthetic agent in the dental setting. In addition to the general guidelines, additional professional responsibilities apply when nitrous oxide and oxygen conscious sedation or other forms of sedation and anaesthesia is being administered.¹²

Unauthorized use of nitrous oxide by members or staff has been raised as a fitness to practise concern. The safeguarding of supplies and nitrous oxide equipment and preventative strategies is a key requirement of the practice guidelines.

The RCDSO offers an on-line Adverse Drug Interactions Program to provide timely and reliable information on drugs. Dentists are able to list the medications their patients are taking and receive information about possible drug interactions, along with citations pertinent to drug interactions. A reference index, updated every six months, of over 3,000 drugs by brand names with generic equivalents is also provided. This service is made available by The Medical Letter, a New York-based, independent, peer-reviewed, nonprofit publication that offers critical evaluations of drugs, with special emphasis on new drugs, to members of the health professions.¹³

What Other Leading Jurisdictions Do

HPRAC's jurisdictional review indicates that British Columbia, Alberta, Quebec and Saskatchewan have regulations listing schedules of drugs that dentists in their respective jurisdictions can prescribe. None of these provinces includes specific classes or categories of drugs.¹⁴ In other provinces, such as Manitoba and Nova Scotia, guidelines and by-laws are used to outline the use of anaesthesia and sedation.¹⁵

In Great Britain, there is a list of preparations approved for dental prescribing posted on the Department of Health website.¹⁶ However, recent conversations with the Department of Health Non-Medical Prescriber Program and National Prescribing Centre indicated that Great Britain is moving away from specific lists of drugs for many professions, in favour of a framework where the practitioner must demonstrate competence to administer and prescribe drugs within their professional scope of practice.

Conclusions

HPRAC concurs that the profession of dentistry has the knowledge and

¹² Ibid.

¹³ RCDSO. *The Medical Letter*. www.rcdso.org/medical_letter.html.

¹⁴ HPRAC. *Prescribing and Use of Drugs by Non-Physician Health Professionals: A Jurisdictional Review of the Profession of Dentistry*. November 2008.

¹⁵ Ibid.

¹⁶ Department of Health. *List of preparations approved for dental prescribing*. March 2005. www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4112074?IdcService=GET_FILE&dID=23203&Rendition=Web.

competency in pharmacotherapy, and a record of safe prescribing practices which justifies maintaining open prescribing rights. HPRAC does not see a benefit to increased public protection in moving to classes of drugs that would be authorized in regulations under the *Dentistry Act, 1991*. HPRAC therefore supports the profession's continued access to open prescribing.

In order to bring dentistry in closer alignment with other health professions, HPRAC is recommending that the RCDSO formalize standards of practice through the creation of an interprofessional Dentistry Standards Committee. Increased flexibility is balanced with an enhanced role for the RCDSO to more actively and rigorously regulate the profession in the public interest and ensure appropriate accountability measures to protect the public. HPRAC is aware that this will mean a formalization of existing practices for the profession in some circumstances, but will also allow for the opening of new options in the development of standards of practice.

HPRAC is also aware that the profession of dentistry, despite interventions and proposals to the Ministry over a number of years, lacks a quality assurance regulation and has attempted to guide quality improvement within the profession on the basis of policies, rules and guidelines. While there are reasons for the approach taken by the RCDSO, HPRAC would like to see early initiatives to establish quality assurance regulations under the *Dentistry Act, 1991* to provide clarity to the public, the profession and other health professions. RCDSO leadership, with a collaborative approach to the development of interprofessional standards of practice and quality assurance programs could provide a major impetus for progress in interprofessional care.

HPRAC also recommends that regulation provisions be amended to include the authority to make regulations for prescribing, selling and compounding of drugs, rather than the current regulations that refer to dispensing only. Standards of practice developed by the RCDSO would have legal authority as a result of the regulation. As with recommendations for other professions, HPRAC recommends that dentists be held accountable in their certificates of registration to comply with standards of practice for prescribing, dispensing, selling and compounding of drugs.

HPRAC has concluded that since Ontario dentists have access to controlled drugs and substances under federal statutes and regulations, professional misconduct regulations should be expanded to include contraventions of other laws and the loss of privileges under the *Controlled Drug and Substances Act* (Canada) or privileges under the *Food and Drugs Act* (Canada) as with other professions in this review.

Section 50 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act (DPRA)* gives dental hygienists authority to perform

specified acts under the supervision or direction of a dentist. With the new authorities given to dental hygienists in 2007 under the *Dental Hygienists Act, 1991*, it is HPRAC's view that the DPRA regulation should be repealed and made a regulation under the *Dental Hygiene Act, 1991*.

HPRAC is also making recommendations to update housekeeping matters respecting regulations under the DPRA and the *Dentistry Act, 1991*.

Recommendations

1: That the RCDSO develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 7 of section 4 of the *Dentistry Act, 1991*.

2: That the RCDSO establish a Dentistry Standards Committee that includes members of the College of Physicians and Surgeons of Ontario, the College of Nurses of Ontario, and the Ontario College of Pharmacists.

Implementation Proposals

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That paragraph 7 of section 4 of the *Dentistry Act, 1991* be repealed and the following substituted:
 7. Prescribing, dispensing, selling or compounding a drug.
2. That the *Dentistry Act, 1991* be amended by adding the following section:

Additional requirements for authorized acts

- 4.1 A member shall perform a procedure under the authority of paragraph 7 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.
3. That section 12 of the *Dentistry Act, 1991* be repealed and the following substituted:

Regulations

12. Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations regulating the prescribing, dispensing, selling or compounding of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing, dispensing, selling or compounding of drugs.

4. That Part IV (Registration) of Ontario Regulation 205/94 under the *Dentistry Act, 1991* (General) be amended by adding the following section:

15.1 It is a condition of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 7 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

5. That Ontario Regulation 205/94 under the *Dentistry Act, 1991* (General) be amended by adding the following:

PART V

STANDARDS OF PRACTICE

- 32.** The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 7 of section 4 of the Act.
- 33.** The standards of practice referred to in section 32 shall be developed on the recommendation of the Dentistry Standards Committee.
- 34.** For the purposes of section 33, the College shall establish the Dentistry Standards Committee referred to in section 33 and shall appoint the membership of the Dentistry Standards Committee, which shall include, at a minimum, one or more:
- a) members of the Council;
 - b) members of the College (including practitioners and educators);
 - c) persons who are not and have not been members of the College or of the Council;
 - d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario, who practice family medicine;
 - e) members of the College of Nurses of Ontario, approved by the College of Nurses of Ontario; and
 - f) members of the Ontario College of Pharmacists, approved by the Ontario College of Pharmacists.
- 35.** The College shall post the standards of practice referred to in section 32 on its website.

6. That section 2 of Ontario Regulation 853/93 under the *Dentistry Act, 1991* (Professional Misconduct) be amended by adding the following section:
 - 5.1** Failing to advise the patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such consultation to ensure the proper care of the patient.
7. That section 2(10) of Ontario Regulation 853/93 under the *Dentistry Act, 1991* (Professional Misconduct) be repealed and the following substituted:
 - 10.** Prescribing, dispensing, selling or compounding a drug for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell or compound drugs.
8. That section 2 of Ontario Regulation 853/93 under the *Dentistry Act, 1991* (Professional Misconduct) be amended by adding the following sections:
 - 10.1** Being subjected to the withdrawal or restriction of rights or privileges under the *Controlled Drugs and Substances Act* (Canada) or the *Food and Drugs Act* (Canada) or the regulations under either of those Acts, unless by the member's own request.
 - 10.2** Contravening, while engaged in the practice of dentistry, any federal or provincial law or municipal by-law with respect to the prescribing, dispensing, distribution or sale of any drug or mixture of drug.
9. That sections 1 to 36, 38 to 49, 51 to 60 and Forms 1, 2 and 3 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act* (Dentistry) be repealed and made a regulation under the *Dentistry Act, 1991*.
10. That section 50 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act* (Dentistry) be repealed and made a regulation under the *Dental Hygiene Act, 1991*.
11. That section 37 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act* (Dentistry) be repealed.
12. That all references to drugs listed in Schedules A, B, C, D, E, F, G and N found in sections 39, 41, 44, 45 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act* (Dentistry) be amended to refer to the corresponding drugs listed in Schedules I, II, III or U of the *Drug and Pharmacies Regulation Act* when enacted as a new regulation under the *Dentistry Act, 1991*.

THE PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF MIDWIFERY

The College of Midwives of Ontario (CMO) and the Association of Ontario Midwives (AOM) made a joint submission requesting that the existing list of drugs in the regulation under the *Midwifery Act, 1991* be replaced with a regulation that includes therapeutic classes of drugs, and that the regulatory mechanism for clinical regulations be revised to ensure responsive and timely revision to enable midwives to keep up with current practice.

HPRAC's Central Response

Ontario's midwives have a significant role to play in primary maternity care during normal, healthy pregnancies. To further this role, HPRAC recommends that midwives in Ontario be authorized to prescribe and administer drugs that are identified in the regulation under the *Midwifery Act, 1991* by therapeutic class, and that additional drug classes and agents be authorized to the profession. HPRAC is proposing a new regulatory framework for drug approvals in Ontario which will be based on approval of classes of drugs and will include a more efficient process for approval of individual drugs within classes.

Review of Midwifery Scope of Practice

HPRAC recently reviewed the scope of practice for the profession of midwifery. In that review, the CMO and the AOM partnered in a joint response to HPRAC's investigation. At the same time, HPRAC had also been asked by the Minister to consider the prescribing and use of drugs by non-physicians. HPRAC determined that scope of practice reviews were an essential first step in making recommendations to the Minister on whether a profession should be authorized to prescribe, dispense, sell or compound drugs and under what conditions. HPRAC therefore considered the question of drug regulations under the *Midwifery Act, 1991* as a matter to be considered during this second phase of its examination, following the review of the scope of practice of the profession.¹

Background on Midwifery in Ontario

The Profession

Midwives are trained to manage labour and conduct spontaneous normal vaginal deliveries in their practice settings and have a significant role to play in primary maternity care during normal, healthy pregnancies. The scope of practice of midwifery is: "the assessment and monitoring of

¹ HPRAC, *HPRAC: An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Collaboration Among Health Colleges and Regulated Health Professionals: Phase II, Part I*. September 2008:94.

women during pregnancy, labour and the post-partum period and of their newborn babies, the provision of care during normal pregnancy, labour and post-partum period and the conducting of spontaneous normal vaginal deliveries.”²

Midwives provide antepartum, intrapartum and postpartum care, that is, care before, during and after childbirth, in hospitals, maternity centres and in the woman’s home.³ In 2007–2008, midwives provided care to approximately 12,500 women in Ontario.⁴

Since 1994, midwives have obtained admitting privileges at two-thirds of Ontario hospitals that provide maternity care. Approximately 78 percent of midwifery clients choose to give birth in the hospital setting, while 22 percent opt for home births. About 1.5 percent of all babies in Ontario are born at home. Given demographic and other social trends affecting maternity care, the total number of births that take place in hospitals is expected to rise. Ontario’s experience in home births is comparable to that of Great Britain, where the rate of births taking place in the home is around two percent. In 2006–2007, 366 midwives provided care for eight percent of the 134,141 births in Ontario.⁵

Midwifery is a managed government program in Ontario. Midwives are considered primary care providers and a referral from another health professional is not required. They can provide autonomous prenatal, intrapartum and postpartum care.

The Ontario Ministry of Health and Long-Term Care allocates an annual budget for midwifery services, education and placements in the province. Midwives work as independent practitioners in group practices that are funded by the Ministry’s Ontario Midwifery Program (OMP). Each practice group has a funding arrangement with a Ministry-approved non-profit agency (transfer payment agency) that receives funding from the OMP and distributes it to midwifery practice groups. Each midwifery practice group, usually comprised of two to five midwives, then has a funding agreement with the transfer payment agency to provide services in a particular geographic area.⁶

² *Midwifery Act, 1991, S.O. 1991, c.31, s. 3.*

³ HPRAC. *An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration Among Health Colleges and Regulated Health Professionals: Phase II, Part I.* September 2008: 82.

⁴ College of Midwives of Ontario. *Annual Report 2007-2008.* 7.

⁵ HPRAC. *Review of the Scope of Practice of Midwifery, An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration Among Health Colleges and Regulated Health Professionals: Phase II, Part I.* 85.

⁶ *Ibid.*

How the CMO Regulates its Members

The CMO is the regulatory body for the province's 414 registered midwives (RMs).⁷ The CMO's primary responsibility is the protection of the public, specifically childbearing women and their infants, to whom its members provide care.⁸

Legislative and Regulatory Framework for the Practice of Midwifery

The *Midwifery Act, 1991* regulates the practice of midwifery in Ontario. In addition, midwives' scope of practice is defined through regulations, CMO guidelines and standards of practice as well as other legislation. One of the CMO's key standards for midwifery practice is *Indications for Mandatory Discussion, Consultation and Transfer of Care (Indications)*. This document provides a guide for midwives on when they are required to discuss, consult or transfer primary care responsibility for the patient to another health professional.⁹

Authorized Acts

Under the *Midwifery Act, 1991*, midwives are authorized, in the course of engaging in the practice of midwifery, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Managing labour and conducting spontaneous normal vaginal deliveries;
2. Performing episiotomies and amniotomies and repairing episiotomies and lacerations, not involving the anus, anal sphincter, rectum, urethra and periurethral area;
3. Administering, by injection or inhalation, a substance designated in the regulations;
4. Putting an instrument, hand or finger beyond the labia majora during pregnancy, labour and the postpartum period;
5. Taking blood samples from newborns by skin pricking or from women from veins or by skin pricking;
6. Inserting urinary catheters into women;
7. Prescribing drugs designated in the regulations.¹⁰

Regulations

The Council may make regulations, subject to the review of the Minister and approval of the Lieutenant Governor in Council as follows:

- (a) designating the substances that may be administered by injection or inhalation by members in the course of engaging in the practice of midwifery;
- (b) designating the drugs that may be prescribed by members in the

⁷ CMO. *Annual Report 2007-2008*. 7.

⁸ CMO. *Mandate*. Available : <http://www.cmo.on.ca/aboutMandate.asp>.

⁹ *An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals: Phase II, Part I*: 91.

¹⁰ *MA*, c.31, s. 4.

- course of engaging in the practice of midwifery;
- (c) specifying the drugs that a member may use in the course of engaging in the practice of midwifery.

Regulations designating drugs that may be prescribed or specifying drugs that a member may use may specify individual drugs or categories of drugs.¹¹

Designated Drug Regulation:¹²

The following is a list of drugs that midwives are currently able to prescribe or use, and the conditions under which they can prescribe or use these drugs:

The following substances may be administered by injection on the member's own responsibility:

- Carboprost;
- Dimenhydrinate;
- Diphenhydramine hydrochloride;
- Epinephrine hydrochloride;
- Hepatitis B immune globulin;
- Hepatitis B vaccine;
- Intramuscular ergonovine maleate;
- Intramuscular or intravenous oxytocin;
- Intravenous fluids;
- Lidocaine hydrochloride with or without epinephrine;
- Phytonadione; and
- RhD immune globulin.

The following substances may be administered by injection on order of a member of the College of Physicians and Surgeons of Ontario:

- Antibiotics;
- Epidural analgesia (continuous infusion maintenance);
- Narcotic antagonists;
- Narcotics; and
- Oxytocics intravenous infusion.

The following substances may be administered by inhalation on the member's own responsibility:

- Nitrous oxide; and
- Therapeutic oxygen.

The following drugs are designated as drugs that may be prescribed by a member on the member's own responsibility:

- Clotrimazole;
- Doxylamine succinate-pyridoxine hydrochloride;
- Erythromycin ophthalmic ointment;

¹¹ MA, c.31, s. 11.

¹² Ontario Regulation 884/93. (Designated Drugs).

- Hepatitis B immune globulin;
- Hepatitis B vaccine;
- Hydrocortisone anorectal therapy compound;
- Miconazole;
- Nystatin;
- Oral ergonovine maleate;
- Phytonadione; and
- RhD immune globulin.

The following drugs may be used on order of a member of the College of Physicians and Surgeons of Ontario:

- Acetaminophen with codeine;
- Antibiotics;
- Antiemetic/sedative agents with narcotic analgesics;
- Barbiturates;
- Cervical ripening agents; and
- Sedatives.

Education and Continuing Competency

The Midwifery Education Program (MEP) in Ontario is a baccalaureate program jointly offered by Laurentian University, McMaster University and Ryerson University and leads to the degree Bachelor of Health Sciences (B.H.Sc.) in midwifery. At McMaster and Laurentian, the program involves four years of full-time study, while at Ryerson the program is offered on a part-time basis.

Competencies for pharmacotherapy are tested as part of the pharmacology course, the life sciences course and in midwifery clinical courses. The pharmacotherapy course includes an overview of basic concepts in pharmacy, pharmacology and therapeutics relevant to the practice of midwifery in Ontario. Content areas include pharmacokinetics, toxicology, adverse drug reactions during pregnancy, drug transfer through lactation and pharmacology in the neonate. In the life science for clinical practice course, concepts of general microbiology including the growth and structure of bacteria are taught. The concepts of microbial control (wound infection, neonatal infection and sexually transmitted microbial disease such as chlamydia and gonorrhea) and virology (e.g., hepatitis viruses, HIV, HPV and herpes) are also taught. All major families of antivirals, antibiotics and antifungals are taught.

In addition to classroom instruction, the program includes six clinical placements, five with midwifery practices and one community placement. Clinical competencies are evaluated on an on-going basis as part of the clinical placement performance. Pharmacology comprises one of five areas of evaluation.¹³

¹³ College of Midwives of Ontario and Ontario Association of Midwives. Submission to Health Professions Regulatory Advisory Council on *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 12, 2008: 15.

The International Midwifery Pre-registration Program (IMPP) is a nine month, part-time bridging program. It provides internationally-educated midwives with skills assessment, information about midwifery practice in Ontario, clinical placements, mentoring and a final pre-registration exam. The IMPP is intended for experienced international midwives, fluent in English, who have practised midwifery within the past five years. It is not a re-education or retraining program. According to the CMO submission, the IMPP program has six years of experience partnering with the MEP in the delivery of MEP-equivalent curriculum for internationally-trained midwives.

There is no national accrediting institution for Canadian midwifery programs at the present time. However, a National Midwifery Assessment Strategy is currently underway to assess and facilitate the entry-to-practice of internationally-trained midwives.

The CMO has three classes of registration: general, general with conditions and supervised. Registrants in the general class practise with no restrictions on their registration. To be registered, all applicants must provide proof of graduation from an MEP or IMPP program or status as a registered midwife in another jurisdiction. They must also have current certification in cardiopulmonary resuscitation, obstetrical emergency skills and neonatal resuscitation.

Maintaining Registration

To be an active practice registrant (APR), the CMO's registration regulations require members to report birth attendance numbers. Requirements vary with years of active practice. If members do not meet or fail to report their active practice numbers, whether in the initial two-year period or in subsequent five-year periods, they are required to take an Individualized Requalification Program as set out by the CMO's Registration Committee. Ontario midwives must also certify every two years in cardiopulmonary resuscitation, obstetrical emergency skills and neonatal resuscitation.¹⁴

Members are also expected to maintain clinical competency regarding drug regulations as part of routine professional development. Members are required to participate in continuing education as part of the CMO's quality assurance program.

Quality Assurance

The CMO's quality assurance program contains seven components, which include: the provision of clinical information, continuing education and professional development, peer case review, quality of care evaluation, self-assessment, random practice audits and remediation.

¹⁴ HPRAC *Review of the Scope of Practice of Midwifery*. September 2008: 89.

HPRAC Scope of Practice Review

HPRAC has recently completed a review of the scope of practice of midwives in Ontario. The review concluded that Ontario's midwives have a significant role to play in primary maternity care during normal, healthy pregnancies. HPRAC recommends that midwives acquire additional tools to strengthen their role as primary, low-risk maternity care providers, as regulatory and structural barriers to their practice are removed.

HPRAC did not find that the expansion of the scope of midwifery practice into high-risk, complex care is supported by their current training and clinical experience. HPRAC did not recommend expanding the scope of practice for midwives in Ontario, nor recommend the creation of an extended class of midwives in Ontario.

HPRAC has recommended that midwives be given access to a number of tools to strengthen their role as primary, low-risk maternity care providers. Changes recommended include that midwives be authorized to:

- Communicate a diagnosis of a disease, disorder or dysfunction that can be identified through a midwifery assessment;
- Take blood samples from fathers and donors from veins or by skin pricking;
- Put an instrument, hand or finger beyond the anal verge for the purpose of administering suppository medications; and
- Order additional laboratory tests and diagnostics, consistent with their scope of practice, except for orders for maternal postpartum ultrasounds and newborn follow-up ultrasounds.

HPRAC also recommended that the CMO develop comprehensive standards of practice, with terms, limitations and conditions for emergencies and that these standards be incorporated into the CMO's *Indications* document and indicate the education and clinical training required to maintain competency for emergency procedures. This recommendation is intended to address requests for a number of authorities that midwives may need in emergency situations.

In the scope of practice review, midwives requested access to a number of drugs that they have not previously been authorized to prescribe or administer. These include prescribing and administering oxytocin, prescribing and administering antibiotics for Group B streptococcus, mastitis, bacterial vaginosis, urinary tract infections and sexually transmitted infections. They also requested the authority to order and administer mumps, measles and rubella vaccine (MMR) and to order and administer varicella. These requests have been referred to this review for consideration.

What the CMO and AOM Proposed

The CMO and AOM are proposing a new regulation that would give midwives the authority to prescribe and/or administer any drug from a category specified in the chart, within the scope of midwifery.¹⁵ They also recommend that the regulatory mechanism for clinical regulations be amended to respond to ongoing changes in standards of practice in maternity care in a timely manner and that midwives be granted the authority to prescribe or administer any substance on the order of a physician.

Request 1: Classes versus Lists

The proponents are requesting that the existing list of drugs in the midwifery designated drugs regulation be revoked and replaced with a regulation that includes therapeutic categories of drugs, specific to the clinical indication. They recommend that midwives have the authority to prescribe 23 categories of drugs.

Proponents' Rationale

Classes/Categories of Drugs

Access to drug categories, as opposed to the individual pharmaceuticals, would greatly enhance midwives' capacity to stay apace of emerging best practices as primary care providers.¹⁶ In its submission, the proponents note that "the standards regarding the use of antibiotics in particular are regularly changing as bacteria become resistant to specific courses of treatment and new, and sometimes older, antibiotics become effective".¹⁷

Under the current regulation-making process, new drugs are difficult to add to the list and there is an inevitable lag between development of new drug regimes and implementation by midwives. Giving midwives access to categories of drugs will ensure that they have the resources to provide the best standard of care to women over the long term.¹⁸

Changing the drug regulation to include categories of drugs will also bring Ontario in line with the standard of midwifery care across the country.¹⁹

In addition to requesting regulation by class of drugs, the proponents are also requesting that a number of new classes of drugs be added to those that midwives can prescribe and administer on their own authority.

¹⁵ CMO and AOM. Submission to HPRAC. 7.

¹⁶ Ibid: 9.

¹⁷ Ibid.

¹⁸ Ibid: 10.

¹⁹ Ibid.

Significant delays to treatment and costs to the health care system occur when clinically unnecessary consultations with or referrals to physicians are required due to restrictions created by the current drug regulation. Examples of unnecessary consultations include the need to refer women to physicians simply because of the lack of authority to prescribe a needed medication, for example, antibiotics for urinary tract infections. These unnecessary consultations place extra strain on the health care system, add costs, and can create tension in the relationship between midwife and physician.

The submission also notes that midwives have a clear standard of practice that supports appropriate discussions with physicians and, with appropriate prescribing rights, would avoid unnecessary consultations. A standard on prescribing and administering drugs for midwives will be developed to accompany an amended drug regulation and establish the necessary guidelines and parameters required for the safe application of the revised regulation. This standard will include clinical situations where midwives will be required to consult with a physician if a client is not responsive to the prescribed treatment.²⁰ The CMO also notes that an updated drug regulation will be included in the CMO's quality assurance program.

According to the AOM, the drugs proposed reflect day-to-day practice in midwifery. They address normal indicators that may occur in a typical, low-risk birth. Lack of access to these drugs is a core barrier to safe and cost-effective midwifery practice. Under the current regulatory regime midwives can conduct clinical assessments, order laboratory tests, interpret the laboratory test results, make a diagnosis, ask for treatment and monitor the treatment. The missing link is ordering, that is, prescribing and administering, the treatment. At the current time, midwives are not required to communicate a diagnosis in advance of prescribing the treatment. In its scope of practice review, HPRAC has recommended that midwives have the authority to communicate a diagnosis.

The following chart provides a list of the 23 classes of drugs requested:

Indication	Therapeutic Category
Repair of episiotomies and lacerations	Anaesthetics (local)
Relief of pain in labour	Analgesics
<ul style="list-style-type: none"> • Intra-partum chemoprophylaxis for Group B strep • Treatment of topical bacterial infections common to pregnancy and the postpartum period • Treatment of breast infection • Treatment of urinary tract infection • Prophylaxis of ophthalmia neonatorum • Treatment of lower reproductive tract infections 	Antibiotics

²⁰ Ibid: 14.

Indication	Therapeutic Category
Treatment of candidiasis	Antifungals
Treatment of maternal nausea and vomiting	Anti-nauseants/Anti-emetics
Treatment of herpes simplex virus	Antivirals
Induction of labour	Cervical ripening agents
Prevention of conception	Contraceptives**
Treatment of skin inflammation and hemorrhoids	Corticosteroids
Relief of pain in labour	Epidural analgesia (continuous infusion maintenance)
Enhancement of milk production	Galactagogues
Treatment of anaphylaxis related to the administration of drugs, vaccines or sera	Histamine antagonists
<ul style="list-style-type: none"> • Viral prophylaxis in the neonate • Viral prophylaxis or treatment of the woman in pregnancy or the postpartum period • Prevention of Rh disease 	Immune globulins
Nitrous oxide for pain relief in labour or the immediate postpartum	Inhaled general anaesthetics
<ul style="list-style-type: none"> • Prophylaxis or treatment of dehydration • Treatment of hypovolemia • As a route of administration for medications 	Intravenous fluids
Treatment of uterine hypertonus	Nitrates
Relief of inflammation and pain	Non-steroidal anti-inflammatories
Reversal of opiate-induced depression	Opiate antagonists
Induction or augmentation of labour	Oxytocics
Oxygen for maternal and neonatal resuscitation	Therapeutic gases
Prophylaxis and treatment of uterine atony and postpartum hemorrhage	Uterotonic agents
Establishing an immune response	Vaccines **
Nutritional therapy and support	Vitamin and mineral supplements

** contraceptives and vaccines (with the exception of the Hepatitis B vaccine which midwives are currently authorized to administer to newborns) are proposed as a component of the proposed extended class of Midwifery as recommended by the CMO in the Scope of Practice Review.

The following categories, if approved, would give midwives the authority to prescribe drugs that they have not previously been authorized to prescribe.

Antibiotics

The inability to prescribe antibiotics for a number of common conditions, such as urinary tract infections and lower reproductive tract infections, and prophylaxis for Group B strep, is limiting the ability of midwives to practise to their full competencies. It is placing a strain on health human resources through unnecessary consultations and referrals, and can delay treatment for patients. Midwives use culture and sensitivity investigations (laboratory), oral history and assessment of physical symptoms to determine the condition that requires treatment.

The CMO has developed draft standards of practice for the prescribing of intravenous, topical or oral antibiotics for the following conditions:²¹

- Group B streptococcus (GBS),
- Urinary tract infections (UTI),
- Mastitis (unclogged ducts),
- Bacterial vaginosis, and
- Breast and nipple pain (breast infection).

CMO notes in its submission that it is estimated that 15 to 40 percent of all pregnant women are GBS colonized. Between 40 and 70 percent of colonized mothers pass the bacteria on to their babies during the birthing process. A very small number of these babies go on to develop a GBS infection. Prescribing antibiotics in labour to clients at risk of transferring GBS to their newborns is a standard prophylactic treatment. The proponents state that midwives have the competency and necessary education to manage these clinical scenarios. In instances where there is no medical directive, timely access to care can be impeded by the inability to prescribe antibiotics.

Obstetricians have complained to us that they feel it is ridiculous that we cannot order antibiotics and a few have even told me that I should be speaking with my College about this limitation. It often causes OB annoyance as they must be woken in the night to consult for GBS prophylaxis at times.

Joint submission by CMO and AOM
November 12, 2008

Midwives also noted in consultations with HPRAC that there are cases, particularly in rural areas, where the physician who is contacted to prescribe the antibiotic is not current with obstetrical protocols and needs to receive additional information and consultation to be comfortable prescribing the latest antibiotic.

Continuous Infusion Maintenance of Epidural Analgesia

This procedure would be performed in a hospital setting only. Maintenance involves changing the bag and maintaining the level of the block and sedation level. Registered nurses may also do this in the absence of a midwife. Proponents state that, although the responsibility for epidural analgesia throughout the course of labour and delivery rests with the anaesthetist at all times, the proponents would like to provide midwives with the opportunity to provide continuing monitored care.

This will relieve pressure on nurses and obstetricians in hospitals, and provides the patient with the option of having someone familiar to them monitor the epidural. The proponents recommend that a midwife who wishes to provide continuing monitored care for epidural anaesthesia be certified annually. The process of annual recertification would likely depend on the number of epidurals monitored by the midwife in the preceding twelve months. The provision of epidural analgesia monitored care is an additional certification which a midwife may elect to obtain.

²¹ Ibid, Appendix A: Draft Standard for Prescribing and Administering Drugs.

To gain initial certification, the following knowledge is required:

- the pharmacology, action, and side effects of local anaesthetics and narcotics used in epidural analgesia;
- the effects of epidural analgesia on the progress of labour;
- the advantages, disadvantages and contraindications of epidural analgesia;
- anaesthetic requirements for preparation of the client for epidural analgesia;
- recognition of, response to, and management of immediate anaesthetic complications of epidural analgesia;
- technique of epidural insertion;
- initiation of epidural block;
- maintenance of analgesia in all stages of labour;
- postpartum management; and
- knowledge of when to adjust the rate of an infusion pump.

Galactagogues

Galactagogues (domperidone) are a relatively new class of drugs that assist women with milk production. The proponents state that prescribing these drugs is well within the scope of practice of midwives. Proposed standards have been developed in the CMO draft standard for prescribing and administering of drugs for the prescribing of domperidone to treat inadequate milk supply.²²

Immune Globulins

This class falls within the drugs that midwives normally prescribe for the occasional case. It is part of the regular care for low-risk births. Midwives currently have access to RhD immune globulin. The proponents are requesting the authority to prescribe varicella zoster immune globulin to treat women who have been exposed to the varicella zoster virus (chicken pox). This is a standard treatment for women who have been exposed to this virus, and is important to prevent maternal infections.

Proposed standards have been developed for prescribing varicella zoster immune globulin for the prevention or reduction of severity of maternal infections when exposure to the varicella zoster virus has occurred. The proposed standard is located in the CMO draft standard of practice for prescribing and administering of drugs.²³

Non-steroidal Anti-inflammatories (NSAIDs)

This is a first line treatment for postpartum pain, and prescribing these drugs is within the competencies of midwives. In consultations with midwives, the AOM has said that there is very little variety in the drugs within this class, and that it makes sense for midwives to have access to these drugs. Proposed standards have been developed by the CMO for prescribing oral NSAIDs to treat postpartum pain.²⁴

²² Ibid.

²³ Ibid.

²⁴ Ibid.

Postpartum Uterotonics (Oxytocics)

Midwives are asking for access to the oxytocics for use in treating postpartum hemorrhaging. Oxytocin is routinely offered to control hemorrhaging immediately after delivery (management in the third stage). According to the AOM, research shows this reduces chances of postpartum hemorrhaging and excessive blood loss. It can be administered by intramuscular (IM) or intravenous (IV), depending on the care setting. If the patient does not respond to treatment, a second dose is administered. The AOM notes that this is within a midwife's scope of practice and is routine practice. This is the first line of anti-hemorrhagic treatment.

This is emergency treatment, but it will be effective in the vast majority of cases. Midwives are trained to respond to an emergency situation. Any prolonged labour would automatically be transferred to a hospital, so hemorrhaging is most likely treated there. The request for this drug suits midwives who are working in rural areas who may have a long wait, should emergency medical services be required. The midwives' intervention is useful because it helps prevent a more serious situation.

Proposed standards have been developed for prescribing antihemorrhagics and oxytocics to treat postpartum bleeding in the CMO draft standard for prescribing and administering of drugs.²⁵

Vaccines for Contraceptives

As part of their request for an extended class of midwives, the CMO has requested that midwives be given the authority to prescribe vaccines for contraceptive purposes.

Narcotics

Midwives have no independent access to narcotics; they may only administer morphine and meperidine under the order of a physician. If a narcotic is administered, a narcotic antagonist is available for the baby as a safety measure. In certain cases, a newborn may be given a narcotic antagonist if the mother was given a narcotic during childbirth.

Midwives are seeking direct access to controlled substances for pain relief. Health Canada is considering changes to regulations under the Controlled Drugs and Substances Act (Canada) to permit midwives and other designated practitioners (e.g., nurse practitioners and podiatrists) to possess, administer, prescribe, sell or provide and/or transport certain controlled substances as defined by the regulation.²⁶

Emergency Medications

The CMO provides a list of equipment all midwives should have with them for home births. An emergency home birth kit comprises treatment for anaphylaxis, epinephrine, IV solutions and equipment, oxytocin, ergonome,

²⁵ Ibid.

²⁶ Ibid: 8.

carbotosin and oxygen. Midwives do not carry nitroglycerine for home births, since the need is extremely rare. However, a midwife could administer nitroglycerine in a hospital where a standing order has been issued.²⁷

Request 2

The CMO and AMO are requesting that the regulatory approvals mechanism for clinical regulations be revised.²⁸

Proponents' Rationale

The proponents said that currently, approval of and modifications to regulations occur within the Ministry. Revising the regulatory mechanism for regulations related to clinical practice will enable the CMO, and by extension midwives, to respond to ongoing changes in the standard of practice in maternity care in a timely way.²⁹

Request 3

The CMO and AMO are requesting the authority to prescribe and/or administer any substance on the order of a physician.³⁰

Proponents' Rationale

In comparison to other health professions that administer drugs, the midwifery profession is the only one that has a specific list of drugs its members can administer under the order of a physician. For registered nurses, the *Nursing Act, 1991* states that a member shall not perform a controlled act unless the procedure is ordered by a person who is authorized to do the procedure such as chiropodists, dentists, physicians and midwives.³¹ Respiratory therapists have a similar provision in its profession specific regulation³² as do medical radiation technologists.³³

What HPRAC Found

Epidemiological Trends

Changes in the population of childbearing women are having an impact on the type of care that women require. The submission notes that the increase in the average maternal age, as well as increases in rates of obesity and the associated risk of increased blood pressure, genetic abnormalities, and overall greater morbidity have resulted in the need for more tests and for different treatment protocols.

²⁷ HPRAC meeting with AOM, December 11 2008

²⁸ Ibid: 7.

²⁹ Ibid: 10.

³⁰ Ibid: 7.

³¹ *Nursing Act, 1991, S.O. 1991, c. 32, s.5. (1).*

³² *Respiratory Therapy Act, 1991, S.O. 1991, c.39, s.5. (1).*

³³ *Medical Radiation Technology Act, 1991, S.O. 1991, c.29, s.5. (1).*

HPRAC agrees that midwives need access to appropriate tools to strengthen their role as primary low-risk maternity care providers.

Health Human Resources, Access to Care and Coordination of Care

HPRAC's scope of practice review discussed in detail the growing maternity crisis in Canada. Over the past 15 to 20 years, demographic and other social trends have had a significant effect on the provision of maternity care. These trends include a shortage of maternity care providers and regional disparities in the provision of maternity care. There are fewer family physicians attending births. The number of family physicians attending births has decreased by 43 percent from 1992 to 1999. By 2003-2004, only 6.9 percent of family physicians billed OHIP for more than one birth.³⁴ Obstetricians now attend over 80 percent of births. Obstetricians are seeing more patients and are spending more time on call to address the shortage of family physicians delivering babies. There are indications that the shortage of obstetricians will become more severe in the near future. At least 34 percent of obstetricians are planning to retire within the next five years.

A report released recently by the Society of Obstetricians and Gynaecologists of Canada confirms that there is a serious crisis looming in Canada because of a critical shortage of obstetricians. This report was extensively covered in the media.

The problems facing obstetricians are part of a larger, more complex human resources struggle occurring throughout Canada's health-related professions. Cross-country shortages of family doctors, midwives, nurses and nurse practitioners have resulted in an increasing number of obstetricians taking on bigger workloads and responsibilities that normally don't fall to a specialist.

According to the executive director of the Canadian Women's Health Network, Madeline Boscoe, "(The) problem...not only leaves obstetricians overworked, but also underutilizes their expertise...[and] it may prevent women with serious health issues that require a specialist from getting sufficient care."³⁵

As noted in its scope of practice review, HPRAC views midwives as playing an important role in addressing the health human resources shortage by providing primary maternal care for low-risk births in Ontario.

HPRAC's Observations

Classes versus Individual Drugs

HPRAC is recommending a revised process for drug approvals in Ontario that will be based on the approval of classes of drugs in regulations under health profession Acts. A new and expedited process for the approval of individual drugs within classes is also being proposed. The implementation

³⁴ HPRAC. *Review of the Scope of Practice of Midwifery*. 80-81.

³⁵ *The Globe and Mail*. December 5, 2008.

of these recommendations will address the request for regulation by class rather than individual drug.

Specific Classes of Drugs

Readiness for Change

HPRAC's review of the drug education of midwives in Ontario concluded that the program is comprehensive. It includes pathophysiology/diagnosis, drug history (including limitations), pharmacodynamics, pharmacokinetics, toxicology and patient communication and monitoring.

Midwives currently have prescribing rights, and in HPRAC's view, midwives are educated and trained on an on-going basis to prescribe the most current drugs to treat conditions within their scope of practice. HPRAC found that there is a high level of consistency in midwifery programs across the country, and precedent for prescribing drugs within the midwifery scope of practice.

Members of the CMO support moving to classes from individual drugs in regulation, and they support the addition of the specific classes that the CMO is requesting. The CMO held formal consultations with its members regarding the proposed changes to the scope of practice. Of those who responded (64 percent of members), 98 percent supported the addition of antibiotics for the treatment of GBS, mastitis, UTIs and bacterial vaginosis. Ninety percent supported the inclusion of antibiotics for the treatment of some STIs.

Managing the Risk of Harm

Members are expected to maintain clinical competency as part of their routine professional development. As well, members are required to participate in continuing education as part of the CMO's quality assurance program. These requirements include continued competency in pharmacology. The CMO will determine any additional training and upgrading that is needed to ensure midwives are trained to prescribe and administer new classes of drugs that are approved.

Supporting Collaboration

The proponents have noted that giving midwives the authority to prescribe certain drugs, antibiotics in particular, will enable them to participate more fully in interprofessional teams. HPRAC heard that this will also relieve the strain on physician-midwife relationships by eliminating unnecessary consultations and referrals.

Individual Classes of Drugs

Antibiotics

In its scope of practice review, HPRAC heard that, within the current scope of practice, Ontario midwives do not have the authority to order

antibiotics, unlike other Canadian jurisdictions, where there is broad authority to prescribe antibiotics.

HPRAC remains concerned that midwives are not authorized to prescribe antibiotics for Group B streptococcus. During the scope of practice review consultations, HPRAC heard numerous examples of the need to prescribe antibiotics to provide appropriate and safe patient care.

While there are risk of harm issues concerning the misuse of antibiotics, such as the development of antibiotic drug resistance and opportunistic infections, on balance HPRAC is convinced of the need for midwives to have the authority to prescribe antibiotics within their scope of practice, and that these risks can be mitigated by appropriate education, training and standards of practice.

Continuous Infusion Maintenance

HPRAC heard that there is some variability in midwives monitoring continuous infusion maintenance for in-hospital births across Ontario. In certain hospitals midwives monitor and adjust infusions whereas in others this task is performed by nurses. In either case, a prescriber has ordered the infusion and an anaesthesiologist has administered the injection. HPRAC agrees that midwives are competent to monitor and adjust continuous infusion maintenance but feels that this is an issue best left for individual hospitals to decide.

Galactagogues

HPRAC heard that Galactagogues (domperidone) are a relatively new class of drugs that assist women with milk production. HPRAC's review of this class of drugs indicates that they are safe to use, and that midwives have the competencies to prescribe them to treat inadequate milk supply.

Immune Globulins

HPRAC heard that this class falls within the drugs that midwives normally prescribe for occasional cases. It is part of the regular care for low-risk births. The profession is requesting the authority to prescribe varicella zoster immune globulin within this class of drug to treat women who have been exposed to the varicella zoster virus (chicken pox). HPRAC notes that this is a standard treatment for women who have been exposed to this virus and is important to prevent maternal infections. HPRAC agrees that this drug should be added to the immune globulins class to enable midwives to treat women who may be at risk from exposure to the varicella zoster virus. Midwives have the education and training needed to prescribe this drug, and will have appropriate standards of practice in place for prescribing and administering the drug.

Non-steroidal Anti-inflammatories (NSAIDs)

This is a first line treatment for postpartum pain and prescribing these drugs is within the competencies of midwives. HPRAC agrees that there is very little variety in the drugs within this class, and that it makes sense for

midwives to have access to these drugs. Proposed standards have been developed for prescribing oral NSAIDs to treat postpartum pain in the CMO draft standard of practice for prescribing and administering of drugs.³⁶

Postpartum Uterotonics (Oxytocics)

As noted in the scope of practice review, oxytocin is a drug that is used for two purposes in labour and delivery: postpartum, to contract the uterus to decrease bleeding, or intrapartum to contract the uterus to augment labour. Oxytocin has known complications and has been classified as a high alert medication by the Institute of Safe Medications Practices (ISMP). This classification indicates that oxytocin bears a heightened risk of harm when used in error.

The authority to prescribe oxytocin varies across jurisdictions. In British Columbia, it must be ordered and administered by a physician, and its use is restricted to a hospital setting for the purposes of augmentation and induction of labour. British Columbia is currently considering the use of oxytocin in specialized midwifery practice. In Manitoba, administering oxytocin is limited to postpartum use and Saskatchewan requires advanced competency for its administration. In Alberta, midwives are authorized to administer oxytocin intravenously or in muscles and the dosage is controlled by guidelines.

HPRAC heard during the scope of practice review of midwifery that prescribing oxytocin to augment labour is not part of a normal low-risk birth. It is an indication that the birth is not low-risk, (e.g., the need to induce labour in a case of pregnancy induced hypertension), that care should be transferred to a physician and management of labour should occur in a hospital setting.

In Great Britain, The Maternity Care Working Party, which includes the Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives, defines normal labour and birth as occurring without epidural anaesthetic before or during delivery.³⁷

The limitations were usually placed on the management of oxytocin induction or augmentation and on the management of epidural analgesia maintenance, and were established in hospital policies, through delegation protocols or medical directives.

The normal delivery group excludes women who experience induction of labour (with prostaglandins, oxytocics or ARM); epidural or spinal general anaesthetic; forceps, ventouse (also called vacuum-assisted vaginal delivery or vacuum extraction) or caesarean section delivery or an episiotomy.³⁸

HPRAC is of the view that there is a solid case for providing midwives with oxytocin as a first line of treatment for postpartum bleeding. While there

³⁶ CMO and AOM. *Submission to HPRAC*. Appendix A.

³⁷ HPRAC. *Review of the Scope of Practice of Midwifery*. 123.

³⁸ *Ibid*: 124.

are risks associated with the administration of oxytocin postpartum, it is a useful tool for midwives to have in the case of an emergency. In many cases, one administration of the drug will be sufficient to address the emergency situation. This is particularly important for midwives operating in rural and remote areas where transfer of care may be delayed due to transportation times. As well, HPRAC notes that proposed standards for prescribing antihemorrhagics and oxytocics to treat postpartum bleeding have been developed in the CMO draft standard of practice for prescribing and administering of drugs.

Vaccines for Contraceptives

As part of their request for an extended class of midwives, the proponents requested that midwives be given the authority to prescribe vaccines for contraceptive purposes. In the scope of practice review, HPRAC did not recommend that the extended class of midwives proceed. As such, HPRAC does not consider that access to vaccines for contraceptives is within the current scope of practice of midwives

Emergency Medications

The CMO provides a list of equipment all midwives should have with them for home births. An emergency home birth kit comprises treatment for anaphylaxis, epinephrine, IV solutions and equipment, oxytocin, ergonome, carbosin and oxygen.

As noted earlier in the report in the discussion of emergency medications, all professions that are carrying out in-office procedures should have access to the tools they need to handle emergency situations, provided they are trained to administer the medication properly and take actions to transfer patients to a hospital or other facility as necessary.

HPRAC agrees that midwives need to have an emergency kit on hand to handle emergencies before labour, during labour and after delivery. In HPRAC's view, the emergency kit should include: oxygen, epinephrine, IV solutions and equipment. HPRAC is also recommending that the class of uterotonics be approved for postpartum use. These include oxytocin, ergonome and carbosin, which can be used by midwives in emergency situations for postpartum care only.

Nitrates

HPRAC conducted independent research, discussed the issue with representatives from both the CMO and the AOM, and spoke with several leading obstetricians about what midwives should have access to in their emergency medications kit, or crash cart. Nitrates such as nitroglycerin can pose a significant risk of harm to the mother and fetus because they are potent smooth muscle relaxants. Conversely, administration of nitrates may be a life-saving measure in certain cardiovascular emergencies. Given the potential need for nitrates in emergency situations and the pharmacological training of midwives, HPRAC recommends midwives have access to nitrates in their emergency medications kit and recommends the development of practice standards for this and other emergency medications.

Anti-nauseants

Diclectin is a combination product containing doxylamine succinate (a first-generation, sedating antihistamine) and pyridoxine hydrochloride (vitamin B6). This product is the only antinauseant specifically indicated for nausea and vomiting in pregnancy and has an excellent safety record for both the mother and the developing fetus. HPRAC has classified this combination product as an “antihistamine”, however HPRAC expects this product to be prescribed to treat the nausea and vomiting associated with pregnancy.

Cervical Ripening Agents

Cervical ripening agents include the prostaglandin E1 analog, misoprostol, low-dose oxytocin, mifepristone, relaxin and other physical mechanisms to ripen the cervix. In its scope of practice review of midwifery, HPRAC concluded that the role of midwives involves providing care for normal births and deliveries. In that report, HPRAC stated that deliveries requiring cervical ripening agents fall outside the definition of a normal, uncomplicated birth and delivery and are therefore outside the scope of practice of midwifery. HPRAC also notes a significant risk of harm may be posed to the fetus and the mother by these agents.

Measles, Mumps and Rubella (MMR)

MMR vaccines contain live, attenuated measles, mumps, and rubella and the vaccine is administered by subcutaneous injection in Ontario after a child turns one, usually at twelve and at eighteen months. In the scope of practice review of midwifery, HPRAC recommended that the midwifery scope of practice not be extended to include well baby care, and does not recommend that MMR vaccines be included in the drug regulation under the *Midwifery Act, 1991*.

HPRAC’s Conclusions

HPRAC recognizes that there is a growing crisis in maternity care in Ontario, and sees midwives as playing an important role in providing primary maternity care for low-risk women and their newborns. Midwives require the ability to prescribe a number of medications to carry out their primary maternity care role and to enable them to participate fully in interprofessional teams.

Recommendations

Recommendation 1: That the *Midwifery Act, 1991* be amended to include the authority to prescribe a specified list of therapeutic drug classes. Dispensing and selling of drugs are not included in this authority.

That the existing list of drugs in the regulation under the *Midwifery Act, 1991* be replaced with a regulation that includes therapeutic classes of drugs.

Recommendation 2: That midwives be authorized to prescribe and/or administer any substance on the order of a physician.

Recommendation 3: That the following therapeutic classes of drugs be included in the designated drugs regulation under the *Midwifery Act, 1991*. The specific agents and any terms, limitations or conditions attached to the authority to prescribe drugs would be developed through a new drug approvals framework.

Class	Specific Agents
Class: Antihistamines	Doxylamine succinate-pyridoxine HCl
Class: Anti-infective Agents Sub-class: Antibacterials	Erythromycin ophthalmic ointment Ampicillin vs. neonatal Group B streptococcal disease Cefazolin vs. neonatal Group B streptococcal disease Clindamycin vs. neonatal Group B streptococcal disease Doxycycline Erythromycin vs. neonatal Group B streptococcal disease Penicillin G vs. neonatal Group B streptococcal disease Vancomycin vs. neonatal Group B streptococcal disease Amoxicillin-clavulanic acid vs. mastitis Azithromycin Cephalexin vs. mastitis Ciprofloxacin Clindamycin Cloxacillin erythromycin Nitrofurantoin for UTI Metronidazole Ofloxacin Trimethoprim Trimethoprim-sulfamethoxazole
Class: Anti-infective Agents Sub-class: Antifungals	Mupirocin-betamethasone valerate-miconazole
Class: Anti-infective Agents Sub-class: Antivirals	Acyclovir Valacyclovir
Class: Blood Derivatives	RhD immune globulin
Class: Galactagogues	Domperidone
Class: CNS Agents Sub-class: General Anesthetics Sub-sub-class: Inhalation Anesthetics	Nitrous Oxide
Class: CNS Agents Sub-class: Analgesics and Antipyretics Sub-sub-class: NSAIDs	Diclofenac Naproxen
Class: CNS Agents Sub-class: Opiate Antagonists	Naloxone Naltrexone

Class	Specific Agents
Class: CNS Agents Sub-class: Anxiolytics, Sedatives, and Hypnotics Sub-sub-class: Benzodiazepines	
Class: Hormones and Synthetic Substitutes Sub-class: Adrenals	Hydrocortisone Mupirocin-betamethasone valerate-miconazole
Class: Local Anesthetics	Lidocaine HCl with or without epinephrine chloroprocaine
Class: Uterotonics	Carboprost Prostaglandins/oxytocic IM ergonovine maleate IM or IV oxytocin Ergonovine maleate Misoprostol rectal
Class: Serums, Toxoids, and Vaccines	Varicella Zoster Immune globulin Hepatitis B immune globulin Hepatitis B vaccine MMR vaccine
Class: Vitamins	Phytonadione (vitamin K) Folic acid greater than one mg/dose
Class: Emergency Medications	Oxygen Epinephrine (IV or IM), Antihistamines (IM) Salbutamol ASA
Class: Local Anesthetics	Bupivacaine Lidocaine hydrochloride (with or without epinephrine) Mepivacaine hydrochloride

Implementation Proposals

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That section 4 of the *Midwifery Act, 1991* be repealed and the following substituted:

Authorized acts

4. In the course of engaging in the practice of midwifery, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Communicating a diagnosis of a disease, disorder or dysfunction that may be identified through a midwifery assessment.

2. Managing labour and conducting spontaneous normal vaginal deliveries.
3. Performing episiotomies and amniotomies and repairing episiotomies and lacerations, not involving the anus, anal sphincter, rectum, urethra and periurethral area.
4. Administering, by injection or inhalation, a substance that the member may administer under the regulations.
5. Putting an instrument, hand or finger beyond the labia majora during pregnancy, labour and the postpartum period.
6. Putting an instrument, hand or finger beyond the anal verge for the purpose of administering suppository drugs that the member may administer under the regulations.
7. Taking blood samples from newborns by skin pricking or from women, fathers or sperm donors from veins or by skin pricking.
8. Inserting urinary catheters into women.
9. Prescribing a drug that the member may prescribe under the regulations.

2. That the *Midwifery Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts

- 4.1 A member shall perform a procedure under the authority of section 4 in accordance with any requirements prescribed in the regulations.

Individual scope of practice for midwives

- 4.2 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

3. That sections 11(1) and 11(2) of the *Midwifery Act, 1991* be repealed and the following substituted:

Regulations

11. (1) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,
 - (a) requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing of drugs; and
 - (b) specifying requirements for the performance of procedures under the authority of section 4.

4. That the title of Ontario Regulation 884/93 (Designated Drugs) be renamed Drugs and Substances.

5. That sections 1 to 5 of Ontario Regulation 884/93 (Designated Drugs) be repealed and the following substituted:
1. For the purposes of paragraph 4 and paragraph 9 of section 4 of the Act,
 - (a) a member may prescribe or administer, on the member's own responsibility, the following classes of drugs and substances:
 - i. antihistamines,
 - ii. anti-infective agents – antibacterials, antifungals, antivirals,
 - iii. blood derivatives,
 - iv. galactagogues,
 - v. CNS agents: general anaesthetics, analgesics and antipyretics, opiate antagonists, anxiolytics, sedatives and hypnotics,
 - vi. hormones and synthetic substitutes – adrenals,
 - vii. local anaesthetics,
 - viii. uterotonics,
 - ix. serums, toxoids and vaccines,
 - x. vitamins, and
 - xi. emergency medications.
 - (b) a member may prescribe or administer by injection or inhalation, on order of a member of the College of Physicians and Surgeons of Ontario, any drug or substance.
 2. A member may use, on order of a member of the College of Physicians and Surgeons of Ontario, any drug.
 3. A member may prescribe, administer or order any drug or substance that may lawfully be purchased or acquired without a prescription.
 4. For the purposes of subsection 1(a), a member may only prescribe or administer, on the member's own responsibility, those drugs and substances within the classes designated in subsection 1(a) that are listed in the Drug List and must prescribe or administer those listed drugs and substances in accordance with the terms, limitations and conditions contained in the Drug List. For the purposes of this section, "Drug List" has the meaning given to it in the *Regulated Health Professions Act, 1991*.
6. That Ontario Regulation 867/93 (Registration) under the *Midwifery Act, 1991* be amended by adding the following:
- 3.1 It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

- 3.2** It is a term, condition and limitation of a certificate of registration of any class that the holder must comply with the standards, limitations and conditions set out in the publication of the College entitled, “*Indications for Mandatory Discussion, Consultation and Transfer of Care Guideline*,” as that publication is amended by the College from time to time.
7. That Ontario Regulation 858/93 (Professional Misconduct) under the *Midwifery Act, 1991* be amended by adding the following:
- 1.1** Exceeding the scope of practice of the profession.
8. That section 1(2) of Ontario Regulation 858/93 under the *Midwifery Act, 1991* be repealed and the following substituted:
- 1(2)** Contravening or failing to maintain a standard of practice of the profession.
9. That section 1(4) of Ontario Regulation 858/93 (Professional Misconduct) under the *Midwifery Act, 1991* be repealed and the following substituted:
- 4.** Delegating an act set out in paragraph 2, 3, 4, 5, 6, 7 or 8 of section 4 of the Act except as permitted by the *Regulated Health Professions Act, 1991* or the regulations made thereunder or under the Act, or delegating an act set out in paragraph 1 or 9 of section 4 of the Act.
10. That section 1(7) of Ontario Regulation 858/93 (Professional Misconduct) under the *Midwifery Act, 1991* be repealed and the following substituted:
- 7.** Prescribing or administering drugs or substances for an improper purpose, or otherwise using improperly the authority to prescribe or administer drugs or substances.
11. That Ontario Regulation 858/93 (Professional Misconduct) under the *Midwifery Act, 1991* be amended by adding the following sections:
- 16.1** Failing to advise a patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such a consultation to ensure the proper care of the patient.
- 16.2** Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.
- 16.3** Recommending or providing unnecessary services.

- 33.** Being subjected to the withdrawal or restriction of rights or privileges under the Controlled Drugs and Substances Act (Canada) or the Food and Drugs Act (Canada) or the regulations under either of those Acts, unless by the member's own request.
- 34.** Contravening, while engaged in the practice of midwifery, any federal or provincial law or municipal by-law with respect to the prescribing of any drug or mixture of drugs.

THE PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF NATUROPATHY

HPRAC received a combined submission from the Board of Directors of Drugless Therapy – Naturopathy (BDDT-N), the Ontario Association of Naturopathic Doctors (OAND), the Canadian Association of Naturopathic Doctors (CAND) and the Canadian College of Naturopathic Medicine (CCNM) requesting that naturopathic doctors (NDs) be granted the authorized act of prescribing, dispensing, compounding or selling a drug or natural health substance as defined in the regulations. HPRAC considered this request during its review of naturopathy in 2006 and has again carefully reviewed it.

2. HPRAC's Central Response

Providing NDs with the ability to prescribe, dispense, compound and sell natural substances that fall within the definition of either “drug” as defined in the *Drug and Pharmacies Regulation Act* or “prescription therapeutic products” defined in the *Food and Drugs Act* will ensure that NDs can continue to practice to their full competencies, and be able to exercise their full scope of practice based on their knowledge, skills and judgment. HPRAC is also of the view that NDs can play a larger role in primary care, and that they have the competencies required to prescribe a limited number of Schedule I drugs. Providing NDs with tools to support them in the provision of primary health care may be one way to improve access to care for Ontarians who choose this primary care alternative and may assist in reducing pressures on emergency rooms by keeping care in the community.

3. Background on Naturopathy

The Profession

According to the OAND and BDDT-N, naturopathic medicine is a primary care health profession that focuses on the promotion of health, the assessment of the physical and mental condition of an individual, and the diagnosis, prevention and treatment of diseases, disorders and dysfunctions through the integrated use of therapies and substances that promote the individual's inherent self-healing processes.¹

NDs provide primary and adjunctive health care to people of all ages focusing on the use of natural therapies to support and stimulate healing processes.² NDs make a diagnosis using standard medical diagnostic tools and procedures including: case history, physical examination, in-office functional measurements, laboratory investigations and diagnostic imaging.³

¹ BDDT-N, OAND, CCNM and CAND. Joint submission to *HPRAC: Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 2008.

² Health Professions Regulatory Advisory Council. *New Directions*. Available at: www.hprac.org/en/reports/resources/new_directions_april_2006_en-orig.pdf. 2006: 172.

³ Ibid: 173.

There are currently 950 NDs registered in Ontario. Of those, approximately 90 percent hold a baccalaureate degree, primarily in the sciences.

Applicants seeking entry into the ND program for the 2008–2009 academic year will be required to hold a baccalaureate degree from an accredited university prior to entry.⁴ Ninety-seven percent of NDs are graduates of the Canadian College of Naturopathic Medicine (CCNM), which trains the majority of NDs who practice in Canada. More than ten percent of currently regulated NDs are dual registrants of other health colleges that are regulated under the *Regulated Health Professions Act, 1991 (RHPA)*.⁵

Legislative and Regulatory Framework for the Practice of Naturopathy in Ontario

Naturopathic medicine is currently regulated under the *Drugless Practitioners Act (DPA)* and will become regulated under the *RHPA* when the *Naturopathy Act, 2007* is proclaimed in force at the conclusion of the transition process. Currently, NDs are not authorized under the *DPA* to “prescribe or administer drugs for use internally or externally, or use or direct or prescribe the use of anesthetics for any purpose whatsoever”. The *DPA* does permit NDs to administer natural substances such as injectable vitamins, minerals and amino acids that are available only from a pharmacist.

Authorized Acts:

Under the *Naturopathy Act, 2007*, NDs are authorized, subject to the terms, conditions and limitations imposed on their certificate of registration, to perform the following:⁶

1. Putting an instrument, hand or finger beyond the labia majora but not beyond the cervix.
2. Putting an instrument, hand or finger beyond the anal verge but not beyond the rectal-sigmoidal junction.
3. Administering, by injection or inhalation, a prescribed substance.
4. Performing prescribed procedures involving moving the joints of the spine beyond the individual’s usual physiological range of motion using a fast, low amplitude thrust.
5. Communicating a naturopathic diagnosis identifying, as the cause of an individual’s symptoms, a disease, disorder or dysfunction that may be identified through an assessment that uses naturopathic techniques.
6. Taking blood samples from veins or by skin pricking for the purpose of prescribed naturopathic examinations on the samples.

⁴ Canadian College of Naturopathic Medicine. Application for Admission, Available at: http://www.ccnm.edu/pdf/Application_2007.pdf.

⁵ BDDT-N, OAND, CCNM and CAND. Review of *Non-Physician Prescribing and Administration of Drugs*. November 2008.

⁶ *Naturopathy Act, 2007*, S.O. 2007, c. 10, Sch. P, s. 4.

Regulations

The College Council may make regulations, subject to the review of the Minister and approval of the Lieutenant Governor in Council, as follows:⁷

- (a) prescribing standards of practice respecting the circumstances in which naturopaths shall make referrals to members of other regulated health professions;
- (b) prescribing therapies involving the practice of naturopathy, governing the use of prescribed therapies and prohibiting the use of therapies other than the prescribed therapies in the course of the practice of naturopathy;
- (c) governing the performance of a procedure [naturopaths can prescribe] and prescribing the purposes for which, or the circumstances in which, the procedure may be performed;
- (d) prescribing the substances that a member may administer by injection or inhalation and prescribing the purposes for which, or the circumstances in which, the prescribed substances may be administered;
- (e) prescribing procedures that may be performed [as prescribing], governing the performance of the procedures and prescribing the purposes for which, or the circumstances in which, the prescribed procedures may be performed and prohibiting the performance of procedures other than the prescribed procedures;
- (f) prescribing naturopathic examinations prescribing the purposes for which, or the circumstances in which, the prescribed naturopathic examinations may be performed and prohibiting the performance of examinations other than the prescribed naturopathic examinations.

How Naturopathy is Regulated Today and its Continued Evolution

Naturopathy has a long history of regulation in Ontario. Naturopathic medicine was first regulated in Ontario in 1923 under the *Medicine Act* and then in 1925 under the *DPA* and regulations under that Act. The current governing body for naturopathy is the BDDT-N.

Once proclaimed in force, the *Naturopathy Act, 2007* will bring the profession under the *RHPA* and will establish the College of Naturopaths of Ontario. The new Act is expected to come into force before June 2009, and a transitional council of the new College, which includes all members of the BDDT-N, will develop the foundational regulations, by-laws and standards of practice for the profession.

⁷ Ibid: s. 11.

Education and Continuing Competency

The OAND is a voluntary professional association representing NDs in Ontario. OAND has 617 members and 425 student members, or 75 percent of all active NDs in Ontario.⁸ The CAND provides a national voice for NDs.

The Council on Naturopathic Medical Education (CNME) in Johnson, Virginia, establishes educational standards for the naturopathic profession and accredits colleges in Canada and the United States that offer four-year, graduate-level programs in naturopathic medicine. The CAND recognizes the seven programs registered with CNME, including the Canadian College of Naturopathic Medicine (CCNM) located in Toronto. There are currently four accredited naturopathic colleges in North America, including the CCNM.

The CCNM is the one school in Ontario that educates NDs. The naturopathic education program at the CCNM is a four-year program with three major areas of study:

- **Basic medical sciences:** anatomy, histology, physiology, biochemistry, microbiology and immunology,
- **Clinical disciplines:** physical and clinical diagnosis, differential and laboratory diagnosis, radiology, naturopathic assessment and orthopedics, and
- **Naturopathic disciplines:** acupuncture and Oriental medicine, botanical and herbal medicine, clinical nutrition, homeopathic medicine, physical medicine, and lifestyle counselling.⁹

Applicants to the program must have completed a minimum of three years towards a baccalaureate degree at a university in Canada or its equivalent. Applicants seeking entry into the ND program for the 2008–2009 academic year will be required to hold a baccalaureate degree from an accredited university prior to entry.¹⁰

Upon completion of the CCNM program, graduates must successfully complete the international Naturopathic Physician Licensing Examination (NPLEX) before registration by the BDDT-N is granted. NPLEX is the standard examination used in all jurisdictions that license NDs in North America. It consists of five basic science exams in anatomy, physiology, pathology, biochemistry, microbiology and immunology, as well as seven clinical exams and three elective examinations in homeopathy, minor surgery and acupuncture. Entry level NDs are examined on the pharmacology of commonly prescribed drugs and substances. This includes primary actions and adverse effects; indications, contraindications

⁸ BDDT-N, OAND, CCNM and CAND. Review of *Non-Physician Prescribing and Administration of Drugs*. November 2008.

⁹ HPRAC. *New Directions*: 173.

¹⁰ Canadian College of Naturopathic Medicine. Application for Admission, Available at: http://www.ccnm.edu/pdf/Application_2007.pdf.

and potential interactions with other drugs; botanical medicines and nutritional supplements. Specific emphasis is placed on learning and demonstrating competence in botanical prescribing.¹¹

Graduates of CCNM are eligible for licensure in jurisdictions throughout North America, including those where the prescribing of drugs is part of the scope of practice of the profession.

Ontario NDs participate in a continuing education (CE) program, which has been required by the BDDT-N since 2002. Registrants must complete a minimum of 30 hours of approved CE within each two-year cycle. Of those 30 hours, every registrant must complete a minimum of two hours in pharmacology and another six hours in the naturopathic modalities such as clinical nutrition and botanical medicine, which include the prescribing and administration of substances recently restricted to prescription-only status by the federal government.¹²

4. What the Profession has Proposed

HPRAC received a combined submission from the BDDT-N, OAND, CANM and CAND concerning the Minister's request for advice on those professions that prescribe or use drugs in the course of their practice. The proponents have requested that NDs be granted the authorized act of "prescribing, dispensing, compounding or selling a drug or natural health substance as defined in the regulations". The authority to prescribe would be limited to classes of prescription therapeutic products, a formulary of primary care drugs and additional drugs required to support best practices in-clinic, including crash cart substances to respond to emergencies.

Request for Change: Prescribing

NDs are seeking the authority to prescribe, under the *Naturopathy Act, 2007* to achieve three main outcomes:

To preserve current scope of practice and regain and maintain access to key therapeutic substances

Without prescribing authority under Ontario health profession legislation, Ontario's NDs do not qualify for "practitioner" status under the federal *Food and Drugs Act* (assuming the amendments to the *Food and Drugs Act* as proposed in Bill C-51 are implemented). Only those professions that have been granted prescribing rights by the province in which they practice are recognized as practitioners by Health Canada. Furthermore, only such health professionals will be authorized to prescribe and sell "prescription therapeutic products" under the proposed amendments to the *Food and Drugs Act*.

¹¹ BDDT-N, OAND, CCNM and CAND. Review of *Non-Physician Prescribing and Administration of Drugs*. November 2008: 25.

¹² Ibid: 27.

Natural health products that are not “prescription therapeutic products” and not included in a regulation under the *Drug and Pharmacies Regulation Act (DPRA)* that brings the product within the definition of “drug,” will not require a prescription from a ND. The controlled act of prescribing in the *RHPA* is “prescribing, dispensing, selling or compounding a drug as defined in the *DPRA*, or supervising the part of a pharmacy where such drugs are kept”. Natural health products are exempt from the definition of drug in the *DPRA* unless the product is a substance that is identified in the regulations to the *DPRA* as being a drug either specifically or by its membership in a class or its listing or identification in a publication.¹³

Many natural substances that would be considered “prescription therapeutic products” are essential therapeutic agents used in the general course of naturopathic practice. Examples of these products include amino acids, injectable vitamins, vitamin A or niacin over specified doses, bio-identical hormones, botanical medicines that are not suitable for consumer self-selection and restricted homeopathic medicines.

There is often a delay in obtaining treatment as patients seek a physician who will prescribe drugs and products on the basis of a referral from a naturopathic doctor. In some cases access to the therapy is lost entirely, leaving patients unable to receive the treatments they choose.

To provide a prescription for substances that were formerly considered natural health products but have since been reclassified such that they fall within the definition of drugs under the *DPRA* or will be included within the definition of “prescription therapeutic products” in the *Food and Drugs Act*, NDs in Ontario now must refer patients to a physician registered with the College of Physicians and Surgeons of Ontario (CPSO). Often physicians are not comfortable prescribing these substances, as they have not been trained in their use, are unable to prescribe them with confidence and may not want to accept the accountability that accompanies the making of a prescription for botanical medicines or natural health products.

CAND has been engaged in discussions with Health Canada and expect that additional natural health products and botanical medicines are likely to be considered prescription therapeutic products under the federal and National Association of Pharmacy Regulatory Authorities (NAPRA) schedules, requiring a prescription from an authorized prescriber. Ontario’s NDs themselves, in discussions with federal regulators, have urged that some botanical medications and natural health products should be restricted to prescription by those who have been granted authorized acts of prescribing.¹⁴

The proponents recommend that the authority to prescribe should be limited to classes of therapeutic natural substances, a formulary of primary care drugs, and those required to support best practices in-clinic, including substances to respond to emergencies.

¹³ *Drug and Pharmacies Regulation Act*, R.S.O. 1990, c.H.4. s.1 (1).

¹⁴ HPRAC. *New Directions*: 182.

Classes of Prescription Therapeutic Products

The proponents have submitted that the following classes of prescription therapeutic products should be prescribed in the drug regulations under the *Naturopathy Act, 2007*:

Classes of Prescription Therapeutic Products¹⁵

- Amino acids
- Botanical extracts and their derivatives
- Chelating agents
- Electrolyte and fluid replacement
- Enzymes, digestive and proteolytic preparations
- Homeopathic preparations
- Hormones
- Glandular and organ preparations
- Minerals, trace minerals and their derivatives
- Vitamins and vitamin preparations and derivatives
- Local anaesthetics (for topical use)
- Nutrients and cofactors
- Probiotics

Proponents' Rationale

Proponents note that for years under the *DPA* and Regulation 278 under the Act, NDs have been able to work within established standards of practice to compound, dispense and administer substances that are integral to naturopathic medicine.¹⁶ Until 2004, natural health products recommended and used by NDs were not included in a restricted list under the Natural Health Products regulations, but were in the public domain; therefore, there was little concern about the authority to prescribe them.

Without specific authorized acts granted under the *Naturopathy Act, 2007*, NDs will not be able to practice to their full scope of practice, and their patients will not be able to receive the treatments that they choose and prefer. The *RHPA* was designed to enable patient choice in primary care provider, the therapeutic options available, and the modality options available, including the option of natural health products and botanical medications as a first choice in a treatment regime. The proponents state that:

¹⁵ BDDT-N, OAND, CCNM and CAND. Review of Non-Physician Prescribing and Administration of Drugs. November 2008: 50.

¹⁶ Ibid: 11.

Without the controlled act of prescribing, NDs scope of practice will be less than their professional competencies, patients would not be able to access many natural substances from the ND or be able to receive appropriate primary care, and patient choice and quality of care would be curtailed.¹⁷

NDs have the authorized act of administering a prescribed substance by injection and inhalation. Currently, they administer and recommend substances for oral, topical, inhalant, injection and intravenous use to their patients as part of their diagnostic and treatment protocols. In their traditional practice, NDs administer a number of natural products by inhalation or injection such as injectable vitamins and chelating agents. Without the ability to prescribe these substances that may be re-classified as “prescription therapeutic products”, NDs say they will not be able to obtain the substances due to the proposed restrictions on the purchase and sale of prescription therapeutic products in the amended *Food and Drugs Act*. If NDs cannot obtain these prescription therapeutic products, they will not be able to administer such substances by injection or inhalation as part of the practice of naturopathy.

They argue that providing NDs with the ability to prescribe also supports broader health care goals. Naturopathic medicine considers the whole person, and has a focus on wellness. The Ontario government’s *Chronic Disease Prevention and Management Framework* indicates its commitment to move the health care system from an illness to a wellness orientation. Prescribing rights are essential for NDs to maintain and enhance their role in chronic disease prevention and management. Patients receiving medical treatments for cancers, hypertension, diabetes, cardiovascular disease and arthritis, among other diseases, often seek additional care from a ND in conjunction with treatment by other health professionals.¹⁸

NDs also recognize the importance of collaboration. They indicate they are looking forward to more opportunities to work in collaborative teams as their profession is fully regulated under the *RHPA*. Moving from the *DPA* and regulations to the common regulatory framework of the *RHPA* creates more awareness of the scope of practice of NDs, more certainty for other professions, and the removal of many potential barriers to collaboration.¹⁹ To bring the maximum value to interprofessional teams, NDs need to be able to practice to their full range of competencies. Access to these restricted substances will help to ensure that NDs can practice to their full scope of practice.

Classes of Drugs

The proponents have submitted that the following classes of Schedule I drugs should be prescribed in the drug regulations under the *Naturopathy Act, 2007*:

¹⁷ Ibid: 17.

¹⁸ Ibid: 39.

¹⁹ Ibid: 51.

Classes of Schedule 1 Drugs²⁰:

- Antibiotics
- Antivirals
- Antifungals
- Antiparasitics
- NSAIDs (nonsteroidal anti-inflammatory)
- Dermatological agents
- Dyslipidemic agents

Proponents' Rationale

The proponents are seeking authority to prescribe a limited number of Schedule I drugs to enhance their ability to provide primary care for their patients. They note that within these classes are selected drugs that NDs are competent to prescribe and use in the course of practice, and that these drugs reflect best practices in primary health care.

The proponents provide a number of examples of instances where they can competently treat a number of common ailments using traditional naturopathic medicines first if appropriate, and moving to conventional medicines as necessary, or using traditional naturopathic medicines in conjunction with conventional medicines. For example:

- In cases where NDs diagnose pharyngitis (sore throat) in children, there are a number of circumstances where the naturopath might wish to use traditional medicines. One example of this is if the culture is positive for Group A streptococci infection (strep throat). Treatment within the first nine days is important to prevent acute rheumatic fever – a potentially severe inflammatory response that can appear two to three weeks after strep throat.²¹
- In cases where NDs diagnose shingles in a patient who may have been symptomatic for a number of hours or in addition to appropriate naturopathic therapy, the ND might wish to treat with anti-viral medication (e.g., acyclovir) which is best administered within 72 hours of onset of symptoms under best practice guidelines. Early medication therapy can potentially curtail the duration and severity of symptoms, and potentially prevent complications such as post herpetic neuralgia.²²

²⁰ Ibid: 50.

²¹ Ibid: 37.

²² Ibid: 40.

Prescribing for Emergency Situations

As independent clinical practitioners, NDs are seeking the authority to prescribe drugs to provide a basic crash cart that will enable them to better respond to emergency situations that might arise in the course of in-clinic treatment.

Proponents' Rationale

The proponents said that given the naturopathic scope of practice is that of a generalist, NDs in clinics need to be able to manage a variety of potential adverse reactions or complications. Management of these situations might mean administering drugs such as Benadryl™ (for managing a drug/allergic reaction); diphenhydramine, calcium gluconate, magnesium sulphate and salbutamol (for dealing with laryngeal spasm or bronchospasm).

In cases where intravenous therapies are used, the potential for emergency complications is always present and NDs in clinics might need to administer drugs such as:

- Epinephrine™ for subcutaneous or IV injection, not just an EpiPen™,
- Atropine™, aspirin and nitroglycerine, and
- Oxygen therapy (for dealing with respiratory distress).²³

The proponents stated that the emergency kit would be a standard kit in line with what other professionals require, and indicated that, particularly in rural or under serviced areas, the availability of drugs to deal with emergency situations would better serve the public.

Classes versus Individual Drugs

The joint submission notes that listing classes of natural substances and drugs in regulations under the Act is preferable to listing individual substances and drugs for a number of reasons:

1. There are concerns around possible delays of the inclusion of new drugs or substances if they are listed individually, pending updated regulation. This could compromise optimal patient care. There are concerns about “stagnation” of the profession if new drugs cannot be readily accessed for patient care.
2. There could be delays in prescribing more cost effective drugs.
3. Classes of drugs are well understood within the international medical community, whereas specific drugs tend to be country specific.

²³ Summary Notes from Dec. 2, 2008 meeting between HPRAC and stakeholders: 8-11.

The proponents said that:

Overall providing NDs with classes of drugs rather than specific drugs in the regulations gives NDs more flexibility to use and prescribe the most up-to-date and cost effective medicines, thereby providing patients with the highest quality care.²⁴

To provide needed safeguards, it is expected that the transitional council will recommend specific conditions for the appropriate use of classes of drugs, based on accepted best practice.

Reducing the Risk of Harm

NDs point out that some substances such as botanical medicines can be toxic if used inappropriately, for example *Gelsemium sempervirens*, *Bryonia alba* and *Phytolacca americana*.²⁵ NDs indicate that the prescription and use of proposed drugs and many natural substances currently used by NDs present risks:

- **Drug reactions:** Allergic, anaphylactic, toxic, patient incompatibility
- **Drug interactions:** With other drugs, botanicals, nutrients, enzymes, hormones and other natural health products
- **Inappropriate or incorrect use:** Over-dosage/under-dosage
- **Patient abuse**
- **Duplication of prescriptions:** Result of inadequate communication among medical professionals
- **Errors** in dispensing and drug handling.

The risks are mitigated by education and training, demonstrated competency, and the safe record of the prescribing and administration of the proposed drugs and substances in other jurisdictions.²⁶

The joint submission describes the integrated CCNM curriculum to prepare students for entry to practise as safe and effective prescribers. The first year curriculum stresses the basic sciences and provides an introduction to the modalities of naturopathic medicine. In second year, clinical science is stressed while in the third year there is an increased emphasis on students developing the essential skills they will need to become primary care practitioners. The focus of the fourth year is on clinic internship. Aspects of pharmacology and learning objectives designed to ensure that graduates can safely and effectively use drugs are also covered in a number of courses throughout the four-year program.

²⁴ BDDT-N, OAND, CCNM and CAND. *Review of Non-Physician Prescribing and Administration of Drugs*. November 2008: 46.

²⁵ Ibid: 23.

²⁶ Ibid: 24.

- Enabling competencies established in other year one courses include: Physiology, Anatomy, Histology, Biochemistry, Clinical Nutrition, Principles in Research and Botanical Medicine.
- In addition to the year two course in Pharmacology, students are taught about the safe and effective therapeutic use of botanicals in Botanical Medicine and drug-food interactions in Clinical Nutrition. A large component of the curriculum is devoted to four courses in the fundamentals of diagnosis. These courses include and cover both the theoretical and practical aspects of diagnosis. At the end of the year, students are expected to be competent in reaching a physical and clinical diagnosis; able to use standard medical laboratory tests to assist them in this process; and able to generate a diagnosis by means of differential reasoning.
- In year three, courses related to prescribing competencies include: Primary Care, Botanical Medicine, Clinical Nutrition, Venipuncture and Parenteral Therapy, Pediatrics, Obstetrics, Emergency Medicine and Men's and Women's Health. The Primary Care course integrates previously learned competencies into the program by increasing students' knowledge of first-line pharmacotherapy, current guidelines and best practices. This course also investigates how to critically evaluate therapeutic options through evidence-based risk-benefit assessment, modifiable disease factors and harm reduction in clinical practice. Students serve a twelve-month clinical internship during their fourth year. This internship allows them to apply their skills under the supervision of a licensed ND to patients in the Robert Schad Naturopathic clinic and at five satellite clinics in Community Health Centres in Toronto. All students are evaluated comprehensively as part of an assessment of their clinical skills. Graduates of CCNM are eligible for licensure in jurisdictions such as Arizona where the prescribing of drugs is already part of the scope of practice of the profession.²⁷

NDs indicate that regulation of the profession under the antiquated DPA and the increase in the number of substances placed on restricted schedules has negatively impacted the natural evolution of the naturopathic profession. For many years, ND students have been taught about the indications, contraindications and use of drugs in the curriculum at accredited naturopathic colleges. In Ontario, what has been missing is the clinical experience of using drugs in the teaching clinic and in clinical practice. Pharmacology has been part of the NPLEX, the licensing examinations used by all regulated jurisdictions in North America, since 1994. Graduates from all of the accredited colleges of naturopathic medicine currently practice in jurisdictions that have prescribing authority.²⁸

²⁷ Ibid: 26-27.

²⁸ Ibid: 46.

Request for Change: Dispensing and Compounding

The proponents requested the authority to compound natural substances for individual patients, for use in clinics, or for dispensing and selling when they are not available through a pharmacy. Proponents said that it is expected that NDs would only be authorized to dispense categories of natural substances designated by regulation (i.e., those which they are authorized to prescribe) and in compliance with a standard of practice for conflict of interest.

NDs are not currently restricted under the *DPA* from dispensing and compounding naturopathic substances but these controlled acts have not been included in the *Naturopathy Act, 2007*. Under BDDT-N, NDs have established practice standards in place for the compounding, storage and dispensing of naturopathic medicine.²⁹

Proponents' Rationale

The controlled act of dispensing is key to the practice of naturopathic medicine because the substances used on a regular basis by NDs may not be readily available from other sources. For example, community pharmacies may not encounter sufficient demand for these substances and may also be unfamiliar with their use. As a result, pharmacies often do not stock substances that NDs use as part of their regular course of practice. This issue is particularly prevalent in smaller and remote communities. NDs would not compound, dispense or sell Schedule I drugs.

Compounding of restricted therapeutic natural substances, as well as dispensing and selling, is necessary in order to continue to provide the individualized preparations that are integral to naturopathic care. NDs are not seeking to dispense, sell and/ or compound pharmaceuticals.³⁰

Request for Change: Selling

The proponents are requesting the authorized act of selling to ensure that patients have access to natural substances (Schedule I and II natural health products) not typically available from local pharmacies, especially in small towns and rural areas.

NDs state that they seek to be authorized to sell categories of natural substances designated by regulation that they are authorized to prescribe and in compliance with a standard of practice for conflict of interest.

²⁹ Ibid. Policy on In-Office Preparation and Compounding of Naturopathic Medicines (Appendix 3).

³⁰ BDDT-N, OAND, CCNM and CAND. Review of *Non-Physician Prescribing and Administration of Drugs*. November 2008: 17.

Proponents' Rationale

NDs require the controlled act of selling to enable them to provide certain natural substances to their patients. These might otherwise be difficult to obtain because they are not stocked in community pharmacies or are otherwise unavailable.

5. What HPRAC Found

Readiness for Change

More than 95 percent of OAND members who responded to a recent survey indicated that they are in favour of being authorized the controlled acts of prescribing, compounding and dispensing drugs. Respondents said that continued access to substances integral to naturopathic care depends on being authorized to perform these controlled acts, and that the authority to perform these controlled acts would allow them to increase their role as primary care providers.

HPRAC's review of the ND education and training programs in drug therapies found educational content is similar to the content taught in nursing, pharmacy and medical schools.

The BDDT-N Continuing Education (CE) Policy sets out the minimum CE requirements for NDs to maintain high professional standards in naturopathic practice and to assure the public of the continuing professional competency of NDs in Ontario. CE activities include:

- A total of 30 CE credits for a two-year period that must include ten mandatory credits (two credits in Pharmacology, six credits “in the naturopathic modalities such as Clinical Nutrition and Botanical Medicine, which include prescribing and administration of some substances that are now classified as drugs”, and two credits in Ontario jurisprudence).
- CPR must also be updated in the two-year period.³¹

On balance, HPRAC is satisfied that there is sufficient evidence in the current drug education of naturopathic doctors to recommend prescribing authority for traditional naturopathic remedies that have been rescheduled. However, there may be additional re-education requirements for practitioners who graduated before 1994, when the NPLEX examinations commenced.

HPRAC heard that NDs are well trained in compounding natural substances and are sought out by patients for their ability to provide access to these therapeutic substances. NDs have unique expertise in the therapeutic use of natural substances and are skilled primary care providers.

³¹ Ibid: 94.

NDs are already safely and effectively using natural substances when administered parenterally (e.g., by injection, through intravenous, subcutaneous and intramuscular routes). They recognize that high doses of nutrients and herbs should be administered only by an experienced practitioner, due to the possibility of toxicities and drug-herb interactions. The training that NDs receive, through their foundational clinical and didactic education and continuing education programs, indicates that NDs have the knowledge, skill and judgment to ensure they are competent to safely administer these substances.

There is also adequate foundational education to consider the requests for new prescribing authority for a limited number of Schedule I drugs. Many of the drugs and conditions are similar to those proposed by pharmacists for minor ailments treatment protocols.

The joint submission reiterates requests made in submissions to HPRAC in its 2005 review of the profession of naturopathy. Based on its initial work, including consultation and research, in its *New Directions* report to the Minister in April 2006, HPRAC recommended that NDs be authorized to “prescribe, dispense, sell and/or compound drugs that are consistent with naturopathic practice, as prescribed in regulations”.³²

At the time, HPRAC was advised that the federal Natural Health Products Directorate (NHPD) and the Natural Health Product (NHP) regulations, which came into force in January 2004, excluded from the “natural health products” regulation a number of products or substances that have traditionally been safely prescribed, compounded or dispensed by NDs but are considered to have additional risks of harm in over-the-counter distribution. As a result, NHPD has created a separate schedule for botanical medicines and natural health products that are of higher risk, and that should only be used under the advice and supervision of a health professional who is trained and educated in their use. The profession is continuing to evolve and is showing that it is ready to receive this prescribing authority.

HPRAC also notes the proponents’ statements that the legislative evolution of NDs scope of practice has not kept pace with advancing clinical knowledge, increases in training and competencies, evolutions in other jurisdictions and trends in consumer demands.

What Leading Jurisdictions Do

Information from other jurisdictions provides evidence that NDs are equipped to prescribe within their scope of practice. Evidence from jurisdictions such as Oregon and Arizona that currently authorize prescribing for NDs indicates a high safety record. While prescribing rights for NDs are still limited to natural substances in many jurisdictions, some leading jurisdictions are moving to include Schedule I drugs in a naturopathic formulary. In British Columbia, for example, NDs are subject to

³² HPRAC. *New Directions*:183.

the Naturopathic Physicians Regulation, under the *Health Professions Act* and will have prescribing authority pending the approval of by-laws created by the College Board. In the United States, NDs may prescribe independently in Arizona, California, Hawaii, Idaho, Montana, Oregon, Utah, Vermont and Washington. Kansas and Maine allow prescribing with restrictions. Kansas requires physician supervision and Maine requires collaboration with a physician for one year prior to independent prescribing.

Managing the Risk of Harm

HPRAC found that the education, training and continuing education that NDs receive is sufficient to enable NDs to be aware of the effects and possible side effects, toxicities and interactions of the medications they use. The profession in Ontario and in other jurisdictions has an excellent patient safety record. Where necessary, professional upgrading will be initiated by the transitional council.

As the naturopathic profession transitions to regulation under the *Naturopathy Act, 2007*, the new College will establish a Quality Assurance program, as required under the *RHPA*. This program will include specific requirements with respect to pharmacology and prescribing.

Both the BDDT-N and the profession recognize the importance of ensuring ongoing competencies for continued patient safety, through a QA program.³³

Upgrading to ensure Readiness for the New Controlled Act of Prescribing

While Ontario NDs have the required competencies to prescribe the drugs requested, proponents make it clear that upgrading for some NDs already in practice will be necessary. HPRAC's review of education and training confirms this and expects that professional upgrading and clinical experience will be required by the transitional council.

The CCNM has designed its curriculum to meet the needs of graduates who will be practicing in jurisdictions where NDs have prescribing rights. Proponents say that the curriculum continues to evolve and can be readily adjusted to meet the expectation of the transitional council in Ontario.

The joint submission said that the transitional council might follow an approach similar to that proposed by the College of Naturopathic Physicians of British Columbia (CNPBS). This program includes 60 hours of education in pharmacotherapeutics followed by an examination; 10 hours of continuing education each year on pharmacotherapeutic related issues; and other mechanisms to ensure that pharmacotherapeutics are a major part of the quality assurance program for self, peer and practice assessments.³⁴

³³ BDDT-N, OAND, CCNM and CAND. Review of *Non-Physician Prescribing and Administration of Drugs*. November 2008: 28.

³⁴ Ibid: 47.

6. Other Issues: Communicating a “Naturopathic” Diagnosis

The Naturopathy Act, 2007 describes the scope of practice of naturopathy as follows:

Scope of practice

3. The practice of naturopathy is the assessment of diseases, disorders and dysfunctions and the naturopathic diagnosis and treatment of diseases, disorders and dysfunctions using naturopathic techniques to promote, maintain or restore health.³⁵

The Act also authorizes the act of:

5. Communicating a naturopathic diagnosis identifying, as the cause of an individual’s symptoms, a disease, disorder or dysfunction that may be identified through an assessment that uses naturopathic techniques.³⁶

This has led to significant confusion as to what is meant by a naturopathic diagnosis.

While NDs are authorized to “communicate a naturopathic diagnosis”, proponents said that a “diagnosis” is arrived at using both naturopathic and traditional medical diagnostic techniques, including comprehensive health histories and examinations, laboratory tests and other investigations. The algorithm used by NDs to arrive at the diagnosis, and diagnosis expressed, is consistent with any internationally recognized diagnostic criteria. Thus, a diagnosis communicated to a patient by a ND is consistent with that of other health professions with the same authority.³⁷

In its 2001 and 2006 recommendations to the Minister, HPRAC recommended that the word “diagnosis” not be modified by the word “naturopathic”. In its consultations relating to the prescribing and use of drugs, HPRAC has found that the modifier has been interpreted as meaning that the diagnosis to be communicated to a patient may be less expert, exacting or complete as a diagnosis made by other professions such as nursing or medicine. HPRAC was told that members of the profession themselves did not understand the term “naturopathic diagnosis”, and expressed concerns about the legislative intent of the phrase.

7. Recommendations: Lists or Categories of Drugs and Prescription Therapeutic Products in Regulation

HPRAC is recommending approval of both a designated drug class and a prescription therapeutic product class in the regulations under the *Naturopathy Act, 2007*. This will allow for the continued use of traditional

³⁵ *Naturopathy Act, 2007, S.O. 2007, c. 10, Sch. P, s. 3.*

³⁶ *Ibid.*: s. 4 (1) 5.

³⁷ Summary Notes from December 2, 2008 meeting between HPRAC & key intervenors.

agents currently being rescheduled at the federal level and the expansion of the primary care role of NDs. Vitamins and minerals and “dyslipedemic agents” are not included as separate classes since these agents can be added under the prescription therapeutic product class. It is intended that the classes be named in the regulation, and that the list of specific agents and the conditions and limitations for the prescribing of the drugs to be included in the class be reviewed by the Drug and Therapeutics Formulary Committee when it is established. At the outset and until the Committee is established, the agents and conditions identified in the lists below would be considered appropriate for prescribing by NDs, and be authorized to the profession.

Class	Examples of Specific Agents
Class: Prescription Therapeutic Products	<p>Antilipemic Agents (Lovastatin - derived from <i>Monascus purpureas</i>)</p> <p>Nicotinic acid (Niacin)</p> <p>Amino Acids</p> <p>L-carnitine</p> <p>L-tryptophan</p> <p>Acetyl-L-carnitine</p> <p>Ornithine</p> <p>Enzymes (digestive and proteolytic preparations)</p> <p>Pancreatin</p> <p>Papain</p> <p>Hormones</p> <p><i>Female</i></p> <p>Bioidentical estrogens</p> <p>Bioidentical progesterone</p> <p>Pregnenolone</p> <p>DHEA</p> <p><i>Male</i></p> <p>Bioidentical testosterone</p> <p>Pregnenolone</p> <p><i>Other</i></p> <p>Dessicated thyroid USP (Thyroid / Armour thyroid)</p> <p>Salmon derived calcitonin</p> <p>Melatonin</p>

Class	Examples of Specific Agents
Class: Prescription Therapeutic Products (cont.)	<i>Animal glandular extracts</i> Pituitary Thyroid Adrenal Thymus Spleen Liver <i>Phyto- hormones</i> Vitamins and Minerals Niacin > 500 mg Vitamin A > 10,000 IU Vitamin D > 2,000 IU
Class: Anti-infectives Sub-class: Antibiotics	Amoxicillin Amoxicillin/clavulanate Azithromycin Clarithromycin Ciprofloxacin Erythromycin Fusidic acid Gentamicin Sulfate Metronidazole Mupirocin (topical) Nitrofurantoin Penicillin V Silver Sulfadiazine
Class: Anti-infectives Sub-class: Antifungals	Clotrimazole Tolnaftate (topical) Miconazole(topical) Fluconazole (Oral) Boric acid (topical) Itraconazole Ketoconazole Metronidazole/nystatin (topical)

Class	Examples of Specific Agents
Class: Anti-infectives Sub-class: Antifungals (cont.)	Nystatin (oral) Nystatin (topical) Terbinafine (topical)
Class: Anti-infectives Sub-class: Antivirals	Acyclovir (oral and topical)
Class: Anti-infectives Sub-class: Miscellaneous	Mebendazole Metronidazole Lindane lotion Permethrin (topical)
Class: CNS Agents Sub-class: Analgesics and Antipyretics Sub-sub-class: NSAIDs	Diclofenac Sodium Naproxen
Class: Skin and Mucous Membrane Agents	Benzoyl Peroxide Capsaicin Selenium Sulfide (Topical) Urea cream Salicylic and lactic acid (topical) Gentian violet

8. Recommendations

- 1: That NDs be authorized to prescribe, dispense, compound and sell drugs and prescription therapeutic products as prescribed by the regulations and in accordance with the standards of practice of the College.
- 2: That the standards of practice for prescribing, dispensing, compounding and selling drugs and prescription therapeutic products should be developed by an interprofessional committee and should be equivalent to those expected of a physician.

- 3: A list of designated classes of prescription therapeutic products should be approved in regulations under the *Naturopathy Act, 2007*. The list should be comprised of the following:

Class: Prescription Therapeutic Products

- 4: A list of designated classes of drugs should be approved in regulations under the *Naturopathy Act, 2007*. The list should be comprised of the following:

Class: Anti-infectives

Subclass: Antibiotics

Subclass: Antifungals

Subclass: Antivirals

Subclass: Miscellaneous

Class: CNS Agents

Subclass: Analgesics and antipyretics

Subclass: NSAIDs

Class: Skin and Mucous Membrane Agents

9. Implementation Proposals

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That subsection 1(1) of the *Naturopathy Act, 2007* be amended to add the following:

“Prescription therapeutic product” has the same meaning as in the *Food and Drugs Act* (Canada).

2. That paragraph 5 of section 4(1) of the *Naturopathy Act, 2007* be repealed and the following substituted:

Authorized acts

5. Communicating a diagnosis made by the member identifying, as the cause of an individual's symptoms, a disease, disorder or dysfunction that can be identified from,
- i. the individual's health history,
 - ii. the findings of a comprehensive health examination, or
 - iii. the results of any prescribed naturopathic examinations.

3. That section 4(1) of the *Naturopathy Act, 2007* be amended by adding the following section:
 7. Prescribing, dispensing, selling or compounding a prescription therapeutic product or drug that the member may prescribe, dispense, sell or compound under the regulations.
4. That sections 4(2) and 4(3) of the *Naturopathy Act, 2007* be repealed and the following substituted:

Additional requirements for authorized acts

- 4(2) A member shall perform a procedure under the authority of paragraph 3, 5 or 7 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.

Individual scope of practice for naturopaths

- 4(3) A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring individuals to other health care professionals.

Grounds for misconduct

- 4(4) In addition to the grounds set out in subsection 51(1) of the Health Professions Procedural Code, a panel of the Discipline Committee shall find that a member has committed an act of professional misconduct if the member contravenes subsections (2) or (3).
5. That section 11(d) of the *Naturopathy Act, 2007* be repealed.
 6. That section 11 of the *Naturopathy Act, 2007* be amended by adding the following section:

Regulations

- (f) regulating the prescribing, dispensing, selling or compounding of prescription therapeutic products or drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing, dispensing, selling or compounding of prescription therapeutic products or drugs.
7. That the regulations to be made under the *Naturopathy Act, 2007* (General) include the following provisions:

For the purposes of this section, “Designated Drug List” has the meaning given to it in the *Regulated Health Professions Act, 1991*.

A member may prescribe, dispense, sell or compound the following classes of prescription therapeutic products as defined under the *Food and Drugs Act* (Canada):

- Amino acids,
- Botanical extracts and their derivatives,
- Chelating agents,
- Electrolyte and fluid replacement,
- Enzymes, digestive and proteolytic preparations,
- Homeopathic preparations,
- Bioidentical hormones,
- Glandular and organ preparations,
- Minerals, trace minerals and their derivatives, and
- Vitamins and vitamin preparations and derivatives.

A member may prescribe the following classes of drugs:

- Anti-infectives: antibiotics, antifungals, antiparasitics, antivirals,
- Skin and mucous membrane agents,
- CSN agents: analgesics and antipyretics: NSAIDs.

A member may only prescribe, dispense, sell, compound or use those prescription therapeutic products and drugs within the classes designated in the foregoing sections that are listed in the Drug List and must prescribe, dispense, sell, compound or use those listed prescription therapeutic products and drugs in accordance with the terms, limitations and conditions contained in the Drug List.

It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 3, 5 or 7 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 3, 5 or 7 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 3, 5 and 7 of section 4 of the Act.

The standards of practice referred to above shall be developed on the recommendation of the Naturopathy Standards Committee.

For the purposes of the foregoing section, the College shall establish the Naturopathy Standards Committee referred to in section · and shall appoint the membership of the Naturopathy Standards Committee, which shall include, at a minimum, one or more a) members of the Council; b) members of the College (including practitioners and educators); c) persons who are not and have not been members of the College or of the Council; d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario; and e) members of the Ontario College of Pharmacists, approved by the Ontario College of Pharmacists.

The College shall post the following on its website:

The standards of practice referred to in the foregoing section; and

A list of those members, who are authorized to perform a procedure under the authority of paragraph 3, 5 and 7 of section 4 of the Act.

8. That the regulations to be made under the *Naturopathy Act, 2007* (Professional Misconduct) including the following acts of professional misconduct for the purposes of clause 51 (1) (c) of the Health Professions Procedural Code:

Contravening a term, condition or limitation imposed on the member's certificate of registration.

Exceeding the scope of practice of the profession.

Contravening or failing to maintain a standard of practice of the profession.

Failing to advise an individual to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such consultation to ensure the proper care of the individual.

Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.

Practising the profession while the member is in a conflict of interest.

Recommending or providing unnecessary services.

Prescribing, dispensing, selling, compounding or using a prescription therapeutic product or drug for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell, compound or use prescription therapeutic products or drugs.

Being subjected to the withdrawal or restriction of rights or privileges under the *Food and Drugs Act* (Canada) or the regulations under either of those Acts, unless by the member's own request.

Contravening, while engaged in the practice of naturopathy, any federal or provincial law or municipal by-law with respect to the distribution, sale, prescribing or dispensing of any prescription therapeutic product or drug or mixture of prescription therapeutic products or drugs.

Delegating an act set out in paragraph 3, 5 or 7 of section 4 of the Act.

9. That section 10 of Ontario Regulation 107/96 under the *Regulated Health Professions Act, 1991 (Controlled Acts)* be repealed.

THE PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF NURSING

Introduction and Scope of HPRAC's Review

The College of Nurses of Ontario (CNO), the Registered Nurses' Association of Ontario (RNAO) and the Nurse Practitioners' Association of Ontario (NPAO) each submitted responses to HPRAC's review of the prescribing and use of drugs by non-physician health professionals. HPRAC carefully considered each of these submissions as well as input from research and consultation in developing its recommendations. The changes proposed by the CNO, the RNAO and the NPAO would not require a change to the scope of practice for the nursing profession.

HPRAC's Central Response

HPRAC recommends that members of the CNO be authorized to dispense, sell and compound drugs, according to standards of practice that have been developed by an interprofessional standards committee. HPRAC also recommends that regulations under the *Nursing Act, 1991* should authorize therapeutic classes of drugs for prescribing by nurse practitioners (NPs). HPRAC's recommendations for a new framework for drug approvals for health professions incorporates therapeutic classes of drugs in the regulation and provides a framework for approval of specific agents within those classes. This will address concerns about the regulation-making and approval process and provide the assurance that matters of public interest and protection are upheld.

Background on Nursing in Ontario

The Profession

Nursing has been a self-regulating profession in Ontario since 1963 and plays a vital role in Ontario's health care system.

There are three categories of nurses in Ontario:

- **Registered Practical Nurses (RPNs):** The entry to practice requirement for registration as an RPN in Ontario is a diploma in practical nursing from an Ontario college of applied arts and technology or equivalent;
- **Registered Nurses (RNs):** The entry to practice requirement for registration as an RN in Ontario is a four-year baccalaureate degree in nursing or equivalent, and
- **Nurse Practitioners (NPs):** Only RNs who have obtained advanced education and successfully completed the extended class examination can join this class.

NPs¹ work with an expanded scope of practice in the areas of assessment, diagnoses, prescription of tests and treatments and health promotion.²

Nurses work collaboratively with other health professionals in the full range of settings, including hospitals, long-term care homes, public health units, correctional facilities, community clinics, workplaces and private practice. They provide a wide range of services to people of all ages along a care continuum that spans health promotion to acute, chronic and palliative care. Many practise in remote communities with limited access to health care services.

The CNO regulates the practice of nursing in the public interest. Its regulatory components include developing and implementing standards of practice, establishing requirements for entry to practice, administering a quality assurance program and enforcing standards of practice and conduct.

Three voluntary professional associations support nurses in Ontario: the RNAO, which represents RNs and NPs; the Registered Practical Nurses' Association of Ontario (RPNAO), which represents RPNs; and the NPAO, which represents NPs.

The CNO reports a membership of more than 145,000 RPNs, RNs and NPs.³ As of December 1, 2008, the membership was comprised of 112,985 RNs, 34,371 RPNs and 1,118 NPs registered to practice in Ontario.⁴

Recent Changes to Regulations under the *Nursing Act, 1991*

Changes to regulations under the *Nursing Act, 1991* in August 2007 introduced three new specialty areas for NPs: paediatrics, adult, and anaesthesia as well as a new title for the primary health care specialty, NP-primary health care (NP-PHC).⁵

In June 2007, the *Health Systems Improvement Act, (2007)* amended the *Nursing Act, 1991* to broaden NP prescribing authority by permitting NPs to prescribe drugs from categories or classes of drugs designated in the regulation under the Act rather than limiting them to lists of individual drugs. No changes to the regulation under the Act have been made since the amendment was adopted.

¹ Nurse Practitioners (NPs) and Registered Nurses in the Extended Class (RN(EC)s) are synonymous.

² College of Nurses of Ontario. Classes of Registration. Available: <http://www.cno.org/reg/regclasses.html>.

³ CNO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 12, 2008: 1.

⁴ CNO. Membership Totals-at-a-Glance. Available: <http://www.cno.org/about/stats/totalcurrent.htm>.

⁵ HPRAC. *A Report to the Minister of Health and Long-Term Care on the Review of the Scope of Practice for Registered Nurses in the Extended Class (Nurse Practitioners)*. March 2008: 9.

HPRAC's Scope of Practice Review for Nurse Practitioners

In March 2008, HPRAC completed a review of the scope of practice of NPs in Ontario, concluding that an expansion of the NP scope of practice is in the public interest.⁶

The review considered broader challenges facing health care services in Ontario. It involved extensive consultations, an environmental scan, literature and jurisdictional reviews and a jurisprudence review. The review took into account current competencies, educational preparation and trends in the evolution of the nursing profession towards providing more complex care.

In the review, HPRAC heard that, due to changes in technology, clinical practices and population needs, including an aging population and increases in complex chronic diseases, the scope of practice of NPs is too narrow and restricts them in providing needed services. The drugs NPs may prescribe, the procedures they may perform and the laboratory and diagnostic tests they may order are largely prescribed in regulations. These regulations can be complex, time-consuming and difficult to amend or change.

To address this issue, a process of medical directives was developed (largely in hospitals) through which physicians authorize other health professionals in advance to perform specific acts under specific conditions for specific patient populations. In nursing, many of these directives directly relate to prescribing and administering drugs.

In documentation provided by the CNO for both the scope of practice review and as proposed in its submission to HPRAC on drug regulations for non-physician health professionals, the CNO requested that NPs be given access to open prescribing and that members of the profession receive authority to dispense, sell and compound drugs.⁷

HPRAC had also been asked by the Minister to consider the prescribing and use of drugs by non-physicians. HPRAC determined that scope of practice reviews were an essential first step in making recommendations to the Minister on whether a profession should be authorized to prescribe, dispense, sell or compound drugs, and under what conditions. HPRAC therefore considered the question of drug regulations under the *Nursing Act, 1991* as a matter to be considered during the second phase of its examination, following the review of the scope of practice of the profession.⁸

⁶ Ibid: 5.

⁷ Ibid: 13-14.

⁸ Ibid: 94.

Scope of Practice

In its scope of practice review, HPRAC found that the scope of practice statement in the *Nursing Act, 1991* is adequate and should remain unchanged. The scope of practice for nursing is defined in the Act as follows:

The practice of nursing is the promotion of health and the assessment of, the provision of, care for, and the treatment of, health conditions by supportive, preventive, therapeutic, palliative and rehabilitative means in order to attain or maintain optimal function.⁹

Nonetheless, HPRAC recognized that within the parameters of the nursing scope of practice, the profession encompasses a wide range of specialties, competencies, practice settings and accountabilities.

Authorized Acts

The *Nursing Act, 1991* defines the authorized acts for nurses as follows:

In the course of engaging in the practice of nursing, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Performing a prescribed procedure below the dermis or a mucous membrane.
2. Administering a substance by injection or inhalation.
3. Putting an instrument, hand or finger,
 - i) beyond the external ear canal,
 - ii) beyond the point in the nasal passages where they normally narrow,
 - iii) beyond the larynx,
 - iv) beyond the opening of the urethra,
 - vi) beyond the labia majora,
 - vii) beyond the anal verge, or
 - viii) into an artificial opening into the body.

Note: On a day to be named by proclamation of the Lieutenant Governor, section 4 is amended by the Statutes of Ontario, 2007, chapter 10, Schedule R, section 16 by adding the following paragraph:

4. Treating, by means of psychotherapy technique, delivered through a therapeutic relationship, an individual's serious disorder of thought, cognition, mood, emotional regulation, perception or memory that may seriously impair the individual's judgement, insight, behaviour, communication or social functioning.¹⁰

⁹ *Nursing Act, 1991, S.O. 1991, c. 32, s.3.*

¹⁰ *Ibid:* c. 32, s.4.

Additional requirements for authorized acts

A member shall not perform a procedure unless,

- (a) the performance of the procedure by the member is permitted by the regulations and the member performs the procedure in accordance with the regulations; or
- (b) the procedure is ordered by a person who is authorized to do the procedure by section 5.1 of this Act or by the *Chiropody Act, 1991*, the *Dentistry Act, 1991*, the *Medicine Act, 1991* or the *Midwifery Act, 1991*.

Additional Authorized Acts: Extended Class Nursing

The *Nursing Act, 1991* includes additional authorized acts for the extended class of nurses (NPs) as follows:

In the course of engaging in the practice of nursing, a member who is a registered nurse who holds an extended certificate of registration in accordance with the regulations is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following additional acts:

1. Communicating to a patient or his or her representative a diagnosis made by the member identifying, as the cause of the patient's symptoms, disease or disorder that can be identified from,
 - i) the patient's health history,
 - ii) the findings of a comprehensive health examination, or
 - iii) the results of any laboratory tests or other tests and investigations that the member is authorized to order or perform.
2. Ordering the application of a form of energy prescribed by the regulations under this Act.
3. Prescribing a drug designated in the regulations.
5. Administering, by injection or inhalation, a drug that the member may prescribe.¹¹

Consultation

A member is not authorized to communicate a diagnosis unless the member has complied with the prescribed standards of practice respecting consultation with members of other health professions.

¹¹ Ibid: c. 32, s.5.1(1).

Regulations

The *Nursing Act 1991* authorizes the CNO Council to make regulations, subject to the review of the Minister and approval of the Lieutenant Governor in Council, including designating the drugs that a member may prescribe, as well as the circumstances in which a member may prescribe the drugs.¹² A regulation may designate individual drugs or categories of drugs.¹³

Education and Continuing Competency

Ontario's education programs for nursing are well established and well respected. The entry to practice requirement for RNs is a four-year baccalaureate degree in nursing from a community college-university collaborative program or a university. RPNs are graduates from a two-year diploma in practical nursing from a community college. NPs are RNs who have obtained advanced education and passed the extended class examination. NPs have an expanded scope of practice in the areas of assessment, diagnoses, prescription of tests and treatments and health promotion.¹⁴

Training in pharmacotherapy is embedded through all levels of nursing education, with RNs completing two years of study in addition to the education received by RPNs.

Nursing studies include the following elements:

- General concepts related to pharmacology;
- How to accurately calculate drug dosages;
- Various forms of drug preparation;
- How to interpret the components of a medication order;
- The principles of medication administration (which aligns with dispensing), and
- The action and interaction within the body of selected pharmaceutical preparations and the impact on nursing care.¹⁵

All practicing nurses must demonstrate that they have met entry to practice competencies related to pharmacotherapy, including safe medication practices. For NPs, entry to practice requirements include demonstrating two years of safe nursing practice over the past five years, including one year in an advanced NP role, graduation from an approved NP education program, successful completion of a regulatory exam and registration or eligibility to register as an RN.

¹² Ibid: s. 14(1)(d).

¹³ Ibid: s. 14(1.1).

¹⁴ CNO. Classes of Registration. Available: <http://www.cno.org/reg/regclasses.html>.

¹⁵ CNO. Submission to HPRAC: 15.

The CNO submission outlined principles related to dispensing that are taught in the entry-level curriculum. Students are given opportunities to participate in dispensing drugs as part of their clinical training. Clinical simulation laboratories address many areas of the medication process, including dispensing. Programs focus on creating a culture of client safety and introduce the CNO's standards of practice.

Core competencies of NPs have been identified through a consensus process conducted by the Canadian Nurse Practitioner Initiative (CNPI), which developed the Canadian Nurse Practitioner Core Competency Framework. The framework sets out four broad competencies that are shared by all NPs:

- Health assessment and diagnosis;
- Health care management and therapeutic intervention;
- Health promotion and prevention of illness, injury and complications; and
- Professional roles and responsibility.

Students studying to become NPs are taught the primary components of drug therapy as part of a standardized curriculum provided by a network of nine accredited Ontario universities. NP candidates must be competent to:

Critically appraise and interpret concepts and frameworks integral to pharmacotherapy, advanced counselling, and complementary therapies for common conditions across the lifespan. Develop, initiate, manage, and evaluate therapeutic plans of care that incorporate client values and acceptability, goals of therapy, analysis of different approaches, pharmacotherapeutic principles.¹⁶

The “Health Care Management and Therapeutic Intervention” of the Canadian Nurse Practitioner Core Competency Framework clarifies the expectations relating to NPs’ ability to function competently with all components of pharmacology (e.g., pharmacokinetics and pharmacodynamics). NPs must be knowledgeable of best practices in selecting, prescribing, monitoring and dispensing drugs.¹⁷

Continuing Education

With support from the Ministry of Health and Long-Term Care, the Council of Ontario University Programs in Nursing (COUPN)¹⁸ provides continuing education to NPs and RNs working under an expanded mandate.

Starting in February 2009, the course “Pharmacotherapeutics in Primary Health Care” will offer further opportunities for nursing professionals to develop their competencies in the area of prescribing.

¹⁶ Ontario Primary Health Care Nurse Practitioner Program. *Therapeutics in Primary Health Care I*. Available: <http://np-education.ca/index.php?fuseaction=public.welcome&intMenItemId=19&nid=36>.

¹⁷ Canadian Nurses Association. *Canadian Nurse Practitioner Core Competency Framework*. January 2005.

¹⁸ Council of Ontario University Programs in Nursing. *Continuing Education for Primary Health Care Nurse Practitioners*. Available: <http://cert.np-education.ca/ce/index.cfm?main=main.html>.

“Content focuses on common drugs used to treat particular client conditions, their effects, side effects, interactions along with non-pharmacological interventions that may improve client conditions and quality of life.”¹⁹

Requests for Change

HPRAC received three submissions respecting drug authorities for nurses. The CNO has recommended that RNs and RPNs be authorized to dispense drugs, and that NPs be authorized to dispense, sell and compound drugs, in addition to existing prescribing authorities. The CNO also supports open prescribing by NPs, comparable to existing authorities for physicians and dentists, in which limits are self-imposed, based on individual competencies and a legislated scope of practice. Accordingly, there would be no regulations listing a schedule of drugs under the *Nursing Act, 1991* related to prescribing, whether by class, category or individual list of drugs. In conjunction with the request for open prescribing, the CNO is requesting that limitations on administering a substance by injection and inhalation be removed.

The NPAO is also requesting that NPs be given the authority to prescribe oxygen and blood products. The CNO proposals are supported by the RNAO and the NPAO.

The changes proposed are meant to facilitate access to controlled acts as part of the current scope of practice of nursing.

Request 1: Dispensing a Drug

The profession is seeking authority to dispense drugs for all classes of registrants as an activity that falls within the existing scope of practice.²⁰ The knowledge and skills involved in this controlled act are part of entry-level competencies and the routine practice of all nurses. The proposed change is intended to apply in situations where there is no pharmacist readily available and to a wide variety of practice settings such as acute care units, long-term care facilities, northern outposts, community clinics and public health clinics. Limitations and conditions related to these circumstances would be developed in the CNO’s practice standards. The CNO would work in collaboration with other colleges such as the Ontario College of Pharmacists (OCP) and the College of Physicians and Surgeons of Ontario (CPSO) to develop these standards of practice.

Proponents’ Rationale

Under the *Nursing Act, 1991*, nurses are unable to dispense a drug without a separate order to dispense a drug that has been prescribed. The CNO interprets the act of dispensing as providing medication to clients for self-administration. This includes providing medications for clients to take at

¹⁹ Council of Ontario University Programs in Nursing. *Pharmacotherapeutics in Primary Health Care*. February 2009. Available: http://cert.np-education.ca/ce/pharm_coursedesc.html.

²⁰ CNO. Submission to HPRAC: 6.

home or providing medications to be taken in another setting, such as in a long-term care residence. It does not include immediate administration of medications to clients.

Proponents have indicated that giving nurses direct authority to dispense drugs would ensure patients have timely access to needed drugs in situations where a physician or pharmacist is not available. HPRAC was told that nurses see patients and clients in a variety of settings, which may include circumstances where there is no pharmacist or physician available, or where patients do not want or might be unable to receive services in traditional settings. Examples of such circumstances include vulnerable populations like older adults living with Alzheimer's or degenerative joints who may have difficulty travelling to a pharmacy and young women seeking services in birth control clinics. Nurses working in smaller or remote communities with no pharmacy might be able to better serve clients if they had the authority to dispense drugs.

Proponents state that the act of dispensing is central to the practice of nursing. Nurses were dispensing routinely and safely before the introduction of the *Regulated Health Professions Act, 1991 (RHPA)*. Following the introduction of the *RHPA*, nurses continued to dispense medications under delegation of another professional.

Medical Directives and Delegation

Delegation is a process whereby a regulated health professional legally authorized to perform a controlled act transfers that authority to someone, regulated or unregulated, who is not so authorized.²¹ A medical directive is a process by which physicians authorize other health professionals in advance to perform specific acts under specific conditions for specific patient populations. Medical directives in hospitals frequently delegate the dispensing of drugs to nurses.

In community settings, authorizing mechanisms such as medical directives may not exist or may be withdrawn. This creates, in effect, an administrative impediment to good patient care. For example, nurses frequently dispense medication in travel clinics, correctional facilities, community health clinics, public health clinics and nursing stations under orders from a physician. If the physician moves or retires, the orders are no longer valid, leaving the nurses unable to provide this service. The proposed change is intended to apply to situations where access to a physician or pharmacist is often an issue and lack of dispensing authority becomes an impediment to timely and effective patient care.

The CNO agrees that delegation is an appropriate mechanism to allow an authorized profession, such as medicine or pharmacy, to give nurses the authority to perform procedures beyond the current scope of practice. They also contend that delegation is less useful when it is being used to

²¹ Ibid: 8.

“work around” inadequacies in legislation that fail to reflect the routine practice of the profession.²² The CNO argues that there comes a time when the delegated activities need to be subsumed within the receiving profession.²³

Proponents argue that authorizing mechanisms create uncertainty with regard to the accountability for the performance of the controlled act. Eliminating the requirement for delegation of dispensing drugs would bring accountability for their practice to the regulatory authority of the CNO, which would then have the means to hold nurses accountable to established practice standards and guidelines.

The CNO stated that allowing nurses to dispense drugs would clarify the lines of accountability for the controlled act. The CNO would set specific practice expectations for its members through standards of practice. The CNO would be able to monitor the actions of its members relating to dispensing through its quality assurance program.

Request 2: Authority for NPs to Sell and Compound Drugs

The CNO states that allowing NPs to compound and sell drugs would help address access to medications for people unable to get to a pharmacy. Examples of the need for compounding drugs include reconstituting medications, such as antibiotic prescriptions for children, and mixing topical medications, such as treatment for poison ivy. Residents of long-term care homes and people living in remote communities would also benefit from the convenience of NPs having this authority.

Standards of Practice for Dispensing, Selling or Compounding Drugs

The CNO's Medication Practice Standard includes a number of requirements to ensure safe medication practices and reduce errors, including in dispensing drugs. The standard requires that systems be in place to track, address and learn from any adverse events that occur in practice settings. In addition, the CNO has prepared draft standards of practice for the proposed authorities, and educators have identified where curricula need to be expanded or have already incorporated strategies to enable graduates to perform the new controlled acts.

The CNO's draft standard of practice for dispensing, selling and compounding drugs is as follows:

Dispensing

A NP shall dispense drugs in accordance with federal and provincial legislation.

²² Ibid: 8.

²³ CNO. Submission to HPRAC: *Registered Nurse in the Extended Class: Scope of Practice Review*. August 24, 2007: 16.

A NP shall only dispense drugs for clients the NP reasonably believes would have difficulty accessing the drug as a result of one or more of the following:

- lacking health insurance;
- lacking access to drug benefit programs;
- lacking reasonable access to a pharmacy; and/or
- limited financial resources.

A NP who dispenses a drug shall:

- ensure either a written or verbal prescription is provided; and
- document the drug dispensed and the rationale for dispensing in the client record.

Selling

A NP shall only sell drugs to clients that the NP reasonably believes would have difficulty accessing the drug as a result of:

- lacking reasonable access to a pharmacy; or
- the inability to pay the fees associated with the dispensing of the drugs by a pharmacy.

A NP shall not sell a drug that is defined as a “controlled substance” in the *Controlled Drugs and Substances Act, 1996* (Canada) (*CDSA*).

- A NP who sells a drug shall:
- do so in accordance with federal and provincial legislation;
- ensure there is a written prescription for each drug sold; and
- document the transaction and rationale for selling drugs in the client record each time a drug is sold.

Compounding

A NP shall only compound drugs that are non-sterile topical creams.

A NP shall only compound drugs for a client that the NP reasonably believes would have difficulty accessing the drug as a result of one or more of the following:

- lacking health insurance;
- lacking access to drug benefit programs;
- lacking reasonable access to a pharmacy; and/or
- limited financial resources.

A NP shall not compound drugs that are defined as “controlled substances” in the *CDSA*.

A NP who compounds drugs shall:

- do so in accordance with federal and provincial legislation;
- ensure there is a written prescription for each drug compounded; and
- document in the client record the compounding process including the name and quantity of each drug and include the rationale for compounding.

What HPRAC Found

Dispensing Drugs

Readiness for Change

The CNO has received feedback from its members, during a number of consultations through outreach programs, the CNO's teleconference series and various events and conferences. Members spoke out in favour of being granted the authorized act of dispensing drugs.²⁴ NPs have stated that being authorized to dispense birth control pills and samples of drugs to marginalized clients would better serve clients and improve overall access to quality health care.²⁵

Other Jurisdictions – Dispensing Drugs

RPNs

According to the CNO,²⁶ RPNs functioning in Canada are authorized to dispense drugs, with limitations, in New Brunswick and Quebec. In British Columbia and Alberta, licensed practical nurses (LPNs), which are equivalent to RPNs, are authorized to repackage medication for patients on leave or refill their dosette for daily self-dosing. In the Yukon, LPNs may only dispense under supervision by a RN or a physician. In the Northwest Territories, employers may transfer drug dispensing functions to RPNs. The situation is slightly different in the United States, where two of eleven jurisdictions, Colorado and Oregon, authorize dispensing by RPNs.

RNs

The CNO reports that RNs are authorized to independently dispense drugs, with limitations, in Newfoundland, Saskatchewan, Alberta, British Columbia, the Yukon and the Northwest Territories. In Quebec, RNs working in travel clinics may dispense and administer drugs according to protocols. New Brunswick RNs may only dispense under delegation. Dispensing is not authorized to RNs in Manitoba or Prince Edward Island.

²⁴ CNO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs*: 27.

²⁵ CNO. Submission to HPRAC: *Registered Nurse in the Extended Class, Scope of Practice Review*: 35.

²⁶ CNO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs*: 232-233.

RNs in Oregon may dispense medication for family planning and communicable diseases, such as STDs. In North Carolina and Missouri, public health RNs are authorized to dispense medications. Montana limits RN dispensing authority to those who work in an emergency department situated at least ten miles (16 kilometres) from an open pharmacy and when there is no staff pharmacist on duty at the time. The Virginia Board of Pharmacy has approved the dispensing of contraceptive medication and tetracycline by RNs when a physician, nurse practitioner or pharmacist is not on the premises. Maryland, New York, Kansas and New Hampshire do not authorize RNs to independently dispense.

In New Zealand, RNs may dispense drugs independently in a limited number of situations, for example, dispensing the emergency contraceptive pill. In Australia and South Africa, RNs require specific authorization to dispense, as this is considered to be outside the normal scope of practice of the profession. In Great Britain, RNs may, in limited circumstances, label medication from stock and supply a clinically appropriate medicine to a patient, against a written prescription for self-administration or administration by another professional.

NPs

NPs are authorized to dispense drugs in the majority of Canadian provinces and territories. In New Brunswick, NPs may administer a limited quantity of a specific drug to the patient so that the patient may start therapy immediately while waiting for a pharmacy to open and fill a prescription.²⁷ In Alberta, NPs may dispense Schedule I or II drugs.²⁸ In Manitoba, NPs may prescribe and distribute samples of drugs as specified in the regulations. NPs in Saskatchewan may dispense Schedule I, II and III drugs, drugs included in the Health Canada Non-Insured Health Benefits and medications not requiring a prescription.²⁹ In the Northwest Territories and Nunavut, a community NP may select, dispense, compound and repack medication under medical directives, policies and guidelines, as community health nurses do, in addition to prescribing.³⁰

In British Columbia, NPs may prescribe or give an order to compound, dispense or administer by any method a drug as specified in the regulations. The College of Registered Nurses of British Columbia (CRNBC) has established detailed standards, limits and conditions for the three categories of NP practice: NP (Family); NP (Adult) and NP (Paediatrics).³¹ These standards each focus on the following three areas:

- Diagnosis and health care management;
- Prescribing and dispensing drugs; and
- Physician consultation and referral.

²⁷ Nurses Association of New Brunswick. *Competencies and Standards of Practice for Nurse Practitioners in Primary Health Care*. October 2002: 8.

²⁸ College and Association of Registered Nurses of Alberta. *Health Professions Act: Standards for Registered Nurses in the Performance of Restricted Activities*. October 2005: 7.

²⁹ Saskatchewan Registered Nurses Association. Bylaw VI Categories of Practice. s.2(c).

³⁰ RNANT/NU. Prescriptive Authority Guidelines for NWT Primary Health Care Nurse Practitioners (PHCNPs). 2.

³¹ College of Registered Nurses of British Columbia. *Scope of Practice for Nurse Practitioners: Standards, Limits and Conditions*. October 2007. Family: 24; pediatrics: 25; adult: 25.

NPs who dispense medications in British Columbia may only do so in situations where a pharmacist is not available or accessible, or it is in the best interest of the patient.³² NPs who dispense other than drug samples or small quantities of medications must receive approval from the CRNBC to be designated as a dispensing practitioner and comply with procedures for Approval Process for Dispensing Practitioners PharmaNet/Pharmacare as set out by the College of Pharmacists of British Columbia.³³

NPs are authorized to dispense prescription medications in a majority of jurisdictions in the United States. Authority may be limited to medications NPs are authorized to prescribe. States authorizing NP dispensing include Oregon,³⁴ Virginia,³⁵ California³⁶ and North Carolina.³⁷

The Scottish government provides guidance on prescribing and dispensing by nurses:

Whilst there is no legal bar to nurse/midwife dispensing there must be in place a local policy agreed to endorse the registrant's actions. [...] Nurse prescribers must ensure separation of prescribing and dispensing whenever possible, including within dispensing practices. [...] In exceptional circumstances, where nurses are involved in both prescribing and dispensing a patient/client's medication, a second suitably competent person should be involved in checking the accuracy of the medication provided. Accuracy checks are as guidance and not required in law.³⁸

In Australia, the states of Victoria and New South Wales authorize NPs to use, sell or supply scheduled drugs.^{39, 40} In the Australian Capital Territory, NPs are authorized to delegate the dispensing of prescriptions and controlled substances.⁴¹

The CNO submission notes that there are four areas of agreement in Canadian jurisdictions in which nurses are given the authority to dispense medications:

- In emergency areas, when the pharmacist is not readily available and there is an urgency to dispense a small portion of the prescribed medications;

³² Ibid.

³³ Ibid.

³⁴ Oregon Revised Statute 678.390(2). Available: <http://www.leg.state.or.us/08ssorlaws/0004.html>.

³⁵ Code of Virginia, *Professional use by practitioners*. c.54.1-3408.

³⁶ Board of Nursing of California. *New Authority to Provide Medication*. January 2000. Available: <http://www.rn.ca.gov/pdfs/regulations/npr-b-26.pdf>.

³⁷ North Carolina Board of Pharmacy. *Pharmacist FAQs*. Available: http://www.ncbop.org/faqs/Pharmacist/faq_FreeClinics.htm.

³⁸ Government of Scotland. *Non Medical Prescribing in Scotland: Guidance for Nurse Independent Prescribers and for Community Practitioner Nurse Prescribers in Scotland: A Guide for Implementation*. August 2006. Available: <http://www.scotland.gov.uk/Publications/2006/08/23133351/12>.

³⁹ Victoria Consolidated Acts. *Health Professions Registration Act 2005*, s.20. Available: http://www.austlii.edu.au/au/legis/vic/consol_act/hpra2005356/s20.html.

⁴⁰ New South Wales Consolidated Acts. *Poisons and Therapeutic Goods Act, 1966*, s.17A. Available: http://www.austlii.edu.au/au/legis/nsw/consol_act/patga1966307/s17a.html.

⁴¹ Australian Capital Territory Consolidated Acts. *Poisons Act, 1933*, s.16 AA. Sale or supply of biological preparations or restricted substances to ineligible people. Available: http://www.austlii.edu.au/au/legis/act/consol_act/pa1933121/s16aa.html#eligible_receiver.

- To cover a client's short leave of absence period or a pass from a health care facility, by accessing the night cupboard or a stock supply established by a pharmacist;
- In remote communities, where the nurse may be the only health care provider available to assume the responsibility for dispensing on an ongoing basis; and
- The dispensing of specific drugs by public health nurses under specific circumstances such as family planning, communicable disease, and sexually transmitted disease (STD) Clinics.

Education and Continuing Competence

HPRAC's review of nursing educational programs indicates that members are qualified to dispense drugs that they prescribe and drugs that they are currently dispensing under delegation. Dispensing drugs is an entry-level competency for all nurses in Ontario.

Managing the Risk of Harm

Prior to registering with the CNO, individual members must demonstrate that they have met the entry to practice competencies, including those related to pharmacotherapy.⁴²

HPRAC heard some concerns that should be taken into account in extending the authority to dispense drugs, since the second check on the accuracy and appropriateness of the prescription that occurs in the pharmacy does not happen. When pharmacists dispense a drug, they are required to make an overall therapeutic assessment of the patient's symptoms, conditions or diseases, drugs and alternate therapies currently being used. This information is included in the patient's profile. Responsibilities also include inventory management, checking for expiry dates and safe storage, including record-keeping, inventory counts and safe disposal.

Pharmacists have said that nurses should be held to the same dispensing standards. The absence of strict protocols for dispensing drug samples, for example, may mean that the drug that is dispensed is the one that is available rather than the one that best serves the needs of the patient. As a safeguard, pharmacists suggest that standards of practice for dispensing protocols must be rigorous.

The College of Physicians and Surgeons of Ontario (CPSO) has developed a new drug dispensing guideline, which is being circulated for comment and is expected to be adopted in January 2009. The guideline holds physicians to the same standards as a pharmacist for dispensing drugs. Physicians must comply with all relevant legislation including the *Controlled Drugs and Substances Act (CDSA)*, the *Drug and Pharmacies Regulation Act*, the *Drug Interchangeability and Dispensing Fee Act* and the *Food and Drug Act (Canada)*. These statutes set out the requirements for the sale and dispensing of drugs, including labelling, record-keeping and retention of records.

⁴² CNO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs*. 14.

The CPSO draft guideline also sets out standards that limit dispensing by physicians to dispensing drugs to their own patients; and using proper methods of procurement to be assured of the origin and chain of custody of the drugs being dispensed. The standards include safe storage, record-keeping, checking expiry dates, proper disposal, appropriate packaging and labelling; providing appropriate material to patients and an audit system.

Selling and Compounding Drugs

HPRAC heard little concern about NPs' competence to sell and compound drugs, provided there were terms, conditions and limitations attached to the practice. The CNO has indicated that the practice would occur rarely, in communities where access to a pharmacy is limited, and where patients might need to attend an emergency department to otherwise obtain the prescribed medication. HPRAC was told that NPs should not have the authority to compound or sell controlled drugs.

Some issues were raised relating to the high standards for hygiene and sterile conditions and storage protocols for ingredients that are required for compounding drugs. It was noted by some that these protocols must be accounted for in standards of practice. Others indicated that there must be a written prescription for the drug and records of the agents used in the compounded medication.

Similarly, standards of practice should define specifically the requirements for records relating to the selling of drugs. No profits should be allowed, and there should be a written prescription and proper documentation relating to the drugs sold, including such matters as a careful tracking of the source of the drug, expiry date, and details of the prescription.

Conclusions

HPRAC has concluded that risks associated with dispensing drugs, an entry-level competence for all nurses who are registered in Ontario, can be mitigated by ensuring appropriate standards and quality assurance programs are in place. Nonetheless, standards of practice should make it clear that the authority should be exercised to address limited situations where a pharmacist or physician is not available. Additionally, HPRAC found that NPs have the foundational education to sell and compound drugs, other than controlled drugs. Standards of practice, developed through an interprofessional process, should be put in place to ensure patient safety.

Request 3: Open Prescribing for Nurse Practitioners

The *Nursing Act, 1991* authorizes NPs to prescribe drugs that are designated in the regulations and the circumstances in which a member may prescribe those drugs. While the regulations currently designate individual drugs, amendments to the Act made in 2007 authorize the regulation to designate individual drugs or categories of drugs.⁴³

⁴³ *Nursing Act*, 2007, c. 10, Sched. B, s. 14 (4).

The CNO and the NPAO have requested that no limitations on prescribing authorities, including designating drugs by classes or categories or lists, be included in the legislation or regulation for NPs.

Proponents' Rationale for Change

Proponents have requested this change as a result of concerns relating to the regulation-making process and experiences with attempts to amend the drug regulation. The CNO argues that “regulating by lists, categories or classes is inconsistent with the philosophy of self-regulation, does not promote safe practice and will not provide NPs with the flexibility or the authority they require to prescribe for the diverse client populations and settings they serve.”⁴⁴

NPs provide care to a full range of patient populations and seek an enabling process rather than one that can limit effective care. The CNO told HPRAC that drug categories do not address the depth and breadth of practice of NPs. The diversity in practice, along with managing patients with multiple co-morbidities, makes the use of limitations in regulation an unworkable option.

An approach that includes drug categories with specific conditions and limitations is also not practical for NPs given that “keeping categories up to date for each of the four specialty certificates and the multiple subspecialties subsumed under these certificates will be difficult and likely impractical, if not impossible to achieve”.⁴⁵

NPs believe that limits and conditions are more appropriately managed in standards of practice rather than legislation because they can more quickly be amended according to emerging best practices.⁴⁶

Limits on scope of practice caused by these lists have delayed the delivery of appropriate patient care in addition to placing burdens on other members of the health care team who are pulled away from their own responsibilities to enact a function NPs are capable of performing on their own.

The amount of time spent developing, reviewing and updating medical directives, as well as taking them through the physician and administrative approval process, is labour-intensive and time-consuming. Furthermore, removing the necessity of medical directives will reduce the risk of blurred accountability and related liabilities, decrease duplication, increase public safety and increase efficiencies and cost-effectiveness within the system.

What HPRAC Found

System Issues

HPRAC heard that there are numerous benefits to NP prescribing. Nurse prescribing is cost- and time-effective for service providers, rates of

⁴⁴ CNO. Submission to HPRAC. 1.

⁴⁵ Nurse Practitioners Association of Ontario, Submission to HPRAC. 5.

⁴⁶ Ibid: 6.

patients' compliance with nurse prescriptions are high, and nurses take detailed medical histories before making a decision about an intervention and may be more likely to prescribe a non-pharmacological intervention.⁴⁷

During the scope of practice review, HPRAC heard from stakeholders that NPs prescribing in specialist roles is useful in hospitals, provided there is a complete record of prescribing activity documented through centralized hospital records. A number of professionals came forward and noted NPs' expertise and contribution to care and supported their right to prescribe.

What Other Leading Jurisdictions Do

In Alberta, NPs have been authorized to prescribe Schedule I drugs since 1994. In British Columbia, the CRNBC sets strict standards outlining what can be prescribed and under what circumstances. These standards are set in consultation with physicians and pharmacists.

In Great Britain, nurse prescribing, introduced in May 2006, is well received and understood by the public and other health practitioners. HPRAC heard in consultations with authorities from Great Britain that nurse prescribing is both time- and cost-effective and results in higher patient compliance.

Among the challenges and barriers identified in the implementation of nurse prescribing in Great Britain were the limitations of the formulary, which impacts the effectiveness of patient care; the bureaucracy associated with writing Clinical Management Plans; the degree of closeness of the working relationship with the physician; a perception by some physicians that their role is being eroded; physicians' concerns about patient safety; the lack of institutional strategy for implementing nurse prescribing; access to computerized prescribing; and a number of education and practice issues that warrant ongoing attention.^{48,49,50}

Managing the Risk of Harm

Physicians told HPRAC in key informant interviews they are concerned about the implications of bypassing the traditional gate-keeping role of MDs and pharmacists if open prescribing by NPs were to become a reality. They raised concerns about the CNO oversight and about the drugs the CNO has recommended for inclusion in the designated drug lists for nurses.

⁴⁷ HPRAC. *Prescribing and Administration of Drugs by Non-Physician Health Professionals: Literature Review*. 19.

⁴⁸ Evaluation of non-medical prescribing within the Essex Health Economy. 2005-2006.

⁴⁹ Latter, S., Maben, J., Myall, M., Courtney, M., Young, A., Dunn, N. (2005) *An Evaluation of Extended Formulary Independent Nurse Prescribing. Executive Summary of Final Report*. Policy Research Program at the Department of Health and University of Southampton.

⁵⁰ Latter, S., Maben, J., Myall, M., Young, A. Evaluating Nurse Prescribers' Education and Continuing Professional Development for Independent Prescribing Practice: Findings from a National Survey in England (2007) *Nurse Education Today*. 27: 685-696.

The CNO has drafted a proposed standard of practice for NPs that includes limits and conditions for open prescribing.⁵¹ The draft standard of practice is very similar to the existing one. The proposed standard of practice is:

***Proposed Practice Standard: Performance of Controlled Acts
by Nurse Practitioners***⁵²

In Regulation:

A member holding extended class certification of registration as a registered nurse may delegate the performance of an act authorized to the member pursuant to section 5.1 of the Act other than the authorized act of prescribing a drug.

A NP shall only prescribe a drug for clients with whom a nurse-client relationship is established and documented.

A NP shall not:

- self-prescribe a drug; or
- prescribe a drug for a family member.

Before prescribing a drug, a NP shall utilize medication reconciliation principles in an effort to prevent errors.

A NP who prescribes a drug shall:

- comply with federal and provincial legislation;
- provide either a written or verbal prescription when necessary;
- document the drug prescribed; and
- provide information about the drug for the client and/or client representative.

After prescribing a drug, a NP shall:

- monitor and document the client's response to the drug therapy until the client is discharged from the NP's care;
- continue, adjust or withdraw the drug therapy, depending on the client's response; and
- consult with an appropriate health care provider when the client's response to the drug therapy is other than the NP anticipated.

When a NP continues drug therapy initiated by another health care provider, the NP shall:

- provide ongoing assessment;
- monitor the client's response to the drug therapy;

⁵¹ CNO. Submission to HPRAC: *Registered Nurse in the Extended Class, Scope of Practice Review*. Appendix C.

⁵² Ibid.

- adjust dosage of the drug therapy, when appropriate; and
- consult with an appropriate health care provider, when appropriate.

In Practice Standard:

The authority of NPs to initiate a prescription for a drug is limited to treating conditions that they can diagnose and for which they can provide the necessary counselling and ongoing management.

Conclusions

On balance, HPRAC is of the view that with the introduction of a new drug approvals framework, many of the concerns about the regulation-making process will be addressed. Classes of drugs would be designated in the regulation, and specific agents would be reviewed through a new and expedited process.

HPRAC contends that additions of new classes of drugs in the regulation will be relatively rare and would merit extensive examination, since such requests may indicate that the profession is seeking a change in its scope of practice.

Transparent standards of practice must be in place to ensure that only NPs with adequate knowledge and competencies are able to prescribe a drug or class of drugs, and this is a key accountability given the number of subspecialties within NP practice. These standards of practice relating to prescribing drugs should be developed through a collaborative process as recommended in the scope of practice review.

Request 4: No Limits for NPs in Administering a Substance by Injection or Inhalation

The CNO and the NPAO are recommending that limitations on the authorized act of administering a substance by injection or inhalation be removed for NPs. Currently NPs may administer by injection or inhalation a drug that they have authority to prescribe, but require an order to administer if a drug is prescribed by another health professional. This request was an adjunct to the request for open prescribing.⁵³

Proponents' Rationale

Given the proponents' request for full prescribing authority, it has been contended that the current restrictions on the administration of drugs and substances by injection or inhalation would continue to limit NPs' ability to provide care.⁵⁴

⁵³ *Nursing Act, 1991*, c. 32, s.5.1(1)4.

⁵⁴ NPAO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs*. November 12, 2008: 7.

Conclusions

HPRAC is not recommending that NPs have open prescribing authority as requested.

HPRAC is recommending that the drug regulation under the *Nursing Act, 1991* be amended to designate drugs and substances by therapeutic class. Specific agents within therapeutic classes, including any terms, limitations and conditions, would be developed through a new drug approvals framework, carried out by the proposed Council on Health Professions Regulatory Excellence (CHPRE) on the advice of a new Drugs and Therapeutics Formulary Committee (DTFC).

Other Issues: An Emergency Kit and Oxygen

HPRAC considered the need for an emergency medications kit, or “crash cart” as it is generally described, for NPs. HPRAC heard during the consultations with colleges and other stakeholders that NPs should have the knowledge and necessary tools to handle an emergency situation.

The standard emergency medications are as follows:

- **Oxygen:** 100 percent for most medical emergencies (same concentration for both adults and children).
- **Epinephrine:** Used for anaphylactic shock, severe asthmatic attack not responsive to inhaled salbutamol, and cardiac arrest. Injected into the muscle (0.3-0.5 mg) or IV (0.1 mg).
- **Nitroglycerin:** Used to treat angina (chest pains). Administered under the tongue (sublingual) at 0.3 to 0.4 mg.
- **Diphenhydramine or chlorpheniramine:** Used for moderate to severe allergic reactions. Administered in the muscle or IV at 10-50 mg, or 1.0 mg/kg in children.
- **Salbutamol:** Bronchodilator for asthmatic bronchospasm. Two puffs (100 micrograms/puff) or one puff for children.
- **ASA:** Administered if acute heart attack suspected. 160-325 mg in adults.⁵⁵

HPRAC concludes that an emergency kit should be available to NPs as required in some practice settings. The CNO will need to establish standards, protocols and practice guidelines for emergency situations, including a requirement that members maintain current certification in basic cardiopulmonary resuscitation.

⁵⁵ Royal College of Dental Surgeons of Ontario. *Guidelines on the Use of Sedation and General Anaesthesia in Dental Practice*. For distribution February 2009. In press and referenced with permission.

Recommendations

Recommendation 1:

- a. That NPs, RNs and RPNs be authorized to dispense drugs that are prescribed by an authorized prescriber;
- b. That the authorization should be based on adherence to transparent standards of practice;
- c. That the standards of practice for dispensing drugs should be developed by an interprofessional committee;
- d. That the standards of practice be equivalent to those required of physicians; and
- e. That the standards of practice address therapeutic needs of the patient.

Recommendation 2:

- a. That NPs be authorized to compound and sell drugs that are prescribed by an authorized prescriber;
- b. That the authorization be based on adherence to transparent standards of practice;
- c. That the standards of practice for compounding and selling drugs be developed by an interprofessional committee; and
- d. That the standards of practice be equivalent to those required of physicians.

Recommendation 3:

- a. That the regulation under the *Nursing Act, 1991* designate drugs that NPs are authorized to prescribe by therapeutic classes;
- b. That specific agents and any terms, limitations or conditions to be attached to the prescribing or administration of drugs included in the class be determined through a new drug approvals framework;
- c. That standards of practice relating to the prescribing of drugs be developed by an interprofessional standards committee; and
- d. That NPs not be authorized to delegate prescribing authority.

Recommendation 4:

- a. That NPs be authorized to prescribe and administer drugs for use in emergency situations; and
- b. That the CNO develop additional standards of practice for emergency situations.

Recommendation 5:

That the following therapeutic classes of drugs be included in a designated drugs regulation under the *Nursing Act, 1991*. The specific agents and any terms, limitations or conditions attached to the

authority would be developed through a new drug approvals framework. At the outset, the specific agents that could be prescribed, dispensed, sold and compounded would include those listed below:

Class	Specific Agents with Conditions
Class: Antihistamine Drugs	Doxylamine succinate and pyridoxine hydrochloride Hydroxyzine hydrochloride (oral preparation)
Class: Anti-infective Agents Sub-class: Anthelmintics	Mebendazole
Class: Anti-infective Agents Sub-class: Antibacterials	Aminoglycosides (Framycetin sulphate) Cephalosporins (Cefixime, for the purpose of treating sexually transmitted diseases, Cefprozil, Ceftriaxone sodium, for the purpose of treating sexually transmitted diseases, Cefuroxime axetil (oral), Cephalexin) Misc Beta-Lactams Macrolides (Azithromycin, Clarithromycin (oral), Erythromycin base, Erythromycin estolate, Erythromycin ethylsuccinate, Erythromycin ethylsuccinate/sulfisoxazole acetyl, Erythromycin stearate) Penicillins (Amoxicillin, Amoxicillin and clavulanate, Aqueous procaine penicillin G, for the purpose of treating sexually transmitted diseases, Benzathine penicillin G, for the purpose of treating sexually transmitted diseases, Cloxacillin (oral preparation), Pivampicillin, Penicillin V) Quinolones (Ofloxacin, Ciprofloxacin extended release, Ciprofloxacin HCl, Moxifloxacin, Levofloxacin) Sulfonamides (Trimethoprim and sulfamethoxazole (oral preparation), Sulfacetamide sodium) Tetracyclines (Doxycycline hyclate, Tetracycline hydrochloride (oral preparation), Minocycline hydrochloride) Misc. (Clindamycin, Trimethoprim, Phenazopyridine HCl (UTI), Nitrofurantoin (misc for UTI), Mupirocin)

Class	Specific Agents with Conditions
Class: Anti-infective Agents Sub-class: Antifungals	Ciclopirox Butoconazole nitrate Ciclopirox olamine (shampoo) Econazole Fluconazole (oral), for vulvovaginal candidiasis only Metronidazole (oral and topical preparations) Nystatin (oral) Terconazole Terbinafine (topical use; or oral use for the treatment of onychomycosis only)
Class: Anti-infective Agents Sub-class: Antimycobacterials	
Class: Anti-infective Agents Sub-class: Antivirals Sub-sub-class: Adamantanes	Amantadine hydrochloride
Class: Anti-infective Agents Sub-class: Antivirals Sub-sub-class: Nucleosides and Nucleotides	Acyclovir Famciclovir Oseltamivir phosphate Valacyclovir hydrochloride Zanamivir
Class: Anti-infective Agents Sub-class: Miscellaneous	Silver sulfadiazine
Class: Autonomic Drugs	
Class: Blood formation, coagulation, and thrombosis agents Sub-class: Antithrombotic drugs	Clopidogrel bisulfate, for renewal only

Class	Specific Agents with Conditions
<p>Class: Cardiovascular Drugs</p>	<p>Antilipemics: (For renewal only: Atorvastatin, Ezetimibe (cholesterol), Fluvastatin, Lovastatin, Rosuvastatin, Simvastatin, Pravastatin)</p> <p>Hypotensives: (For renewal only: Acebutolol (beta-blocker), Atenolol, Bisoprolol, Labetalol, Metoprolol, Nadolol, Propranolol, Timolol, Pindolol, Furosemide, Hydrochlorothiazide, Hydrochlorothiazide/amiloride, Hydrochlorothiazide/candesartan, Hydrochlorothiazide/cilazapril, Hydrochlorothiazide/enalapril, Hydrochlorothiazide/eprosartan, Hydrochlorothiazide/irbesartan, Hydrochlorothiazide/lisinopril, Hydrochlorothiazide/losartan, Hydrochlorothiazide/pindolol, Hydrochlorothiazide/quinapril, Hydrochlorothiazide/spironolactone, Hydrochlorothiazide/telmisartan, Hydrochlorothiazide/triamterene, Hydrochlorothiazide/valsartan, Indapamide (only for hypertension), Spironolactone; Indapamide, Perindopril-indapamide)</p> <p>Vasodilators: (For renewal only: Isosorbide dinitrate (oral, sublingual), Nitroglycerin (sublingual), Nitroglycerin (transdermal))</p> <p>Calcium Channel Blockers (For renewal only: Amlodipine besylate (calcium channel blocker), Diltiazem, Nifedipine, Verapamil extended release)</p> <p>Renin-Angiotensin Agents: (For renewal only: Benazepril, Candesartan cilexetil, Captopril, Cilazapril, Enalapril maleate, Eprosartan mesylate, Fosinopril sodium, Irbesartan, Lisinopril, Losartan potassium, Perindopril erbumine, Perindopril erbumine-indapamide (only for hypertension), Quinapril, Ramipril, Telmisartan, Trandolapril, Valsartan)</p>

Class	Specific Agents with Conditions
Class: CNS Agents Sub-class: Analgesics and Antipyretics Sub-sub-class: NSAIDs	Celecoxib, for renewal only Diclofenac sodium and misoprostol Ibuprofen Ketoprofen Mefenamic acid Meloxicam, for renewal only Naproxen Naproxen sodium
Class: CNS Agents Sub-class: Anticonvulsants	Carbamazepine, for renewal only Gabapentin, for renewal only Phenytoin, for renewal only Topiramate, for renewal only Valproic acid, for renewal only
Class: CNS Agents Sub-class: Psychotherapeutic Agents	Haloperidol, for chronic nausea in palliation Amitriptyline, for renewal only Bupropion, for smoking cessation only Bupropion, for renewal only for antidepressant therapy Citalopram, for renewal only Escitalopram, for renewal only Fluoxetine, for renewal only Fluvoxamine, for renewal only Mirtazapine, for renewal only Nortriptyline, for renewal only Paroxetine, for renewal only Sertraline, for renewal only Venlafaxine, for renewal only
Class: CNS Agents Sub-class: Antimigraine Agents	Almotriptan, for renewal only Rizatriptan, for renewal only Naratriptan, for renewal only Sumatriptan, for renewal only Zolmitriptan, for renewal only
Class: CNS Agents Sub-class: Miscellaneous	Galantamine hydrobromide, for renewal only Donepezil, for renewal only Rivastigmine hydrogen tartrate, for renewal only Betahistine dihydrochloride, for renewal only for the treatment of recurrent vertigo associated with Ménière's disease

Class	Specific Agents with Conditions
Class: Electrolytic, Caloric, and Water Balance	
Class: Enzymes	Collagenase
Class: Respiratory Tract Agents	Bedesonide-formeterol Ciclesonide Beclomethasone (2007) Beclomethasone dipropionate (inhalation), for renewal only Budesonide-formoterol fumarate dihydrate, for renewal only Formoterol fumarate dihydrate, for renewal only Ipratropium bromide, for renewal only Ipratropium bromide/salbutamol sulfate, for renewal only MontelU.K.ast sodium, for renewal only Salbutamol (inhaler or nebulizer solution), for renewal or for use in spirometry Salmeterol xinafoate, for renewal only Salmeterol xinafoate/fluticasone propionate, for renewal only Terbutaline sulfate, for renewal only Tiotropium bromide monohydrate, for renewal only ZafirlU.K.ast, for renewal only Fluticasone propionate (inhalation), for renewal only
Class: Eye, Ear, Nose, and Throat Preparations Sub-class: Anti-infectives (52:04)	Ciprofloxacin HC (otic) Framycetin sulphate/gramicidin/dexamethasone compound otic solution Fusidic acid one percent viscous eye drops Gentamicin sulphate (otic, ophthalmic and topical) Tobramycin 0.3 percent ophthalmic solution
Class: Gastrointestinal Drugs	Orlistat, for renewal only Esomeprazole, for renewal only Lansoprazole, for renewal only Misoprostol Omeprazole, for renewal only Pantoprazole (oral), for renewal only Rabeprazole, for renewal only Ranitidine HCl (oral)

Class	Specific Agents with Conditions
Class: Hormones and synthetic substitutes Sub-class: Adrenals	Adrenals (Betamethasone valerate, Diflucortolone valerate, Flucinolone aetonide, Flunisolide, Fluocinolone acetonide, Flumethasone pivalate/clioquinol compound, Hydrocortisone-17-valerate, Prednicarbate, Triamcinolone acetonide)
Class: Hormones and synthetic substitutes Sub-class: Contraceptives	Contraceptives (Conjugated Estrogens and medroxyprogesterone acetate, Desogestrel and ethinyl estradiol, Levonorgestrel, Norelgestromin and ethinyl estradiol (transdermal patch), Estradiol-17 beta (transdermal), Norethindrone acetate/ethinyl estradiol, Levonorgestrel releasing intrauterine system, Mestranol and norethindrone, Ethinyl estradiol and cyproterone acetate, Ethinyl estradiol/drospirenone, Ethinyl estradiol and ethynodiol diacetate, Ethinyl/etonogestrel (vaginal ring), Ethinyl estradiol and levonorgestrel, Ethinyl estradiol and norethindrone, Ethinyl estradiol and norethindrone acetate, Ethinyl estradiol and norgestimate, Ethinyl estradiol and norgestrel)
Class: Hormones and synthetic substitutes Sub-class: Estrogens	Estrogens (Conjugated Estrogens, Dienestrol, Estradiol-17 beta (micronized), Estradiol-17 beta (Silastic ring), Estradiol-17 beta hemihydrate, Estradiol-17 beta norethindrone acetate, Estrone (cone or cream), Norethindrone, Raloxifene HCl , for renewal only, Estropipate (piperazine estrone sulfate))
Class: Hormones and synthetic substitutes Sub-class: Antidiabetic Agents	Antidiabetic Agents (For renewal only: Acarbose, Metformin hydrochloride, Nateglinide (only for the treatment of type 2 diabetes mellitus), Pioglitazone, Repaglinide (only for the treatment of type 2 diabetes mellitus), Rosiglitazone, Gliclazide, Glyburide; Insulin)
Class: Hormones and synthetic substitutes Sub-class: Progestins	Progestins (Levonorgestrel, Medroxyprogesterone acetate (injectable preparation and oral), Progesterone)
Class: Hormones and synthetic substitutes Sub-class: Thyroid and Antithyroid Agents	Thyroid (Levothyroxine sodium, for renewal only)

Class	Specific Agents with Conditions
Class: Local Anesthetics	Lidocaine hydrochloride one percent and two percent, with or without epinephrine (local anaesthetic)
Class: Serums, toxoids, and vaccines	HPV Diphtheria vaccines, single entity or combination drugs Haemophilus b vaccine Hepatitis A vaccine Hepatitis B immune globulin Hepatitis B vaccine Human papillomavirus (HPV) vaccine Influenza vaccine Measles vaccines, single entity or combination drugs Meningococcal vaccine Mumps vaccine Pertussis vaccine Pneumococcal vaccine Poliomyelitis vaccine Rh (D) immune globulin Rubella vaccine Tetanus vaccines, single entity or combination drugs Tetanus Immune Globulin Varicella vaccine

Class	Specific Agents with Conditions
Class: Skin and mucous membrane agents	Acetic acid/benzethonium chloride/hydrocortisone compound Beclomethasone dipropionate (topical) Benzoyl peroxide Clindamycin phosphate and benzoyl peroxide Clindamycin (topical preparation) Clindamycin phosphate (vaginal cream) Clobetasone butyrate Condylline Erythromycin with ethyl alcohol lotion Erythromycin and benzoyl peroxide Erythromycin and tretinoin Fusidic acid (topical preparation) Hydrocortisone (topical preparation) Imiquimod Ketoconazole (topical) Mometasone furoate Podophyllum resin (genital warts) Prednicarbate Tretinoin (topical) Trichloroacetic acid 50-80 percent Bichloroacetic acid 50-80 percent
Class: Vitamins	Cyanocobalamin (Vitamin B12) Folic acid PregVit
Class: Bone Resorption inhibitors	Alendronate sodium, for renewal only Etidronate disodium/calcium carbonate, for renewal only Raloxifene HCl, for renewal only Risedronate sodium hemi-pentahydrate, for renewal only

Class	Specific Agents with Conditions
Class: Emergency Medications	Oxygen Epinephrine Diphenhydramine hydrochloride (injectable preparation), in an emergency Nitroglycerin Nitroglycerin SL or spray, in an emergency Salbutamol Ipratropium bromide (inhaler or nebulizer solution), in an emergency Diazepam (injectable preparation), in an emergency Lorazepam (injectable preparation, oral and sublingual), in an emergency

Implementation Proposals

To implement HPRAC's recommendations, the following changes to legislation and regulations are proposed:

1. That section 4 of the *Nursing Act, 1991* be amended by adding the following section:

Authorized Acts

4. In the course of engaging in the practice of nursing, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:
 4. Dispensing a drug that has been prescribed by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the prescription.
2. That section 5 of the *Nursing Act, 1991* be repealed and the following substituted:

Additional requirements for authorized acts

5. (1) A member shall not perform a procedure under the authority of paragraph 1, 2, 3 or 4 of section 4 unless,
 - (a) the performance of the procedure by the member is permitted by the regulations and the member performs the procedure in accordance with the regulations; or
 - (b) the procedure is ordered by a person who is authorized to do the procedure by section 5.1 of this Act or by the *Chiropody Act, 1991*, the *Dentistry Act, 1991*, the *Medicine Act, 1991* or the *Midwifery Act, 1991*.

- (1.1) A member shall perform a procedure under the authority of paragraph 5 of section 4 in accordance with any requirements prescribed in the regulations.

Individual scope of practice for nurses

- (1.2) A member is responsible for identifying the limits of his or her education preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

Grounds for misconduct

- (2) In addition to the grounds set out in subsection 51 (1) of the Health Professions Procedural Code, a panel of the Discipline Committee shall find that a member has committed an act of professional misconduct if the member contravenes subsection (1), (1.1) or (1.2).
3. That paragraph 3 of section 5.1 of the *Nursing Act, 1991* be repealed and the following substituted:

Authorized acts by certain registered nurses

- 5.1(1) In the course of engaging in the practice of nursing, a member who is a registered nurse and who holds an extended certificate of registration in accordance with the regulations is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following acts in addition to those the member is authorized to perform under section 4:
3. Prescribing a drug that the member may prescribe under the regulations.
- 3.1 Selling or compounding a drug that has been prescribed by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the prescription.
4. That section 5.1 of the *Nursing Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts

- 5.1(1.1) A member shall perform a procedure under the authority of paragraph 3 or 3.1 of section 5.1 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.

5.2 A nurse practitioner is responsible for identifying the limits of his or her education preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

5. That section 14 of the *Nursing Act, 1991* be repealed and the following substituted:

Regulations

14. (1) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,

- (a) prescribing procedures for the purpose of paragraph 1 of section 4;
- (b) permitting a member to perform a procedure under clause 5(1)(a) and governing the performance of the procedure including, without limiting the foregoing, prescribing the class of members that can perform the procedure and providing that the procedure may only be performed under the authority of a prescribed member or a member of a prescribed class;
- (b.1) regulating the prescribing, compounding, dispensing or selling of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing, compounding, dispensing or selling of drugs; and
- (c) prescribing the forms of energy that a member may order for the purpose of paragraph 2 of subsection 5.1(1) and prescribing the purpose for which, or the circumstances in which, the form of energy may be applied.

6. That Ontario Regulation 275/94 under the *Nursing Act, 1991* (General) be amended by adding the following section:

5(4) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 5 of section 4 of the Act or paragraph 3.1 of section 5.1 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

7. That section 16 of PART III (Controlled Acts) of Ontario Regulation 275/94 under the *Nursing Act, 1991* (General) be repealed and the following substituted:

16(a) For the purposes of this section, “Drug List” has the meaning given to it in the *Regulated Health Professions Act, 1991*.

(b) A member may prescribe the following classes of drugs under the authority of paragraph 3 of section 5.1:

1. antihistamine drugs,
2. anti-infective agents,
3. autonomic drugs,
4. blood formation, coagulation and thrombosis agents – antithrombotic drugs,
5. cardiovascular drugs,
6. CNS agents – analgesics and antipyretics – NSAIDs, anticonvulsants, psychotherapeutic agents, antimigraine agents, miscellaneous,
7. electrolytic, caloric and water balance,
8. enzymes,
9. respiratory tract agents,
10. eye, ear, nose and throat preparations – anti-infectives, anti-inflammatory agents,
11. gastrointestinal drugs,
12. hormones and synthetic substitutes – adrenals, contraceptives, estrogens, antidiabetic agents, progestins, thyroid and antithyroid agents,
13. local anaesthetics,
14. serums, toxoids and vaccines,
15. skin and mucous membrane agents,
16. vitamins,
17. bone resorption inhibitors, and
18. emergency medications.

(c) A member may only prescribe those drugs within the classes designated in subsection 16(b) that are listed in the Drug List and must prescribe or use those listed drugs in accordance with the terms, limitations and conditions contained in the Drug List.

(d) A member may prescribe or administer any drug or substance that may lawfully be purchased or acquired without a prescription.

8. That section 19 of PART III (Controlled Acts) and Schedules 2 and 3 of Ontario Regulation 275/94 under the *Nursing Act, 1991* (General) be repealed.
9. That Ontario Regulation 275/94 under the *Nursing Act, 1991* (General) be amended by adding the following sections:

**PART V
STANDARDS OF PRACTICE**

- 30.** The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 5 of section 4 of the Act or paragraph 3.1 of section 5.1 of the Act.
- 31.** The standards of practice referred to in section 30 shall be developed on the recommendation of the Nursing Standards Committee.
- 32.** For the purposes of section 31, the College shall establish the Nursing Standards Committee referred to in section 31 and shall appoint the membership of the Nursing Standards Committee, which shall include, at a minimum, one or more:
- a) members of the Council;
 - b) members of the College (including practitioners and educators);
 - c) persons who are not and have not been members of the College or of the Council;
 - d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario, who practice family medicine; and
 - e) members of the Ontario College of Pharmacists, approved by the Ontario College of Pharmacists.
- 33.** The College shall post the following on its website:
- a) the standards of practice referred to in section 30; and
 - b) a list of those members, who are authorized to perform a procedure under the authority of paragraph 5 of section 4 of the Act or paragraph 3.1 of section 5.1 of the Act.
10. That Ontario Regulation 799/93 under the *Nursing Act, 1991* (Professional Misconduct) be amended by adding the following sections:
- 1.1 Exceeding the scope of practice of the profession.
 - 11.1 Recommending or providing unnecessary services.
 - 11.2 Prescribing, dispensing, selling, compounding or administering a drug or substance for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell, compound or administer drugs and substances.
 - 11.3 Being subjected to the withdrawal or restriction of rights or privileges under the Controlled Drugs and Substances Act (Canada) or the Food and Drugs Act (Canada) or the regulations under either of those Acts, unless by the member's own request.

- 11.4 Contravening, while engaged in the practice of nursing, any federal or provincial law or municipal by-law with respect to the distribution, sale, prescribing or dispensing of any drugs or mixture of drugs.
 - 12.1 Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.
11. That sections 1, 2, 12, 18 of Ontario Regulation 799/93 under the *Nursing Act, 1991* (Professional Misconduct) be repealed and the following substituted:
- 1. Contravening or failing to maintain a standard of practice of the profession.
 - 2. Delegating an act set out in section 4 or 5.1 of the Act in contravention of section 5 of the Act, or delegating an act set out in paragraph 3.1 of section 5.1 of the Act.
 - 12. Failing to advise a client to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such a consultation to ensure the proper care of the client.
 - 18. Contravening a term, condition or limitation imposed on the member's certificate of registration.

THE PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF OPTOMETRY

Introduction and Scope of HPRAC's Review

The College of Optometrists of Ontario (COO) and the Ontario Association of Optometrists (OAO) submitted responses to HPRAC's review of the prescribing and use of drugs by non-physicians. HPRAC carefully considered each of these submissions, as well as input from research and consultations, in developing its recommendations.

Background

How Optometrists are Regulated Today

In Ontario, eye care services are provided by opticians, optometrists, ophthalmologists and family physicians. These professions have overlapping scopes of practice and share some authorities to perform controlled acts. For example, opticians and optometrists are authorized to dispense eyewear; however, only optometrists and physicians can conduct complete vision tests and prescribe eyewear.

Optometrists are primary care health professionals who play a leading role in vision care for many Ontarians, and they are often the first professional a person sees when eye care is a concern. Many first-time patients visit an optometrist after experiencing eye strain or blurred vision and leave with a prescription or device to correct common refraction disorders, such as near-sightedness. Others may be diagnosed and treated for more serious sensory or oculomotor disorders and dysfunctions of the eye and vision system. Optometrists also play a key role in disease prevention through the provision of annual eye exams. They provide services to patients at all ages and stages of life.

There are approximately 1,500 optometrists currently practising in Ontario, and they see nearly three million Ontarians each year.^{1,2,3} Optometrists tend to work independently in private practice settings. Some optometrists practice in association with ophthalmologists to provide pre- and post-operative care for cataract and refractive surgery patients,⁴ some practice in community health centres and nursing homes, and some commonly collaborate with ophthalmologists and other health professionals in shared care arrangements.⁵

¹ Ontario Association of Optometrists. Submission to the Health Professions Regulatory Advisory Council. April 2005: 10. The OAO reported 1560 members on Dec. 31, 2007. This is an increase from 1505 members on Dec. 31, 2006 as reported in the 2007 Annual Report, College of Optometrists of Ontario: 14.

² College of Optometrists of Ontario. Submission to HPRAC. November 2008:11.

³ OAO Submission to HPRAC. April 2005: 5.

⁴ COO Submission to HPRAC. November 2008: 11.

⁵ Ibid. 6, 13.

The COO is the self-governing body for the profession. The OAO is the voluntary professional association representing the interests of its members.

Scope of Practice

The *Optometry Act, 1991*, describes the practice of optometry as:

The assessment of the eye and vision system and the diagnosis, treatment and prevention of,

- (a) disorders of refraction;
- (b) sensory and oculomotor disorders and dysfunctions of the eye and vision system; and
- (c) prescribed diseases.⁶

Authorized Acts

In the course of engaging in the practice of optometry, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Communicating a diagnosis identifying, as the cause of a person's symptoms, a disorder of refraction, a sensory or oculomotor disorder of the eye or vision system or a prescribed disease.
2. Applying a prescribed form of energy.
- 2.1 Prescribing drugs designated in the regulations.
3. Prescribing or dispensing, for vision or eye problems, subnormal vision devices, contact lenses or eye glasses.⁷

Members of the COO were authorized to prescribe drugs by 2007 amendments to the *Optometry Act, 1991*.

Regulations

Prescribed Drugs

Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the COO Council may make regulations, (a) specifying the drugs that a member may use in the course of engaging in the practice of optometry; and (b) designating drugs for the purposes of prescribing. Regulations may specify or designate individual drugs or categories of drugs.

⁶ *Optometry Act, 1991*, s. 3.

⁷ *Ibid*: s. 4.

Some diagnostic pharmaceutical agents (DPAs) are authorized for use rather than prescription by optometrists by regulation under the *Drug and Pharmacies Regulation Act (DPRA)*.⁸

The following drugs may be used in the practice of optometry for the purposes specified:

1. Topical anaesthetics: proparacaine not over 0.5 percent and benoxinate not over 0.4 percent for facilitating the measurement of intraocular pressure and for facilitating contact lens applications.
2. Mydriatic: tropicamide not over 0.5 percent for facilitating the observation of the fundus of the eye when clinically required.
3. Cycloplegic: cyclopentolate hydrochloride not over 0.5 percent for determining the refractive status of the eye when clinically required.

The authority for optometrists to prescribe drugs for therapeutic purposes was established in 2007. The regulations do not yet include a designated list of drugs or classes of drugs that may be prescribed by an optometrist.

Prescribed Diseases

The regulations provide for prescribed diseases as referenced in the scope of practice statement. Section 21 of Part VIII of Regulation 119/94 under the *Optometry Act, 1991* defines “prescribed diseases” as:

1. In relation to diagnosis and prevention, diseases of the eye and vision system that can be determined by the findings from an oculo-visual assessment.
2. In relation to treatment, diseases of the eye and vision system that can be treated by other than the prescribing of drugs or the application of surgery.⁹

For the purposes of the authorized act of “communicating a diagnosis”, section 22 of Part VIII Section 22 of Part VIII of Regulation 119/94 under the *Optometry Act, 1991* defines “prescribed diseases” as:

For the purposes of paragraph 1 of section 4 of the *Optometry Act, 1991*, a “prescribed disease” is any disease limited to and manifested in the eye and vision system that was determined by the findings from an oculo-visual assessment.¹⁰

⁸ OPTOMETRY, R.R.O. 1990, Reg. 550. <http://canlii.org/on/laws/regu/1990r.550/20080821/whole.html>.

⁹ O. Reg. 152/97, s.1.

¹⁰ Ibid.

Education and Continuing Competency

There are two schools of optometry in Canada – the University of Waterloo and the University of Montreal. Along with 17 schools in the United States, both Canadian schools are accredited by the Accreditation Council on Optometric Education (ACOE). The curriculum at these schools encompasses both academic and clinical training components.

Optometrists graduate from a four-year professional program with a Doctor of Optometry degree. Graduates have the skills to therapeutically manage eye conditions, including ocular surface diseases, eye and eyelid infections, ocular inflammation and pain, ocular allergies, and glaucoma. Graduates of both Canadian schools are able to practise optometry in all Canadian and U.S. jurisdictions, including those where optometrists are permitted to prescribe drugs.

All schools and colleges of optometry in North America are accredited by the ACOE. To be accredited, optometry degree programs must include didactic and clinical training components sufficient to satisfy the registration requirements of the jurisdiction with the broadest scope of practice. The COO has adopted the standard broadly accepted in the United States and other Canadian jurisdictions for practicing optometrists: a 100-hour course in ocular therapeutics that involves didactic and clinical components as well as an examination.¹¹

Waterloo's School of Optometry incorporates two courses related to the preparation for prescribing drugs: Introductory Clinical Pharmacology and Clinical Ocular Pharmacology. Introductory Clinical Pharmacology includes the study of general pharmacokinetic and pharmacodynamic principles, as well as the application of these theories on various systems of the body. Clinical Ocular Pharmacology emphasizes the pharmacological and therapeutic principles of drug absorption following topical application, including the distribution, metabolism, mechanisms of action and elimination from ocular tissues.

Graduates must pass an entry-to-practice examination, the Canadian Standard Assessment in Optometry (CSAO), which is required by all provinces, including those where optometrists are authorized to prescribe drugs. The CSAO is a competency-based examination that includes components that assess the knowledge, skill and judgment of candidates for the range of services provided by optometrists, including prescribing of drugs.

The COO requires that members participate regularly in continuing education. Members are currently required to participate in at least 60 hours of continuing education in each three-year period. With the recent introduction of prescribing authority, the COO Council has increased continuing education requirements. Starting in 2009, optometrists will need to obtain 70 hours of continuing education; at least 20 of those hours must relate to the diagnosis or management of ocular disease or related systemic conditions.¹²

¹¹ COO. Submission to HPRAC. November 2008: 6.

¹² Ibid: 7.

Requests for Change

Request 1: Designated Drugs Regulation

In 2007, the *Health Systems Improvements Act* amended the *Optometry Act, 1991* to include the authorized act of prescribing designated drugs. Following the change to the Act, in May 2008, the COO submitted a list of proposed drugs for inclusion in the drug regulation to the Minister for review. In its submission, the COO proposed a list of topically applied drug categories (anti-infectives, anti-inflammatory, mydriatics, cycloplegics, anti-allergics, decongestants, artificial tears, ocular lubricants and secretagogues and orally taken anti-infectives for the purpose of treating corneal and eyelid infections). Optometrists are now awaiting approval on the classes of drugs to be designated in the regulation. The categories currently under consideration by the Ministry do not include drugs to treat glaucoma.

The proposed regulation as submitted would enable optometrists to prescribe the following categories of drugs:

Topically Applied

1. Anti-infectives
2. Anti-inflammatories
3. Mydriatics
4. Cycloplegics
5. Anti-allergics
6. Decongestants
7. Artificial tears, ocular lubricants and secretagogues.

Orally Taken

1. Anti-infectives for the purpose of treating corneal and eyelid infections.

Proponents' Rationale

There are a growing number of optometrists in Ontario, many of whom work in smaller communities, providing care in areas where many Ontarians may have difficulty accessing a primary care physician. Having the ability to prescribe the categories of drugs identified by the COO would enable optometrists to manage vision care without the interim step of referring to a physician to obtain a prescription for treatment.

When the amendments to the Act and regulations come into full force, optometrists state that they will be better able to practise to the full extent of their education and competence. Patients will have greater access to safe and effective health care from professionals authorized to prescribe drugs, and will be able to receive treatment in a more timely fashion. Duplicated physician visits for the sole purpose of obtaining a prescription following a referral will be avoided. This is particularly important in rural and remote areas, where there may be significant delays before another professional with prescribing rights can see the patient.

Proponents said that medical directives or delegation models have not been employed in Ontario optometry, as the referral model is more commonly

employed. Optometrists indicate that they have good working relationships with physicians on referrals, and that, when prescribing authorities for optometrists are fully in force, serious conditions would continue to be referred to physicians. This will provide highly trained specialists with more time to treat patients with complex conditions.¹³

The referral process is an important factor in the management of chronic diseases. For example, optometrists are often the first health care professionals to diagnose diabetes, through assessments of variations in vision and fluctuating refraction results. If identified through diabetic retinopathy where an optometrist is seeing the patient for the first time, the patient is likely to have had the disease for some time. In all cases, the patient is referred directly to a physician for care.

What HPRAC Found

Readiness for Change

For several years, optometrists have been authorized to administer DPAs for diagnostic purposes. The drugs designated under the *DPRA* include topical anaesthetics, midriatics and cycloplegics.¹⁴

In its 2006 report on Therapeutic Pharmaceutical Agents (TPAs), HPRAC recommended that optometrists have the authority to prescribe drugs, with the exception of anti-glaucoma drugs, and that glaucoma patients should be co-managed with ophthalmologists.¹⁵ HPRAC also indicated that optometrists who graduated prior to 1995 would require additional competencies to prescribe therapeutic drugs. Since the *New Directions* report, the COO has developed extensive bridging and continuous education programs, along with new quality assurance programs, to ensure its members have the necessary competencies for prescribing.

The categories or classes of drugs that optometrists are requesting are identical to those submitted for consideration by HPRAC during the preparation of *New Directions*, although it was not specified whether the drug classes or categories were to be included in both or either topical or oral delivery methods. HPRAC is satisfied that optometrists have the education and competencies to prescribe those drugs included in the proposed designated drug regulation now in the regulation approval process.

There continues to be broad support for this change among optometrists. In the *New Directions* report, HPRAC acknowledged that in 2004 approximately 75 percent of optometrists were qualified to prescribe drugs. Since then, there have been significant continuing education requirements that optometrists have met to prepare themselves for this new authority.

¹³ Meetings with HPRAC and stakeholders. December 2008.

¹⁴ *OPTOMETRY, R.R.O. 1990, Reg. 550*. <http://canlii.org/on/laws/regu/1990r.550/20080821/whole.html>.

¹⁵ HPRAC. *New Directions*. 2006: 125.

The COO believes that the vast majority of optometrists are in favour of the expansion in the scope of practice.¹⁶

Upgrading to Ensure Readiness for the New Controlled Act of Prescribing

To prepare for the new the act of prescribing drugs as set out in the proposed designated drug regulation, starting in 2009, the COO has increased the continuing education requirement to 70 hours over three years, of which 20 hours must be related to the diagnosis or management of ocular disease or related systemic conditions. In addition, it requires a 100-hour course to meet prescribing authority. These new requirements are based on experiences in the United States and other Canadian jurisdictions where optometrists have similar prescribing rights.

The COO has indicated that the practice of optometry is evolving to include treatments by means of injection, although HPRAC has found this to be a very limited competence of members of the profession, and authorized in very few jurisdictions. Currently, the injecting of drugs or substances is not taught in the University of Waterloo optometry program, but COO informed HPRAC that the procedure will soon be examined by the National Board for practice in the United States and in consequence, the school will adjust its curriculum.

COO has recently published revised standards of practice and clinical practice guidelines in the Optometric Practice Reference (OPR). A draft OPR has been prepared, which includes information related to the prescribing of drugs included in the proposed designated drugs regulation.

Managing the Risk of Harm

In preparation for act of prescribing, the COO has increased continuing education requirements to require that members take a 100-hour course, prepared by faculty at an accredited school of optometry, with successful completion of an examination at the end of the course. Additionally, the COO's quality assurance program includes an enhanced requirement for a minimum of 70 hours of continuing education in each three-year cycle, 20 hours of which must be related to the diagnosis or management of ocular or related systemic disease.¹⁷

The COO has reported to HPRAC on extensive take-up by members in continuing education programs, including, among other courses, a 100-hour course being delivered in February 2009 at the School of Optometry at the University of Waterloo, with 110 optometrists registered.¹⁸

The COO has a quality assurance program that includes two components related to quality improvement and quality measurement. These components include the increased continuing education requirements noted above and a practice assessment component, which will be implemented when the designated drug regulation comes into force.

¹⁶ COO. Submission to HPRAC. November 2008: 11.

¹⁷ Ibid: 9.

¹⁸ Key stakeholder interview with Registrar, COO, January 2009.

The COO last updated its professional misconduct regulation in 1994. The regulations deal with:

- Exceeding the scope of practice,
- Treating or attempting to treat a condition that the member recognizes or should recognize as being beyond his or her experience or competence,
- Failing to refer a patient when required, and
- Failing to maintain the standards of the practice.

The COO feels that the new educational components and misconduct regulations “when taken together provide the public with a high level of protection, and that no additional limitations are required”.¹⁹

HPRAC notes, however, that other professions that have the authority to prescribe drugs also include other provisions in their professional misconduct regulations, including:

- Prescribing or using drugs for an improper purpose, or otherwise using improperly the authority to prescribe, dispense or sell drugs;²⁰
- Being subjected to the withdrawal or restriction of rights or privileges under the *Controlled Drugs and Substances Act* (Canada) or the *Food and Drugs Act* (Canada) or the regulations under either of those Acts, unless by the member’s own request;
- Contravening, while engaged in the practice of optometry, any federal or provincial law or municipal by-law with respect to the prescribing or using of any drug or mixture of drugs.

What Other Leading Jurisdictions are Doing

A number of other jurisdictions in Canada permit prescribing of some therapeutic agents by optometrists. Alberta was the first province to grant optometrists the authority to prescribe TPAs in 1996. British Columbia, Newfoundland and Quebec permit prescribing by optometrists. In Manitoba, amendments to legislation were made on June 11, 2008 authorizing qualified optometrists to independently prescribe and administer certain therapeutic drugs. Nova Scotia permits prescribing of certain drugs for limited treatment under specified conditions. British Columbia circulated a consultation draft of proposed legislation in December 2008, authorizing a schedule of mydriatics, cycloplegics, miotics, anti-allergy medications, corticosteroids, antibacterial and antiviral medications and topical medications.

Under Québec legislation, the statute authorizing optometrists to prescribe TPAs was adopted in June 2000 and enacting bylaws were approved in October 2003. Québec optometrists are authorized to prescribe topical anesthetics, mydriatics, cycloplegics and miotics, and optometrists must refer patients to a physician if the patient's condition does not adequately respond to treatment or if the signs and symptoms suggest a condition that

¹⁹ Ibid: 5.

²⁰ Ontario Regulation 853/93, *Dentistry Act, 1991*, s.2 (10) and Ontario Regulation 865/93, *Medicine Act, 1991*, s.1 (6).

is not one of mild morbidity, or that requires a physician to take charge of the patient.

In the United States, many states authorize optometrists to treat, by topical or oral application, certain diseases or abnormal conditions of the human eye and its adnexa with specific TPAs. Many states license diagnostic and therapeutic classes of optometry, separating those who are educated and trained in the use of pharmaceutical agents for diagnostic purposes, and those who are trained in the use and prescribing of drugs for both diagnostic and therapeutic purposes. Typically, states impose limits on the drugs which may be prescribed and require referral of a patient to a medical or osteopathic doctor when additional evaluation or treatment is necessary. Few jurisdictions authorize medications given by injection or intravenously.

Request 2: Classes or Lists of Drugs

The COO noted in its submission that it would prefer the designated drug regulation include classes of drugs, rather than lists of individual drugs. The use of classes permits optometrists to be able to access the most appropriate and current drugs in a timely way. The COO states that members will be expected to exercise professional judgment in selecting the appropriate drug for diagnostic or treatment purposes, and will be expected to be current with new drugs and best practices for pharmacotherapeutic interventions. The OAO said that Ontario educational programs are sufficient to support prescribing by class.

The designated drugs regulation that the COO has put forward includes classes of drugs, as well as some individual drugs. The COO explains that:

The Designated Drugs Regulation that the College proposed does include some specificity as to the purpose of oral anti-infective agents. The proposal includes “(oral) anti-infectives for the purpose of treating corneal and eyelid infections.” Certain classes of topically applied drugs included in the proposed regulation are obvious as to their purpose. For instance, “cycloplegics” and “artificial tears, ocular lubricants and secretagogues” are quite obvious as to their purpose. Drugs in other categories may be prescribed to treat multiple conditions.

In the 2007 amendments to the *Optometry Act, 1991*, the legislation was changed to enable drug regulations to include classes or categories rather than individual lists of drugs.

Request 3: Prescribing Anti-Glaucoma Drugs

Ontario optometrists currently have no authority to prescribe anti-glaucoma drugs. Optometrists must refer patients to a physician, usually an ophthalmologist for treatment for glaucoma or high intraocular pressure.

The COO has proposed approval in the designated drugs regulation of the addition of four anti-glaucoma agents and one class of drugs to reduce intraocular pressure.

The classes proposed by COO within the anti-glaucoma category are the following:

- Beta-blockers
- Cholinergics
- Alpha-Agonists
- Prostaglandins
- Carbonic Anhydrase Inhibitors

The OAO has also requested the authority to prescribe anti-glaucoma agents. However, its proposal requested only the approval of topical carbonic anhydrase inhibitors and topical prostaglandin analogs for the treatment of glaucoma. According to the OAO, “limiting the prescription of anti-glaucoma drugs to those classes of drugs with minimal or no systemic adverse effects, will not only satisfy HPRAC’s concerns with patient safety but would also provide immediate access to glaucoma care for the patient”.²¹

Proponents’ Rationale

Glaucoma is an eye disease caused by increased pressure within the eye. It is one of the most common causes of blindness and affects one in every hundred Canadians over 40 years.²² Although it often occurs in older people, it can affect anyone at any age.

It is suspected that people with glaucoma lose their sight because of increased pressure in the eye and other factors, such as poor blood flow. The eye slowly loses nerve function and loss of side (peripheral) vision. This occurs painlessly and may even not be noticed.²³

As a result, when an optometrist first diagnoses glaucoma, the disease may be quite advanced. Proponents note that optometrists outnumber ophthalmologists nearly five to one, and are situated in nearly every small community and large city in Ontario. The increase in qualified professionals to manage glaucoma will allow patients to access care more easily, possibly with a provider with whom they already have a professional relationship. According to the proponents, the availability of optometrists who are qualified to treat the disease may prevent delays in care, which could negatively affect its management.

Updates to a wait time study commissioned by the COO estimate that the average wait time for a patient to be seen by an ophthalmologist for glaucoma was 49 days, virtually unchanged from the wait times identified in the initial 1996 study.²⁴ According to the study, it is anticipated that patients requiring glaucoma treatment will increase by 30 percent over the next 20 years while the number of available specialists is expected to decline. Forty-four percent of specialists plan to decrease their clinical load in the next five years.²⁵

²¹ OAO. Submission to HPRAC. November 2008: 4.

²² Canadian Ophthalmological Society. *Glaucoma It Can Take Your Sight Away*. 2008

²³ Ibid.

²⁴ Robinson. B. *Ontario Glaucoma Wait Times Study – Interim Report*, Prepared for the COO. 2008: 7.

²⁵ Ibid.

Proponents also say that higher risk drugs used to treat glaucoma are being overtaken by newer generation drugs that provide lower risk to patients. Coupled with proper prescribing procedures and training, these new drugs will provide significantly safer care. According to the OAO, topical carbonic anhydrase inhibitors and topical prostaglandin analogs are classes of drugs with minimal or no systemic adverse effects. The COO agreed that “some older drugs used to treat glaucoma have a potential effect on the cardiovascular system in some at risk patients; however, recent professional literature indicates this risk is minimal. Appropriate training and proper prescribing techniques mitigate against the risk of harm”.²⁶

The COO commissioned a report on anti-glaucoma drugs, prepared by Dr. William Black.²⁷ This report responds to several points raised in a study commissioned by HPRAC from Dr. Denis Grant in 2006, which concluded that glaucoma medications carry a significantly higher level of risk beyond other agents used for eye disorders such as infections.

Dr. Black states that risks associated with prescribing drugs can be mitigated by good prescribing practices, which should eliminate all but the rarest of adverse reactions. He underlines that a careful history must be taken of a patient to ensure that medication will not lead to serious adverse reactions; if a drug can potentially lead to a worsened situation, the patient should be referred to a specialist for evaluation before a prescription is given. Dr. Black notes that a collaborative working model between optometrists and ophthalmologists jointly dealing with glaucoma could greatly improve services and reduce wait times to initiate treatment.

Proponents state that if optometrists are authorized to manage glaucoma and intraocular pressure, opportunities for greater collaboration between optometrists, physicians and ophthalmologists will emerge in medical and surgical management. As optometrists manage glaucoma in primary care cases, ophthalmologists will be able to focus on more serious secondary and tertiary care.²⁸

In Ontario, optometrists frequently work with ophthalmologists, family physicians and other health professionals in providing patient care.

Optometrists are often called upon to refer patients to, or consult with, other regulated professionals in order to achieve desirable outcomes for their patients. Examples of situations where optometrists currently collaborate with ophthalmologists include co-management of cataract surgery and refractive surgery patients, ophthalmologists working in optometrists' offices and vice-versa, optometrists in community health centers and nursing homes.²⁹

With collaboration on protocols for referrals, records maintenance and other matters, it would be relatively simple to establish working

²⁶ COO. Submission to HPRAC. November 2008: 715.

²⁷ Black, W. *Report to the Ontario College of Optometrists – Comments on the Grant Report*, College of Optometrists of Ontario. 2008.

²⁸ COO. Submission to HPRAC. November 2008: 10.

²⁹ Ibid: 13.

relationships that would provide ongoing glaucoma care for the patient while respecting the expertise of each profession.

What HPRAC Heard

Glaucoma is an eye disease, often with no symptoms, that can suddenly result in vision loss. Without proper treatment, glaucoma can lead to blindness. A number of medications, some used in combination, can reduce elevated intraocular pressure (IOP) and prevent damage to the optic nerve.³⁰

There are several forms of glaucoma. Primary open angle glaucoma is the most common form of the chronic disease and often goes undetected. IOP slowly rises, without pain, and can be slowed or arrested by treatment. In angle-closure glaucoma, which affects approximately one percent or less of the population, IOP increases rapidly and can become very painful. Damage to the optic nerve may proceed quickly and cause permanently impaired vision. An acute attack is an emergency condition. Glaucoma in childhood is less common and often hereditary. Uveitis is an inflammation of the iris and acute or chronic, open-angle or angle-closure glaucoma is a frequent complication.³¹

A prevalence rate for primary acute closure glaucoma has been estimated at 0.06 percent of American, European, Australian, Mongolian and Japanese populations (aged 40 plus years), as compared to the more common open angle glaucoma (1.6 percent).³² Older academic articles (1996) put the prevalence rate in the UK at 0.1 percent to 0.2 percent.³³

Glaucoma can be treated with eye drops, medication, surgery or a combination of methods, and the IOP must be constantly controlled. Optometrists in Ontario requested the authority to prescribe anti-glaucoma drugs in the 2005 scope of practice review. In its current request, the COO is requesting prescribing rights for four anti-glaucoma agents, and one class of drugs to reduce intraocular pressure.

Concerns have been raised about the risk of harm associated with the use of glaucoma drugs. While early intervention is important to protect against loss of vision and to limit further damage to the ocular nerve, some professionals note that there are also risks to early treatment and use of anti-glaucoma agents may not be the best treatment in all cases. Other treatment options of choice, once the IOP has been reduced to a safe level, include the use of laser iridotomy. There are also concerns that if drugs are given too early in the progress of a case, the complexity of the patient's condition may not be immediately clear to an ophthalmologist.³⁴

Glaucoma drugs are known to have side effects:

- Adrenergic drugs may cause allergic reactions and blurred vision. Cardiac side effects may include rapid heart rate or fluctuations in heart rhythm;

³⁰ Glaucoma Research Foundation. <http://www.glaucoma.org>.

³¹ New York Glaucoma Research Institute. www.glaucoma.net.

³² Shields, Bruce M., Tombran-Tink, Joyce and Barnstable, Colin J. *Mechanisms of Glaucoma*. 2008.

³³ Siriwardena, D. et al. Misdiagnosis of Acute Angle Closure Glaucoma. *Age and Ageing*. 1996;25:421-423 <http://ageing.oxfordjournals.org/cgi/reprint/25/6/421.pdf>.

³⁴ HPRAC interview with Dr. Kyle Bryden, Head OMA Section on Ophthalmology. August 2008.

- Alpha-agonists may cause burning or stinging, fatigue, drowsiness, dry mouth and dry nose;
- Beta blockers may cause low blood pressure, reduced pulse rate and fatigue; shortness of breath in people with a history of asthma or respiratory disorders; additionally, they can change cardiac activity by decreasing the amount of blood the heart pumps out, reducing the pulse rate, and slow the heart's response rate during respiration;
- Carbonic anhydrase inhibitors in pill form may cause tingling or loss of strength in the hands or feet, upset stomach, memory problems or mental fuzziness, depression, kidney stones and frequent urination; the eye drop form of this medication is relatively new, and studies are yet to be completed current effects noted including stinging, burning and other eye discomfort;
- Cholinergic agents (miotic) may cause dim vision due to constriction of the pupil;
- Combined agents, which are a combination of either beta blocker and alpha-agonists or beta blocker and carbonic anhydrase inhibitors may include the symptoms of the basic drugs; since they are new to the market, long-term follow-up of people using the medications is not available;
- Prostaglandin analogs may cause gradual change in eye colour, along with stinging, blurred vision, eye redness, itching and burning; these medications are new to the market, and long-term follow-up of people who use them is not available.³⁵

The risk of adverse events associated with the use of glaucoma drugs requires that prescribers conduct complete physical and medical histories to ensure persons with histories of renal disease, pulmonary edema, heart disease, asthma and chronic obstructive pulmonary disease and liver disease are prescribed appropriate medications, and that their response to medications is followed carefully.

The COO indicated that it had carefully reviewed the safety profiles of glaucoma drugs, along with malpractice reports, and said that with the exception of the beta-blocker category, glaucoma drugs have an outstanding safety record.

Patient compliance is also a key factor in managing glaucoma:

One of the most difficult problems faced by glaucoma patients is that of having to take medicines which may have both ocular and systemic side effects to control a disease which is usually painless and has no symptoms. Understanding the necessity for the medication often helps to reduce the severity of a side effect, since it is often magnified by anxiety.

A side effect is any action produced by a drug beyond the intended one of lowering IOP. Some patients have no side effects whatsoever, while others find them too severe to tolerate. Why a drug causes side effects

³⁵ Glaucoma Research Foundation. <http://www.glaucoma.org>.

in some persons and not others or why the same side effect of the same drug is severe in one person and mild in another are poorly understood.³⁶

The COO indicates that if optometrists are given authority to prescribe anti-glaucoma drugs, the rigour of its professional misconduct rules and standards of practice will be increased to be at least equivalent to those of medicine. This is a common requirement in American jurisdictions.

Patients with glaucoma can be managed in stages through collaborative arrangements. The COO said that glaucoma care should be recognized as a continuum of treatment from simple to advanced. Initial treatment by an optometrist could commence for simple glaucoma, with continuing assessments to determine any increasing complexity of the disease. If the initial disease management therapy does not proceed well or fails, then the patient should be referred to an ophthalmologist for treatment of the increasing complexity. The need for immediate complex treatment requirements is rare. The COO indicates that additional standards and guidelines with respect to the continuum are needed.

As is required in many jurisdictions, the COO said that any patient under 18 years diagnosed with glaucoma would automatically and immediately be transferred to a specialist, as this would indicate a highly complex disease state.

COO also spoke of concerns regarding the availability of clinical placements for Ontario optometric students seeking to qualify in glaucoma care. These placements are not available in the province, and because student visas to the United States have been reduced, placements are increasingly difficult to obtain in the United States. HPRAC was told that the University of Waterloo School of Optometry has made arrangements for clinical placements in Oklahoma for Ontario students to address this issue.

HPRAC was told by both physicians and optometrists that there is some support for a team approach, including staggered visits between optometrists and ophthalmologists in a collaborative model, such as exists in Kingston and Ottawa. This could have particular value in rural and remote regions, such as Northern Ontario, but would likely benefit patients in urban areas as well.

HPRAC carefully reviewed the proposal of the OAO that a selection of two of five anti-glaucoma drugs would “not only satisfy HPRAC’s concerns with patient safety but would also provide immediate access to glaucoma care for the patient”.³⁷ HPRAC’s review of issues associated with the prescribing of anti-glaucoma drugs indicates that a full regimen of drugs to meet specific patient care needs based on a range of conditions is necessary. Some anti-glaucoma medications are contraindicated in patients with certain conditions, including liver disease and heart conditions. This proposal does not meet the tests of good pharmacotherapeutic care.

³⁶ NY Glaucoma Research Institute. <http://www.glaucoma.net>.

³⁷ OAO. Submission to HPRAC. November 2008: 4.

Both the COO and the OAO indicated that there had been little success in arranging formal collaboration with ophthalmologists, (meetings were cordial, but no steps were taken towards implementation) although on-the-ground experience at the practice level was different. Both the COO and OAO were open to a tiered certification arrangement or tiered shared care between optometrists and ophthalmologists for care of glaucoma patients.³⁸

HPRAC learned from the Ontario Medical Association that consultation between an ophthalmologist and optometrist is not recognized as part of the Schedule of Benefits and Fees for physicians, and this is a roadblock to increasing collaboration between the professions. Thus, some ophthalmologists will not accept a direct referral from an optometrist, instead requiring a physician referral for a glaucoma patient, which means a patient is referred to a family or general practitioner by an optometrist, who refers the patient to an ophthalmologist. Any written report is then made by the ophthalmologist to the family practitioner, who may or may not send it on to the optometrist who is providing continuing eye care.

Managing the Risk of Harm

In October 2007, the COO, in preparing documentation for its request for the prescribing of glaucoma drugs, circulated for comment a draft standard of practice outlining the options optometrists could employ while managing glaucoma patients. This followed HPRAC's recommendation that optometrists collaborate with physicians in co-managing glaucoma patients. The COO stated that while it was of the opinion that optometrists are qualified to manage glaucoma, co-management was a reasonable step to immediately improve access to glaucoma care and proposed a mentoring process for members leading to independent prescribing of glaucoma drugs, a model which is used in several American states.

In the COO model, to achieve certification as a glaucoma specialist, the optometrist would collaborate or consult with a physician (usually an ophthalmologist) or optometrist who is certified to prescribe drugs for the treatment of glaucoma on the management of ten glaucoma patients for a period of at least two years. The optometrist would then submit the records for these patients to the COO for assessment. Upon successful completion of the process, the optometrist would be certified by the COO to independently prescribe drugs to treat glaucoma patients.

This was one of three models proposed in the draft standard of practice. A second model proposed direct referral to an ophthalmologist, and a third proposed a consultative arrangement. Depending on the complexity of the case and individual competence and experience, the optometrist may choose to treat some glaucoma patients using one of three models: referral, collaboration or consultation. In addition, the optometrist may conclude that it is appropriate, at any point in the treatment, to change to a different model to ensure that the patient is receiving appropriate care.³⁹

³⁸ Key informant meetings with HPRAC, COO and OAO, December 2008.

³⁹ COO. *Draft Standard of Practice for Prescribing Medications for the Treatment of Glaucoma*. October 22, 2007: 2-3.

Each of these models presumed that working arrangements with ophthalmologists could be introduced and become productive and effective ways of providing patient care.

HPRAC also considered measures that the COO is taking to prepare its members for prescribing or use of drugs to treat glaucoma, and to improve their training and continuing competence.

What Other Jurisdictions are Doing

Alberta authorizes optometrists to prescribe anti-glaucoma drugs only in a consultative, co-management arrangement with an ophthalmologist who is licensed to practice in Canada.⁴⁰ The Alberta College of Optometry *Guidelines to Standards of Practice* also require that the patient's physician must be contacted when indicated, particularly when systemic complications of the ocular condition or its treatment are suspected.⁴¹

The Yukon authorizes optometrists to prescribe only topical anti-glaucoma agents to manage gradual open angle glaucoma, which affects the vast majority of those with the disorder. In the Yukon, optometrists are authorized to function only within a co-management relationship with an ophthalmologist.⁴²

New Brunswick authorizes optometrists to provide emergency prescription of anti-glaucoma drugs for angle closure or acute narrow glaucoma.⁴³ Neither Nova Scotia nor Manitoba authorize optometrists to prescribe anti-glaucoma medications.^{44, 45}

Under Division II of Quebec regulations under the *Optometry Act, 1991*, Quebec optometrists may renew or change a prescription for anti-glaucoma medication. The optometrist must, however, prior to every renewal or change, obtain verbal or written approval from the original prescribing physician or from the physician designated by the original prescribing physician. The optometrist must, in addition, write the name and professional permit number of the physician from whom consent was obtained on the prescription.⁴⁶

In Saskatchewan, members who hold a TPA certificate may prescribe agents for the treatment of ocular diseases and abnormal conditions with the exception of anti-glaucoma agents. Members who use and prescribe topical corticosteroid agents for the treatment of anterior uveitis must arrange for the patient to be examined by an ophthalmologist if no improvement is noted. The treatment of posterior uveitis is not permitted.⁴⁷

⁴⁰ *Optometrists Profession Regulation, Alta. Reg. 83/2003*, s.11 and s.12.

⁴¹ Alberta College of Optometrists. *Guidelines to the Standards of Practice*. <http://www.collegeofoptometrists.ab.ca/pdf/guidelines-sp.pdf>.

⁴² Optometrists Regulation, Y.O.I.C. 1999/150 *Subject: Prescribing topical therapeutic medications and removing superficial foreign bodies from eyes*, s. (g).

⁴³ Prescribing and Use of Drugs by Non-Physician Health Professionals: A Jurisdictional Review of the Profession of Optometry, (2008) HPRAC: 7.

⁴⁴ Nova Scotia *Optometry Regulations* made under Sections 19 and 20 of the *Optometry Act* S.N.S. 2005, c.43. <http://www.gov.ns.ca/just/regulations/regs/optoregs.htm>.

⁴⁵ C.C.S.M. c. O70 *Optometry Act*.

⁴⁶ O.C. 1025-2003, s.5.

⁴⁷ Saskatchewan Association of Optometrists. The Optometric Professional Bylaws. <http://www.optometrists.sk.ca/files/OptometricProfessionalBylaws.pdf>.

Data collected by the OAO indicates that in the United States, all states except Massachusetts authorize the prescription of topical anti-glaucoma drugs, while a large portion authorized the prescription of both topical and oral anti-glaucoma drugs.⁴⁸

Further investigation revealed that, in many states, evidence of a tiered certification structure involving co-management of glaucoma patients with ophthalmologists is required prior to certifying optometrists to independently manage glaucoma. In most states, optometrists are not authorized to treat acute angle closure glaucoma patients or patients under 18-years-old.

Some states authorize the prescribing of topical anti-glaucoma agents to certified optometrists, and oral or topical anti-glaucoma agents for the emergency treatment of acute angle closure glaucoma with immediate referral to an ophthalmologist (e.g., New Hampshire); in other states, only certified glaucoma licensees may prescribe glaucoma drugs, and the treatment plan must be confirmed by an ophthalmologist (e.g., Kansas).

In South Carolina, a therapeutic certified optometrist is one who is educated and trained for diagnostic and therapeutic purposes. When prescribing oral and topically applied medications, an optometrist is limited to specific pharmaceutical agents. In treating and managing glaucoma an optometrist must strive to achieve a stable range of intraocular pressures considered unlikely to cause further optic nerve damage in that patient. Once this range of pressures is selected based on conditions presented by the patient, the optometrist must enter this range in the patient's chart. If no measurable progress is achieved in realizing the selected range of pressures within 60 days of initiating treatment, the optometrist must refer the patient to an ophthalmologist. However, when treating acute angle closure glaucoma, an optometrist shall immediately initiate treatment, and must make an appropriate referral to an ophthalmologist.⁴⁹

In Massachusetts, a TPA certificate authorizes an optometrist to use pharmaceutical agents which are required or used for the diagnosis, prevention, correction, management or treatment of abnormal ocular conditions or diseases, except glaucoma.⁵⁰

The Delaware Board of Examiners in Optometry authorizes optometrists who are therapeutically certified to use and prescribe anti-glaucoma drugs in topical and oral form. To be certified, newly licensed optometrists are required to complete a six-month internship with a therapeutically certified optometrist, physician or optometrist.⁵¹

⁴⁸ HPRAC.Prescribing and Use of Drugs by Non-Physician Health Professionals: A Jurisdictional Review of the Profession of Optometry. <http://hprac.org/en/projects/resources/hprac-drug-Optometryjurisrevnov08.pdf>. 20-21.

⁴⁹ Title 40 - Professions and Occupations, Chapter 37. Optometrists.
<http://www.scstatehouse.gov/code/t40c037.htm>.

⁵⁰ Board of Registration in Optometry, Division of Professional Licensure Boards 246 CMR 1.00: Purpose, Authority and Definitions.
<http://www.mass.gov/?pageID=ocasubtopic&L=4&L0=Home&L1=Licensee&L2=Division+of+Professional+Licensure+Boards&L3=Board+of+Registration+in+Optometry&sid=Eoca>.

⁵¹ Title 24 Professions and Occupations Chapter 21. Optometry.
<http://www.dpr.delaware.gov/boards/optometry/newlicense.shtml>.

In Texas, a therapeutic optometrist is licensed and authorized to administer and prescribe a drug, but may independently administer oral carbonic anhydrase inhibitors for emergency purposes only, and must immediately refer the patient to an ophthalmologist.⁵² The Texas Optometry Board requires therapeutic optometrists to complete educational courses and pass an examination to be certified as “optometric glaucoma specialists” in order to administer or prescribe an oral or parenteral medication or treat glaucoma.⁵³

Texas laws respecting care of glaucoma patients are prescriptive. No later than 30 days after the initial diagnosis of glaucoma, a therapeutic optometrist must consult with an ophthalmologist to develop a jointly approved treatment plan, including a plan for co-management of the patient with periodic reviews of the patient’s progress. A patient must be referred to an ophthalmologist if the patient is younger than 16 years-of-age and has been diagnosed with glaucoma, if the patient has been diagnosed as having closed angle glaucoma, if the patient has been diagnosed as having malignant glaucoma or neovascular glaucoma, if the therapeutic optometrist determines that the glaucoma is caused by a diabetic complication and the patient should be referred, or if the therapeutic optometrist determines that a patient’s glaucoma is not responding appropriately to a treatment and should be seen by a specialist.

On making an initial diagnosis of glaucoma, a therapeutic optometrist must set a target pressure of not more than 80 percent of the initial IOP, and determine when the patient’s glaucoma is responding appropriately to treatment. Before prescribing a beta blocker, a complete history of the patient must be taken, and if the patient has a history of specific conditions, the optometrist must refer the patient to a physician before initiating beta blocker therapy.⁵⁴

In addition, Texas has established an Optometric Health Care Advisory Committee, whose mandate is to:

- establish requirements for the education and clinical training necessary for certification as an optometric glaucoma specialist;
- establish the parameters of care for treatment of ocular diseases and conditions by optometric glaucoma specialists as health care technology advances; and
- identify additional classes of pharmaceuticals that are effective treatments for ocular diseases and conditions and that may be effectively used by certified optometric glaucoma specialists.⁵⁵

In Virginia, the Board of Optometry may provide TPA certification to qualified optometrists to prescribe for and treat diseases or abnormal conditions of the human eye and its adnexa with oral and topical TPAs. Treatment of angle closure glaucoma is limited to initiation of immediate emergency care. Treatment of infantile or congenital glaucoma is prohibited. The training and examination of TPA certified optometrists sets a minimum number of hours of clinical training to be supervised by an ophthalmologist.⁵⁶

⁵² Texas Optometry Board. <http://www.tob.state.tx.us/>.

⁵³ The *Texas Optometry Act*, Sec. 351.3581.

⁵⁴ *Ibid.* Added by Acts 2001, 77th Leg., ch.1420, Sec. 14.152(c), eff. Sept. 1, 2001.

⁵⁵ *Ibid.*: Sec. 351.165.

⁵⁶ Code of Virginia Optometry. Chapter 32 of Title 54.1: s.54.1-3222, s.54.1-3223. http://www.dhp.virginia.gov/optometry/optometry_laws_regs.htm.

In July 2006, Colorado's laws changed to require that an optometrist must be certified as a therapeutic optometrist to use pharmaceutical agents for the treatment of eye disease or disorder or for any therapeutic purpose. An optometrist who meets the requirements established by the board pursuant to sections may treat anterior uveitis and glaucoma. The classes of pharmaceutical agents approved for optometric use by certified therapeutic optometrists for treatment of glaucoma include topical and oral anti-glaucoma agents.⁵⁷

In Rhode Island, an “amplified optometrist” is an optometrist authorized by the Board of Optometry to administer and prescribe all topical pharmaceutical agents in the treatment of conditions of the human eye and its appendages, including anterior uveitis and glaucoma, without surgery or other invasive techniques. Treatment of glaucoma excludes treatment of infantile and congenital glaucoma. Treatment of acute angle closure glaucoma is limited to initiation of immediate emergency care.

To qualify for licensure as an amplified optometrist, the applicant must have consulted with an ophthalmologist or optometrist with amplified privileges to treat glaucoma, who has been treating glaucoma for no less than three years regarding no less than 20 glaucoma-related patients, and the ophthalmologist or optometrist has provided written confirmation of this consultation. Up to ten of these glaucoma-related patients may have been diagnosed as glaucoma-related up to one year prior to completion of the requirements. All 20 glaucoma-related patients shall be followed for a minimum of one year or until the patient is stabilized (i.e., symptoms controlled, vision loss arrested, medication changes not required), whichever is longer; and for each glaucoma-related patient, the applicant shall develop, in consultation with the ophthalmologist or optometrist: a) a confirmatory evaluation and diagnosis by the ophthalmologist or optometrist with amplified privileges to treat glaucoma; b) a written plan for diagnostic workup for each patient, which must be in accordance with the prevailing community standard of care; and c) a treatment plan for each patient which shall take into account the assessment of the optic nerve, the level of the intraocular pressure, and stability of the clinical course.⁵⁸

An optometrist licensed in Vermont must possess the endorsement of the Vermont Optometry Board to administer and prescribe TPAs for the appropriate diagnosis, management and treatment of the eye and adnexa. A licensee may treat the following types of glaucoma on patients who are 16 years-of-age or older: (1) adult primary open angle glaucoma; (2) exfoliative glaucoma; (3) pigmentary glaucoma; (4) low tension glaucoma; (5) inflammatory (uveitic) glaucoma, and (6) emergency treatment of angle closure glaucoma.⁵⁹

If a glaucoma patient does not respond to up to three topically administered pharmaceutical agents within a reasonable time, the licensee must refer the patient to a licensed ophthalmologist. No glaucoma patient shall be treated

⁵⁷ Colorado Revised Statutes. Title 12 Professions and Occupations Article 40 Optometrists.
<http://www.dora.state.co.us/Optometry>.

⁵⁸ Rules and Regulations Pertaining to Optometrists. (R5-35-OPT)
<http://www2.sec.state.ri.us/dar/regdocs/released/pdf/DOH/4991.pdf>.

⁵⁹ Vermont Secretary of State – Office of Professional Regulation. Board of Optometry. 1728a.
<http://vtprofessionals.org/opr1/optometrists/>.

by an optometrist with more than three topically administered agents at any given time.

If an oral medication is required to obtain an adequate clinical response, the licensee must consult with a licensed ophthalmologist as soon as clinically prudent following initiation of the oral medication. This does not require that care of the patient be transferred to the consulting ophthalmologist, but does require that the patient be seen by the consulting ophthalmologist.⁶⁰

In California, an optometrist who is certified to use TPAs may also diagnose and exclusively treat the human eye or eyes, or any of its appendages, for all of the following conditions: a) infections of the anterior segment and adnexa, excluding the lacrimal gland, the lacrimal drainage system and the sclera; b) ocular allergies of the anterior segment and adnexa; c) ocular inflammation, nonsurgical in cause, limited to inflammation resulting from traumatic iritis, peripheral corneal inflammatory keratitis, pteritis, and unilateral nonrecurrent nongranulomatous idiopathic iritis in patients 18 years-of-age or older. Unilateral nongranulomatous idiopathic iritis recurring within one year of the initial occurrence shall be referred to an ophthalmologist. An optometrist shall consult with an ophthalmologist if a patient has a recurrent case of episcleritis within one year of the initial occurrence. An optometrist shall consult with an ophthalmologist if a patient has a recurrent case of peripheral corneal inflammatory keratitis within one year of the initial occurrence; d) traumatic or recurrent conjunctival or corneal abrasions and erosions; e) Corneal surface disease and dry eyes; f) Ocular pain, not related to surgery, associated with conditions optometrists are authorized to treat; and g) primary open angle glaucoma in patients over the age of 18. Optometrists are not authorized to treat a person with AIDS for ocular infections.

California is explicit in the topical anti-glaucoma agents which may be used by certified optometrists. The optometrist may not use more than two concurrent topical medications in treating the patient for primary open angle glaucoma. A single combination medication that contains two pharmacological agents is considered as two medications. The optometrist must refer the patient to an ophthalmologist if requested by the patient, if treatment goals are not achieved with the use of two topical medications or if indications of narrow angle or secondary glaucoma develop. If the glaucoma patient also has diabetes, the optometrist must consult in writing with the physician treating the patient's diabetes in developing the glaucoma treatment plan and notify the physician in writing of any changes in the patient's glaucoma medication. The physician must provide written confirmation of such consultations and notifications.

The State Board of Optometry may grant a certificate to an optometrist certified for the treatment of primary open angle glaucoma in patients over the age of 18 only after the optometrist meets the following requirements:

- (1) Satisfactory completion of a didactic course of not less than 24 hours in the diagnosis, pharmacological and other treatment and management of glaucoma. Any applicant who graduated from an accredited California school of optometry on or after May 1,

⁶⁰ Ibid:1728d. (Added 2003, No. 108 (Adj. Sess.), 9.

2000, is exempt from the 24-hour didactic course requirement.

- (2) After completion of the course requirement, collaborative treatment of 50 glaucoma patients for a period of two years for each patient under the following terms:
- After the optometrist makes a provisional diagnosis of glaucoma, the optometrist and the patient shall identify a collaborating ophthalmologist.
 - The optometrist shall develop a treatment plan that considers for each patient target intraocular pressures, optic nerve appearance and visual field testing for each eye, and an initial proposal for therapy.
 - The optometrist transmits relevant information from the examination and history taken of the patient along with the treatment plan to the collaborating ophthalmologist. The collaborating ophthalmologist shall confirm or refute the glaucoma diagnosis within 30 days. To accomplish this, the collaborating ophthalmologist shall perform a physical examination of the patient. Once the collaborating ophthalmologist confirms the diagnosis and approves the treatment plan in writing, the optometrist may begin treatment.
 - A single combination medication that contains two pharmacologic agents is considered as two medications. The optometrist shall notify the collaborating ophthalmologist in writing if there is any change in the medication used to treat the patient for glaucoma. Annually, after commencing treatment, the optometrist shall provide a written report to the collaborating ophthalmologist about the achievement of goals contained in the treatment plan. The collaborating ophthalmologist shall acknowledge receipt of the report in writing to the optometrist within ten days. The optometrist shall refer the patient to an ophthalmologist if requested by the patient, if treatment goals are not achieved with the use of two topical medications, or if indications of secondary glaucoma develop. At his or her discretion, the collaborating ophthalmologist may periodically examine the patient.
 - If the glaucoma patient also has diabetes, the optometrist shall consult in writing with the physician treating the patient's diabetes in preparation of the treatment plan and shall notify the physician in writing if there is any change in the patient's glaucoma medication. The physician shall provide written confirmation of the consultations and notifications.
 - The optometrist shall provide the following information to the patient in writing: nature of the working or suspected diagnosis, consultation evaluation by a collaborating ophthalmologist, treatment plan goals, expected follow-up care, and a description of the referral requirements. The document containing the information shall be signed and dated by both the optometrist and the ophthalmologist and maintained in their files.

When the requirements contained in paragraphs (1) and (2) have been satisfied, the optometrist must submit proof of completion to the State Board of Optometry and apply for a certificate to treat primary open angle

glaucoma. That proof shall include corroborating information from the collaborating ophthalmologist. After an optometrist has treated a total of 50 patients for a period of two years each and has received certification from the State Board of Optometry, the optometrist may treat the original 50 patients independently, with the written consent of the patient. However, any glaucoma patients seen by the optometrist before the two-year period has expired for each of the 50 patients shall be treated under the collaboration protocols described.⁶¹

A review of a cross-section of Canadian and United States jurisdictions indicates that there are trends to authorizing optometrists to treat open angle glaucoma with the topical administration of TPAs, with immediate referral to an ophthalmologist for cases of acute angle closure, glaucoma diagnosed in patients under 18, glaucoma in patients with diabetes or patients with a history of conditions that would likely create adverse drug reactions. As well, many jurisdictions require clinical experience prior to certification, with co-management of patients under either the supervision of an ophthalmologist or an optometrist who is a specialist in glaucoma.

Competency-Based Performance Standards

The Competency-Based Performance Standards (CBPS) were developed by the Canadian Examiners in Optometry (CEO) Competence Committee and the CBPS Working Group, a group of practicing optometrists from across Canada. The mandate of the Working Group was to develop the minimum quality of practice required to provide safe and effective optometric care in Canada and revising the standards for the CSAO.

The standards require that optometrists meet patients' eye and vision care needs by possessing the functional knowledge to manage patient care, to consult with other health professionals when managing patients' complex needs, and to refer patients to other optometrists, ophthalmologists or family physicians for eye care needs that require specialized management or are beyond the scope of practice of the optometrist.

Optometrists are required to complete a full patient history including critical information such as relevant ocular and vision, medical and social history and risk factors. They must use their knowledge of epidemiological, ocular and medical risk factors to determine the patient's risk and obtain the patient's consent to contact others to obtain relevant information.

The accurate identification of tests that may be appropriate or may be contraindicated in patients with specific conditions, along with application of professional knowledge to determine more detailed examinations that are required, is a key skill. Performance of visual field testing for glaucoma following elevated tonometry readings is an example. As well, the optometrist must recognize when special testing or equipment needs mean that a referral to another optometrist or ophthalmologist is needed, or when the patient's condition requires management by another health professional.

⁶¹ Acts constituting practice of optometry. S.3041. <http://www.optometry.ca.gov/lawsregs/index.shtml>.

Optometrists must be able to synthesize information in order to make a differential diagnosis using evidence-based decision-making, supported by current, relevant literature and guidelines. The pathophysiology underlying the diagnosis, the process followed in reaching a diagnosis and the explanation of why specific test results rule out or lower the probability of other diagnoses are important skills.

Consultation with other health professionals, including pharmacists, family physicians and others when developing or managing the patient's care plan, including discussion of allergic and adverse interactions with current medications or ensuring that diabetes is controlled is expected of the optometrist. The application of professional knowledge to select appropriate treatments, accurate writing of prescriptions and patient education concerning side effects and proper administration of drugs are key skills in the pharmacotherapeutic management of patients.

As with any other health professional, follow-up care to track the patient's progress is expected of the optometrist. Explaining clearly what the expectations are over the period of care, what the patient should observe and report, and scheduling services that meet patient needs and concerns are fundamental to professional performance.⁶²

Other Issues

Regulations under the *Optometry Act 1991* define “prescribe diseases” as referenced in the scope of practice statement of the profession as those “that can be treated by other than the prescribing of drugs or the application of surgery”.⁶³ Surgery is not part of the scope of practice of optometry. In amendments to the *Optometry Act, 1991* in 2007, the profession was granted the authority to prescribe drugs for therapeutic purposes, but the regulation made under the Act was not updated at the time.

HPRAC's Conclusions

HPRAC has considered very carefully the documentation that has been presented, and the information that has been made available through interviews, round-table meetings and through its own research and analysis. HPRAC is confident that the COO has the will, and the profession has or is obtaining the skills, to prescribe topical and oral TPAs as recommended in HPRAC's report to the Minister in April 2006. A review of the course content at the University of Waterloo's School of Optometry, international curricula and examination standards, the Standards of Practice that the COO intends to put into place, along with its educational bridging and continuing education requirements, the requirements of credentialing examinations and the CBPS of the CEO provides satisfactory evidence that members of the profession of optometry in Ontario can provide safe and effective care, and there should be no delay in moving designated drugs regulations forward.

⁶² Canadian Examiners in Optometry. Competency Based Performance Standards for the Canadian Standard Assessment in Optometry. 2005.10. Version 1.2.

⁶³ O. Reg. 152/97, s.1.

The COO and the OAO have asked HPRAC to consider their work with patients who are diagnosed with glaucoma and to add glaucoma drugs to the designated drugs regulation. Having as recently as two years ago recommended to the Minister that optometrists and ophthalmologists should care for glaucoma patients in a co-management model, HPRAC delved further into the issues, including looking at how graduates of the University of Waterloo and the University of Montreal, Canada's two optometry schools, are prepared for professional practice. It was determined that they meet the entry to practice criteria for treating glaucoma patients in North American jurisdictions but do not have the critical clinical practice component, most often in association with an ophthalmologist or specialist optometrist preceptor. This standard is established in law in many jurisdictions, and required for certification by the licensing or regulatory body.

HPRAC also found that other jurisdictions have in large part determined that optometrists who are trained today are competent in dealing with primary glaucoma care, and that the specialist services of highly skilled ophthalmologists are needed for the rare but complex cases. This concurs with HPRAC's observations from the curricula and from competency-based performance standards.

HPRAC was concerned by the discouraged tone of optometry leaders who had attempted to meet and develop protocols for shared patient care, or co-management of patients, with leaders in ophthalmology. Nonetheless, HPRAC found that some leaders in the schools of optometry and ophthalmology and in the professional associations and regulatory colleges appear keen to develop a new interprofessional approach to patient care. System, funding or co-ordination debates are not helpful to patients who need skilled care. For patients, this is a question of who can provide them with the best care to either save them from blindness or postpone its onset.

Two years ago, HPRAC recommended co-management of glaucoma patients. Two years later, there has been little if any progress. Having further investigated the training of optometrists, and the hopes of collaboration with ophthalmologists, HPRAC is recommending:

- That Ontario's optometrists be authorized to treat with topical therapeutic agents patients diagnosed with open angle glaucoma.
- That Ontario's optometrists be authorized to treat acute angle closure glaucoma in emergency situations only, with immediate referral to an ophthalmologist.
- That patients diagnosed with glaucoma who have diabetes should be immediately referred to an ophthalmologist.
- That all patients under 18 who have been diagnosed with glaucoma should be immediately referred to an ophthalmologist.
- That all patients with neovascular or malignant glaucoma should be immediately referred to an ophthalmologist.
- That any patient diagnosed with open angle glaucoma and not responding to topical therapeutic treatment should be referred to an ophthalmologist.
- That any patient with a history of conditions that contraindicate drug therapy should be immediately referred to an ophthalmologist.

These matters will necessarily be dealt with in legislation, in regulation, in standards of practice and in collaborative protocols. It will take time to put them into place, and for professional leadership to ensure it happens, and that patients benefit.

It would not be a surprise to HPRAC, nor to members of the profession, if some optometrists chose not to provide therapeutic care to glaucoma patients, based on their own assessment of their knowledge, skills and judgment. This would be comparable to the response in pharmacy, when some members of the profession chose not to take on additional tasks that were beyond their own individual scope of practice, and where professionals established the limits of their own competence. Nonetheless, the COO will need to be rigorous in determining how it will qualify members of the profession in establishing qualifications for glaucoma care and testing them. New continuing education, competency testing and clinical practice opportunities will be required.

Under this new model of care, optometrists will have enhanced ability to manage and treat primary glaucoma patients using topical anti-glaucoma medications, and protocols for referrals and patient transfers will be put into place. This change should enhance access to care for patients, while still maintaining what HPRAC considers to be important safeguards in the treatment of patients with glaucoma.

In other issues that need to be addressed, HPRAC concurs that regulations made under *Optometry Act, 1991* respecting “prescribed diseases” should be updated to take into account the scope of practice of optometrists today, and their authority to prescribe therapeutic drugs as part of a treatment plan for a patient.

Recommendations:

1: That the following classes of TPAs be included in the designated drugs regulation under the *Optometry Act, 1991*. HPRAC proposes that the regulation should designate the therapeutic class of drugs, and the specific agents would be determined through the proposed drug approvals framework. At the outset, HPRAC is recommending the following classes and specific agents be included in the authorities for the profession:

Class	Specific Agents
Class: Anti-infectives Sub-class: Antibiotics	doxycycline erythromycin
Class: Anti-infectives Sub-class: Antivirals	acyclovir
Class: Eye, Ear, Nose and Throat Preparations Sub-class: Antiallergic Agents	levocabastine pheniramine olopatadine cromoglycate lodoxamide

Class	Specific Agents
Class: Eye, Ear, Nose and Throat Preparations Sub-class: Anti-infectives	erythromycin fusidic acid polymyxin B sulfate gentamicin tobramycin ciprofloxacin norfloxacin ofloxacin moxifloxacin natamycin trifluridine
Class: Eye, Ear, Nose and Throat Preparations Sub-class: Anti-inflammatory Agents	prednisolone dexamethasone fluoromethalone rimoxolone loteprednol diclofenac ketorolac
Class: Eye, Ear, Nose and Throat Preparations Sub-class: Mydriatics	cyclopentolate atropine homatropine
Class: Eye, Ear, Nose and Throat Preparations Sub-class: Vasoconstrictors	naphazoline phenylephrine

2: That the following classes of TPAs for treating glaucoma patients be included in the designated drugs regulation under the *Optometry Act, 1991*. The regulation should name the therapeutic class of drugs, and the specific agents and limitations and conditions for their use would be recommended by the proposed Council on Health Professions Regulatory Excellence (CHPRE) on the advice of the Drug and Therapeutics Formulary Committee, which will from time to time update the Drug List. This regulation will authorize optometrists to prescribe topical anti-glaucoma medications including alpha-adrenergic agonists, beta-adrenergic blocking agents, carbonic anhydrase inhibitors, miotics, osmotic agents, prostaglandin analogs and other agents used in the treatment of open angle glaucoma. Under this model, if open angle glaucoma is diagnosed by an optometrist, the patient can then be managed by the optometrist on an ongoing basis, with referral to an ophthalmologist if the patient's condition changes.

An optometrist would not be authorized to manage patients diagnosed with closed angle glaucoma, glaucoma in patients under 18 years-of-age, patients with both diabetes and glaucoma conditions, neovascular or malignant glaucoma. Standards of practice and clinical practice guidelines would be required for each circumstance, along with educational bridging and continuing education requirements. Patients with closed angle glaucoma must immediately be transferred to an ophthalmologist for care, and a patient who is not responding to treatment should be transferred to an ophthalmologist for care. The Drug List would specify the requirements for co-management of glaucoma patients.

The designated drugs regulation should therefore include the following classes of drugs:

Class	Specific Agents
Class: Eye, Ear, Nose and Throat Preparations Sub-class: Vasoconstrictors	naphazoline phenylephrine
Class: Eye, Ear, Nose and Throat Preparations Sub-class: Anti-glaucoma Agents	Includes alpha-adrenergic agonists, beta-adrenergic blocking agents, carbonic anhydrase inhibitors, miotics, osmotic agents, prostaglandin analogs and other agents used in the treatment of glaucoma
Class: Eye, Ear, Nose and Throat Preparations Sub-class: Miscellaneous	cyclosporine

3: HPRAC recommends that the College of Physicians and Surgeons of Ontario and the COO immediately develop a joint protocol and standards of practice relating to the continuum of glaucoma management and the appropriate shared management of glaucoma patients. This should include matters relating to required education, training, continuing competence, initial diagnosis, record-keeping, and mandatory consultation and referral requirements. Additional provisions concerning compliance with individual scope of practice, general terms, conditions and limitations should be included, comparable to the collaborative approach applied in recommendations regarding midwifery, physiotherapy and pharmacy.

4: HPRAC recommends that the Minister consider adjusting the Physician Schedule of Benefits and Fees to authorize payment for direct referrals for ophthalmologist consultations from optometrists relating to glaucoma patients. This is a matter that could be referred to the Physician Services Committee (PSC), which continues under the recent MOHLTC-OMA agreement to “provide a broad and structured process for regular liaison and communication between the MOHLTC and the medical profession through its representation by the OMA”.⁶⁴

5: HPRAC recommends that the regulation made under the *Optometry Act, 1991* respecting prescribed diseases that is no longer relevant to the scope of practice of optometry be repealed.

Implementation Proposals

To implement the HPRAC’s recommendations, the following changes to statutes and regulations are proposed:

1. That paragraph 2.1 of section 4 of the *Optometry Act, 1991* be repealed and the following substituted:

⁶⁴ OMA/MOHLTC Agreement, s.1.5. November 2008.

2.1 Prescribing a drug that the member may prescribe under the regulations.

2. That the *Optometry Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts

4.1 A member shall perform a procedure under the authority of paragraph 2.1 of section 4 in accordance with any requirements prescribed in the regulations.

Individual scope of practice for optometrists

4.2 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

3. That section 12(1) of the *Optometry Act, 1991* be repealed and the following substituted:

Regulations

12. (1) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,

(a) regulating the prescribing of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing of drugs; and

(b) designating the diseases for which a member may communicate a diagnosis for the purposes of paragraph 1 of section 4.

4. That section 12(2) of the *Optometry Act, 1991* be repealed.
5. That section 10(2) of Part IV (Records) of Ontario Regulation 119/94 under the *Optometry Act, 1991* (General) be amended by adding the following section:

13. The drugs prescribed.

6. That Part VIII of Ontario Regulation 119/94 under the *Optometry Act, 1991* (General) be renamed Prescribed Diseases and Drugs.
7. That sections 21 and 22 of Part VIII (Prescribed Diseases) of Ontario Regulation 119/94 under the *Optometry Act, 1991* (General) be repealed and the following substituted:

- 21.** For the purposes of subsection 3(c) and paragraph 1 of section 4 of the *Optometry Act, 1991*, a “prescribed disease” is any disease limited to and manifested in the eye and vision system that can be determined by the findings from an oculo-visual assessment.
- 22.(a)** For the purposes of this section, “Drug List” has the meaning given to it in the *Regulated Health Professions Act, 1991*.
- (b)** A member may prescribe the following classes of drugs:
- i) anti-infectives – antibiotics and antivirals, and
 - ii) eye, ear, nose and throat preparations – antiallergic agents, anti-infectives, anti-inflammatory agents, mydriatics, vasoconstrictors, anti-glaucoma agents and miscellaneous.
- (c)** A member may use the following classes of drugs:
- i) topical anaesthetics, and
 - ii) eye, ear, nose and throat preparations - mydriatics.
- 24.** A member may only prescribe or use those drugs within the classes designated in section 22 that are listed in the Drug List and must prescribe or use those listed drugs in accordance with the terms, limitations and conditions contained in the Drug List.
8. That Ontario Regulation 837/93 under the *Optometry Act, 1991* be amended by adding the following sections:
- General Terms, Limitations and Conditions**
- 16.** (1) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 2.1 of section 4 of the Act must:
- (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and
 - (b) ensure the procedure performed does not exceed the level of training completed.
- (2) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 2.1 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.
9. That Ontario Regulation 550 under the *Drug and Pharmacies Regulation Act (Optometry)* be repealed and/or made a regulation under the *Optometry Act, 1991*, as appropriate.

10. That section 1(1)13 of Ontario Regulation 859/93 under the *Optometry Act, 1991* (Professional Misconduct) be repealed and the following substituted:
 - 13.** Failing to advise a patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition of the eye or vision system that is beyond the competence or experience of the member or that requires such a consultation to ensure the proper care of the patient.
11. That section 1(1)17 of Ontario Regulation 859/93 under the *Optometry Act, 1991* (Professional Misconduct) be repealed and the following substituted:
 - 17.** Contravening or failing to maintain the standards of practice of the profession.
12. That section 1(1)18 of Ontario Regulation 859/93 under the *Optometry Act, 1991* (Professional Misconduct) be repealed and the following substituted:
 - 18.** Delegating an act set out in paragraph 2 or 4 of section 4 of the Act except as permitted by the *Regulated Health Professions Act, 1991* or the regulations made thereunder or under the Act, or delegating an act set out in paragraph 1 or 2.1 of the Act.
13. That Ontario Regulation 859/93 under the *Optometry Act, 1991* (Professional Misconduct) be amended by adding the following sections:
 - 21.1** Prescribing drugs for an improper purpose, or otherwise using improperly the authority to prescribe drugs.
 - 21.2** Contravening, while engaged in the practice of optometry, any federal or provincial law or municipal by-law with respect to the prescribing of any drug or mixture of drugs.
14. That paragraph 2 of Section 21 of Part VIII of Regulation 119/94 made under the *Optometry Act, 1991* be repealed.

THE PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF PHARMACY

HPRAC received submissions from the Ontario College of Pharmacists (OCP) and the Ontario Pharmacists' Association (OPA) recommending that pharmacists be given open prescribing rights in Ontario for the purposes of medication therapy management. The proponents also request the establishment of a minor ailments program in Ontario. HPRAC has recently completed a scope of practice review of the profession of pharmacy in which it examined the education, quality assurance and continuing competence of pharmacy and the profession's collaborative relations with other health professions. Further research and consultation was conducted, and all contribute to the recommendations made in this report.

HPRAC's Central Response

As recommended in the recent scope of practice review, HPRAC endorses the need and opportunity for pharmacists, as one of the most accessible regulated health professionals, to play a greater role in primary health care. HPRAC is persuaded that pharmacists in Ontario are highly educated and that their formal education and training have evolved to incorporate the skills and judgment required to undertake medication therapy management. HPRAC is of the opinion that a broad list of classes will provide pharmacists with sufficient latitude to adapt, modify and extend an existing prescription.

HPRAC continues to recommend that Ontario consider developing a minor ailments program for Ontario, and that a collaborative process to develop details for such a program be initiated, including an implementation and communications plan.

Background

HPRAC's Scope of Practice Review of Pharmacy

HPRAC recently completed a review of the scope of practice of pharmacy in Ontario, in which it concluded that pharmacists can offer increased, safe and effective patient care to Ontarians and can contribute more to the management of chronic diseases and interprofessional care. In its report to the Minister in September 2008, HPRAC recommended that pharmacists be authorized to perform additional controlled acts and that they should be to equipped with the tools to provide additional services in an expanded scope of practice.¹

In this review, HPRAC undertook a literature and jurisdictional review and an extensive consultation process. It took into account the current competency requirements for pharmacists, their educational preparation, and trends in the evolution of the profession to a patient-centred pharmaceutical care approach.

¹ Health Professions Regulatory Advisory Council. *Review of the Scope of Practice of Pharmacy, Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals: Phase II, Part I*. September, 2008: 19 – 77.

The scope of practice review found that, in today's world, it is an expected standard of practice that pharmacists provide both information and education to patients respecting the use of drugs, health care aids and devices. They are also asked to provide advice and analysis to other health professionals concerning the best options for pharmacotherapeutic management of patients and safe outcomes of drug therapy.

The review also found that pharmacists are part of interprofessional team-based care, whether in the community or in hospitals, and work with patients and other health professionals and providers to ensure optimal patient care. Overall, the review concluded that pharmacist intervention can positively influence the incidence of drug reactions, hospital length of stay and continuity of patient care.

As well, HPRAC found that other regulated health professions expressed support for the greater use of pharmacists in medication therapy management. Stakeholders agreed that pharmacists have the competence, knowledge, skills and judgment to carry out the additional responsibilities of medication therapy management.

Overall, HPRAC concluded that “pharmacists in Ontario are highly educated and that their formal education and training have evolved to incorporate the skills and judgment required to undertake medication therapy management. Pharmacists have the potential to address an increasing public need for access to health care services related to medication therapy and continuity of patient care”.²

To give effect to this conclusion, HPRAC recommended to the Minister:

1. That pharmacists be authorized to prescribe drugs for the purposes of medication therapy management. Within this authority, pharmacists could adapt, modify and extend an existing prescription.
2. That pharmacists be authorized to initiate therapy for smoking cessation, including prescribing Schedule I drugs.
3. That pharmacists be authorized to administer drugs through injection and inhalation for the purpose of patient education and demonstration.
4. That pharmacists be authorized to perform a procedure on tissue below the dermis for the limited purpose of patient self-care education and chronic disease monitoring, including the use of lancing-type devices (i.e., for the management of diabetes).
5. That pharmacists be authorized to order laboratory tests for the purpose of medication monitoring and management.
6. That pharmacists not be authorized to independently initiate therapy for travel prophylaxis.

² Ibid. 60.

7. That pharmacists not be authorized to prescribe Schedule II and III drugs solely for the purposes of patient reimbursement under an insurance plan.
8. That pharmacists not be authorized to perform routine immunizations.

Towards Introducing a Minor Ailments Program

HPRAC recommended that steps be taken towards the introduction of a minor ailments program in Ontario. To that end, HPRAC recommended that the OCP and the OPA lead a working group, in collaboration with the Ontario Medical Association, the College of Physicians and Surgeons of Ontario, the College of Nurses of Ontario, the Registered Nurses Association of Ontario, the Nurse Practitioners Association of Ontario, other health professions, facilities, educators and Ministry representatives to develop the details of a program that would be suitable in Ontario, including: the list of minor ailments that pharmacists could treat; an agreed formulary including Schedule I, II and III drugs; protocols for referral to and communication with other health professionals, obtaining patient consent, and record-keeping; options for reimbursement for professional services; and educational and competency requirements and quality assurance, among other matters.

The working group would also outline an implementation plan, including any pilot projects that might be required, along with communications elements to advise patients of the program. As well, the OCP should incorporate practice standards for a minor ailments program in its regulatory regime, and that those standards should be developed with the participation of other health professions.

HPRAC's Recommended Changes to Pharmacy Scope of Practice

Currently, pharmacists, under the *Pharmacy Act, 1991*, have the following scope of practice:

The practice of pharmacy is the custody, compounding and dispensing of drugs, the provision of non-prescription drugs, health care aids and devices and the provision of information related to drug use.³

In its review of the profession, HPRAC recommended that the scope of practice statement for pharmacists in Ontario be amended to reflect the recommendations to the Minister. The new scope of practice statement would read:

The practice of pharmacy is the promotion of health and the prevention and treatment of diseases, disorders and dysfunction through the monitoring and management of medication therapy; the custody, prescribing, compounding and dispensing of drugs; and the provision of health care aids and devices and education related to their use.⁴

³ *Pharmacy Act, 1991*, S.O. 1991, c. 36, s.3.

⁴ HPRAC *Interim Report to Minister*. September, 2008: 193.

Authorized Acts

The *Pharmacy Act, 1991* currently gives pharmacists access to authorized acts as follows:

In the course of engaging in the practice of pharmacy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to dispense, sell or compound a drug or supervise the part of a pharmacy where drugs are kept.⁵

In the scope of practice review, HPRAC recommended that the current authorized acts be repealed and the following substituted:

Authorized acts

4. In the course of engaging in the practice of pharmacy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:
 1. Dispensing, selling or compounding a drug or supervising the part of a pharmacy where drugs are kept.
 2. Skin pricking for the purpose of educating patients on the use of health care aids and devices and for the purpose of monitoring chronic diseases.
 3. Administering, by injection or inhalation, a substance for the purpose of patient education or demonstration.
 4. Prescribing drugs as prescribed in the regulations.

Additional requirements for authorized acts

- 4.1. A member shall perform a procedure under the authority of paragraphs 2, 3 or 4 of section 4 in accordance with any requirements prescribed in the regulations.
- 4.2 A member shall not perform a procedure under the authority of paragraph 3 of section 4 unless the substance is prescribed by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the prescription.

Individual scope of practice for pharmacists

- 4.3 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

⁵ *Pharmacy Act, 1991*, S.O. 1991, c. 36, s.4.

Regulations

Additionally, HPRAC recommended that a new section be added to the *Pharmacy Act, 1991* as follows:

Regulations

- 14.(1) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,
- (a) designating the drugs that may be prescribed by members in the course of engaging in the practice of pharmacy;
 - (b) designating the circumstances in which a member may prescribe drugs in the course of engaging in the practice of pharmacy; and
 - (c) specifying requirements for the performance of procedures under the authority of paragraphs 2, 3 or 4 of section 4.

Individual drugs or categories

- 14.(2) A regulation made under paragraph 14(1)(a) may designate or specify individual drugs or categories of drugs.⁶

Review of Pharmacy Prescribing and Use of Drugs

In the scope of practice reviews conducted as part of the interprofessional collaboration project, HPRAC indicated that, where relevant, it would consider specific issues relating to the prescribing and use of drugs by non-physician professionals in greater detail in its examination of the Minister's request for advice on this subject. For pharmacy, extensive examination of education, quality assurance, continuing competence and collaborative relations with other health professions was carried out in the scope of practice review.

This report, then, examines, as a result of its previous recommendations to the Minister respecting an expanded scope of practice for the profession of pharmacy, among other matters, whether lists, categories or classes of drugs should be designated in regulations under the *Pharmacy Act, 1991*. This follows directly on the Minister's request to:

...provide advice specific to each of these professions respecting whether lists, categories or classes of drugs should be prescribed by regulation for the profession, or whether restrictions on prescribing of drugs should be placed in regulation under the respective health profession Act.

⁶ For a complete list of HPRAC's recommendations for amendments to other legislation and regulations as part of the scope of practice review for the pharmacy profession, please see pages 73-77 of HPRAC's Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals: Phase II, Part I.

In conducting this review, HPRAC prepared a literature review, jurisdictional reviews and a limited jurisprudence review. Interviews and meetings with educators, members of the profession, other health professions, health care facilities and institutions and community-based agencies were held to capture concerns and comments, and to lead to additional research. Proponents' submissions were posted on HPRAC's website, and responses to the submissions were invited from those with an interest in the subject.

For this review, HPRAC received submissions from the OCP and the OPA. At the time of these submissions to HPRAC respecting the prescribing of drugs, HPRAC's recommendations to the Minister on the scope of practice for pharmacy had not been made public. Because neither the OCP nor the OPA had the opportunity to review the report, their requests for change reflected the proposals made in their respective submissions for the review of the scope of practice for pharmacy.

Requests for Change

1: Open Prescribing for the Purposes of Medication Therapy Management

To enable pharmacists to adapt, modify and extend an existing prescription, the OCP and OPA proposed that no list of specific drugs or classes of drugs be prescribed in designated drug regulations made under the *Pharmacy Act, 1991*.

The OCP supports all pharmacists being permitted to adapt and modify prescriptions for any Schedule I, II or III drug prescribed and to extend prescriptions for Schedule I maintenance drugs prescribed for chronic care. It acknowledges that under federal legislation, the adapting, modifying or extending of all prescriptions for narcotic or controlled substances will continue to be done in collaborative practice through delegation or medical directives.⁷

The OPA has suggested that regulations could include a list of exemptions for drug prescriptions that could not be refilled or modified by a pharmacist.⁸

Proponents' Rationale

As described in the scope of practice review, proponents state that the expansion of the pharmacist's scope of practice will enable pharmacists to practice to the full extent of their education and competencies. This change is also expected to increase patient access to timely health services and increase efficiencies and enhance cost-effectiveness in the health care system by decreasing duplication and clarifying and enhancing accountabilities.

⁷ OCP Submission to HPRAC Review of Non-Physician Prescribing and Administration of Drugs Under the RHPA Questionnaire: 54.

⁸ OPA Submission to HPRAC Review of Non-Physician Prescribing and Administration of Drugs Under the RHPA Questionnaire: 19.

The OCP states that “once a diagnosis has been made, and before a drug is prescribed, pharmacists can play a key role in partnership with physicians and other prescribers to ensure that the right drug is prescribed or that, where no drug is prescribed, the patient understands why...Monitoring patient compliance and effectiveness of medication therapy is a key component of medication therapy management.”

The OPA notes that, as the population continues to age, and as complex chronic diseases continue to rise, pharmacists are called on more frequently to intervene on the patient’s behalf to ensure medication therapy is appropriate and patients are compliant. Enhancing the pharmacist’s ability to meet the needs of elderly patients with complex chronic diseases will relieve some of the strain on the health care system, and free up resources within the system.

Having [Alberta] pharmacists modifying prescriptions reflected what had been happening in the old system informally. Now it is done more openly, the responses from the media and from patients too, have been quite positive.⁹

Dona Carlson
Project Manager, Health Professions Division
Alberta Health and Wellness
Interview with HPRAC, November, 2008

The OCP states that pharmacists are trained to be experts in medication therapy management and to manage overall drug therapy.¹⁰ The OPA said, in its submission to HPRAC, that all pharmacists have the competencies to refill drugs for chronic use, monitoring and adjusting doses of chronic medications under a prescribed protocol and adapting a prescription based upon information available to the pharmacist and the appropriateness for the individual patient. The OPA notes that this does not include narcotics, benzodiazepines or targeted or controlled drugs.¹¹

Lists Versus Classes

The OCP and OPA have both raised concerns about defining specific drugs in regulation schedule(s) under the *Pharmacy Act, 1991*. They say that a list of individual drugs would pose significant challenges to the profession since it would not adapt fast enough to keep pace with changing and emerging drug therapies that continue to become available and reflect best practices.¹²

⁹ Alberta Health and Wellness Meeting Notes. 2008: 5.

¹⁰ OCP Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 53.

¹¹ OPA Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 15.

¹² OCP Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 53.

The OCP said that pharmacists should not be restricted in medication therapy management by the creation of lists of classes of drugs. Pharmacists are expected to be familiar with clinical guidelines and pharmacotherapeutics. Creating a specific or defined list of drugs would severely restrict the ability of pharmacists to optimize patients' drug therapy.¹³

The OCP states:

To fully realize their roles in Medication Therapy Management, pharmacists will be called upon to adapt, modify, adjust doses and extend prescriptions for numerous drugs. The College expects pharmacists to exercise sound professional judgment when making appropriate decisions and recommendations and does not support the creation of a defined list of drugs or categories. It is our view that such a list will not afford the flexibility necessary to accommodate changing drug therapies or treatment modalities as they emerge and could ultimately limit the desired benefits to the public.¹⁴

The OCP also described its experience in the regulation approval process as follows:

...[It] is our experience that the current process required to give effect to proposed regulatory changes or amendments is time consuming, onerous and fraught with ongoing delays and frustrations. As an example, the College initially submitted regulatory amendments under the *Drug and Pharmacies Regulation Act (DPRA)* to government in 1995; in the past twelve years that the proposals have been with government, emerging issues in the practice of the profession have resulted in College Council adding to or further revising the initial proposals. To date we have been unable to attract the necessary attention or political interest/will to give effect to these regulations which will greatly assist the College in more effectively regulating pharmacy practice in Ontario in the public interest.¹⁵

The OPA indicated that restricting pharmacists to refilling classes of drugs, rather than exempting classes that cannot be refilled or modified such as narcotics, controlled drugs and targeted substances could be onerous.¹⁶

What HPRAC Found

Readiness for Change

The OCP and OPA state clearly that medication therapy management is part of pharmacists' core competencies at the entry-to-practice level. The educators have confirmed that this is the case based on the rigorous four-year education curriculum and the *National Qualifying Examination*, administered by the Pharmacy Examining Board of Canada (PEBC) and

¹³ Ibid. 55.

¹⁴ Ibid. 54.

¹⁵ Ibid. 55.

¹⁶ OPA Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 18.

founded on “Professional Competencies for Canadian Pharmacists at Entry to Practice” by the National Association of Pharmacy Regulatory Authorities (NAPRA), which include the key elements of medication therapy management as part of the core competencies of pharmacy practice.

A comparative analysis of the education of pharmacy and medical students conducted by Dr. David Hill suggested that, given access to the same information about a patient that a physician has, the university programs in Canada for pharmacy prepare entry-to-practice pharmacists who would be equally competent in the skill of prescribing drugs and managing drug therapy as medical students at graduation.¹⁷

Another report by Rosemary Bacovsky, prepared for The Alberta College of Pharmacists, concluded that:

- Pharmacists are drug therapy experts and support practice evolution to independent prescribing.
- There was no documentation found to suggest that pharmacists prescribing Schedule I drugs, vaccines, blood products and parenteral nutrition products had resulted in harm or were detrimental to patients; rather, the report suggests that prescribing activities helped to improve patient safety and health outcomes by helping to ensure that appropriate drug therapy was provided in a timely manner and that drug-related problems were prevented or resolved.¹⁸

HPRAC, as it recommended in the scope of practice review of pharmacy, is satisfied that pharmacists have the necessary competencies to prescribe drugs for the purposes of medication therapy management. Within this authority, pharmacists could adapt, modify and extend an existing prescription.

For HPRAC, the request of the OCP and the OPA, regarding what is essentially “open prescribing authority” comparable to that of physicians, led to considerable deliberation. The proponents rightly describe the depth of knowledge regarding pharmacotherapy, including entry-to-practice competencies in physiology, microbiology, pathophysiology and clinical biochemistry, pharmacology, pharmacokinetics, toxicology and pharmaceutical care, and there is evidence in the literature that the entry to practice qualifications of a pharmacist are equivalent to those of a graduating medical student.

However, both the OCP and the OPA confirm that, unlike physicians with extensive post-graduate clinical training experience, pharmacist graduates in their final year complete a 16-week practicum in institutional and community settings, where the ability to practice prescribing skills is

¹⁷ OCP Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 33.

¹⁸ Bacovsky, R. *Pharmacists Prescribing in Alberta: An Examination of the Literature and Pharmacists Practices*, for The Alberta College of Pharmacists. June 2003.

limited, as pharmacists do not have authority to perform limited prescribing, except under a medical directive.¹⁹ HPRAC also considered the OCP's acknowledgement in the scope of practice review that pharmacists are "not trained to make a differential diagnosis".

As a result of these considerations, HPRAC has concluded that pharmacists should be authorized to prescribe drugs as prescribed in the regulations under the *Pharmacy Act, 1991* and that the regulations should prescribe therapeutic classes of drugs.

What Leading Jurisdictions Do

A review of American and Canadian jurisdictions indicates an emerging trend that enhances pharmacists' role and authorizes them to undertake some or all medication therapy management activities. All provinces and territories except Prince Edward Island, Ontario and the Yukon allow pharmacists to authorize further extension of a prescription where there are no existing refills for continuity of care. All except Prince Edward Island, Saskatchewan, Ontario and the Yukon allow pharmacists to adapt an existing prescription to facilitate patient adherence (such as changing the dosage form), and this policy is currently under consideration in Saskatchewan. British Columbia, Alberta, Quebec, and Newfoundland and Labrador authorize pharmacists to adjust the dosage of existing medication in response to monitoring. Saskatchewan, Manitoba and Nova Scotia are considering granting pharmacists the authority to do so as well.

Prescribing pharmacists in Alberta can prescribe any Schedule I drug and blood products if it is not reasonably possible for the patient to see a health professional to obtain the prescription and if there is an immediate need for the drug or blood product, in accordance with the Pharmacists' Standards of Practice.²⁰ There are no lists of drugs; instead, pharmacists are expected to limit their prescribing to situations where they have an adequate understanding of the condition being treated and the drug being prescribed and they have adequate knowledge about the specific patient.²¹

Managing the Risk of Harm

There is an emerging body of evidence that suggests that expanding the role of the pharmacist can benefit the patient. In its scope of practice review of pharmacy, HPRAC highlighted studies cited by the OCP supporting this conclusion. One study states that "in comparing patterns of potentially inappropriate drug therapy prescribing in community-dwelling older adults and nursing home residents in Ontario in 2001, researchers found that nursing home residents were close to half as likely to be dispensed a potentially inappropriate drug therapy as community-dwelling older adults. Clinical pharmacist services, which are mandated in the nursing home setting, were thought to be responsible for these differences."

¹⁹ OCP Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 32.

²⁰ Pharmacists Profession Regulation, AR 129/2006, s. 16.

²¹ HPRAC. *Prescribing and Use of Drugs by Non-Physician Health Professionals: A Jurisdictional Review of the Profession of Pharmacy*. November 2008.

The OCP says that “Medications have been a key concern in patient safety, not only from the perspective of adverse events and interactions with other drugs, but also in accurate communication among health professionals about a patient’s medication therapy as they receive services in different health sectors.” Further, the OCP says that “recognition of the expertise of the pharmacist in medication management and their role in promoting health, preventing and treating diseases, dysfunctions and disorders introduces little or no new risk to patients because, in many cases, pharmacists already perform these duties.” In support of its claim, the OCP says, “Patient safety will increase as more proactive involvement of pharmacists in medication therapy management and other medication-related activities have been found to reduce medication-related problems”.

The number of patients with complex chronic conditions in Ontario is likely to increase as the population continues to age. Pharmacists will be able to assist these patients with their medication therapy management in a wide variety of circumstances.

There is evidence that the OCP is a leader in the development of quality assurance programs for pharmacists. The OCP would be responsible for setting standards of practice associated with the additional clinical services that pharmacists would provide in the proposed practice. It is expected that new standards for record keeping would be developed in addition to guidelines for collaboration with other health professionals.²²

Meeting New Requirements

To provide adequate safeguards in medication management, the OCP has stated that it will put needed safeguards in place to ensure collaboration and ongoing communication among health care professionals to ensure the best care for patients.

Should pharmacists be granted the medication management authority, the OCP would:

- Adopt and/or adapt existing practice standards and guidelines in use in other Canadian jurisdictions where pharmacists are currently able to prescribe.²³
- Adapt and upgrade the Quality Assurance Program to include assessments relating to prescribing.²⁴

As both prescribing and administration of drugs are currently outside of the pharmacists’ scope of practice, the OCP does not now require continuing education or training for members to ensure competency in these areas. The OPA notes that material from other jurisdictions could be adapted for Ontario’s purposes if these acts are granted.²⁵

²² OPA Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 11.

²³ OCP Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 32.

²⁴ Ibid. 31.

²⁵ OPA Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 13.

HPRAC's Conclusions

On balance, HPRAC is confident that any additional risks can be addressed by the detailed standards, with terms, limitations and conditions that would be developed by the OCP through an enabling regulatory framework, including the role of interprofessional collaboration, mandated communication with the original prescriber, and post-registration education.

HPRAC therefore recommends that pharmacists be authorized to undertake medication therapy management activities as an essential part of their scope of practice.

Lists or Classes of Drugs

Pharmacists have requested that drug regulations under the *Pharmacy Act, 1991* should include open prescribing authority rather than therapeutic classes of drugs. HPRAC is of the view that regulations authorizing therapeutic classes of drugs provide pharmacists with enough latitude to practice to their full scope of practice. HPRAC is not convinced that the existence of classes will become onerous or restrict the pharmacist's ability to adapt, modify or extend prescriptions. If the recommended new drug approvals process is put in place, approval of new classes of drugs should proceed more expeditiously. The process of approvals of specific agents within classes, outside of the regulation-making process, should be more efficient as well.

Medication for Emergency Situations

The proponents have requested that medications for use in emergency situations be authorized to the profession of pharmacy. The provision of emergency "crash cart" kits for a number of professions is based on the risks some health professionals face in a clinical practice setting where clinical procedures are carried out in an office or clinic. HPRAC is not convinced that this kit is necessary for pharmacists, as they are not performing in-office or in-clinic procedures. Emergency situations in a pharmacy setting would be relatively rare; therefore, HPRAC has concluded that the emergency provisions under section 29 of the *Regulated Health Professions Act, 1991* are adequate to meet these needs.

Travel Prophylaxis

In the scope of practice review, the OPA proposed that pharmacists be authorized to initiate therapy for travel prophylaxis subject to additional training (including prescribing Schedule I drugs such as mefloquine, chloroquine, atovaquone/proguanil, relevant vaccines, acetazolamide, antibiotics in case of traveller's diarrhea). The OCP did not include this request in its submission. Authorizing pharmacists to initiate therapy for travel prophylaxis subject to additional training concerns two specific controlled acts: prescribing a drug, and administering a substance by injection.

As noted in the scope of practice review, while HPRAC sees this as a potential matter for consideration in the future, it does not find any compelling reason to recommend this proposal at this time.

2: A Minor Ailments Protocol

In response to HPRAC's review of a potential introduction of a minor ailments program in Ontario, the OCP and the OPA have proposed a minor ailment protocol to authorize pharmacists to prescribe from a limited formulary. The OCP proposed that pharmacists be limited to Schedule II and III drugs. The request from the OPA differs in that it proposes that pharmacists be able to prescribe Schedule I, II and III drugs. At the time of their proposals, neither organization had an opportunity to review HPRAC's recommendations about a minor ailments program in Ontario.

As it had in the scope of practice review, the OPA proposed that pharmacists be authorized to prescribe Schedule I drugs from a limited formulary for the purposes of smoking cessation, travel prophylaxis and in emergencies.²⁶ Drugs to be used in emergencies include beta-2 agonists, in the case of an acute asthmatic reaction, and antivirals for influenza treatment/prophylaxis.²⁷

The OPA said that for the initiation of Schedule I drugs, a combination of conditions and circumstances, class of drugs and a list of specific drugs would best respond to the competencies of the profession. Furthermore, the OPA said that any list would have to be reviewed and revised on a regular schedule, at least biannually, to ensure it is current.²⁸ To accommodate the future evolution of pharmacists' scope of practice, the OPA requests that limitations and conditions on the proposed changes to the *Pharmacy Act, 1991* be placed in standards of practice.²⁹

Proponents' Rationale

The purpose of minor ailments programs is to relieve pressure on primary care by providing an alternative for patients seeking treatment for minor ailments. In many cases, a patient will not need to visit a physician to receive treatment.

Minor ailment schemes have been established in Great Britain, and according to HPRAC's interviews with the United Kingdom National Prescribing Centre, are supported by patients and appear to be working well. These programs enable pharmacists to treat a number of common ailments such as athlete's foot and dermatitis. The authority to prescribe drugs is generally centred on a detailed agreement with the local health trust, based on interprofessionally developed formularies and treatment protocols.

²⁶ Ibid. Appendix B.

²⁷ Ibid. 8.

²⁸ Ibid. 19.

²⁹ Ibid. 10.

In managing a patient, you sometimes have to step outside a narrowly defined formulary because each patient is different. Having a limited formulary will defeat the purpose.³⁰

Clive Jackson
CEO, UK National Prescribing Centre
Interview with HPRAC, November, 2008

The OCP cites preliminary data on the British minor ailment schemes that demonstrates increased access by the public to necessary health services for minor ailments, increased access to physicians by patients who are more seriously ill, and overall cost savings to the NHS. IMS Health analysed anonymous patient records from its database of 210 general practices across the United Kingdom, covering four million patient records and 190 million prescriptions. Data from 500,000 patients who had consulted their physician about a minor ailment suggested that, in 2006/2007, 51.4 million general practitioner consultations a year were solely for minor ailments. Estimated at eight minutes per consultation, this represents 18 percent of a general practitioner's workload or an hour a day for each general practitioner.

What HPRAC Found

Readiness for Change

Both the OCP and OPA submit that pharmacists are appropriately trained for initiating a prescription for minor ailments. The OPA in its submission states that “pursuant to in-depth consultations with their patients, pharmacists have been assessing their symptoms and when appropriate, prescribing Schedule II and III medications for decades. Expansion of this role to include a limited number of minor ailments that might require treatment with Schedule I medications can be easily supported through enhanced training ... perhaps in a multidisciplinary fashion alongside medical and nursing students.” The organizations also make it clear that not all pharmacists will undertake these activities, and see the expanded scope as voluntary and not mandatory. The OCP maintains that it is, and will always be, the pharmacist's responsibility to practice within his or her individual scope of practice.

Managing the Risks of Harm

Unlike medication therapy management, in a minor ailments program there would not be an original prescription from another authorized prescriber; rather, the pharmacist would be the first point of contact for the patient and thus initiate drug therapy. Several safeguards would need to be in place to minimize the risk of harm to patients, including interprofessionally developed formularies, clinical protocols and mandatory referral protocols.

³⁰ UK National Prescribing Centre Meeting Notes. November, 2008: 3.

Both the OCP and the OPA maintain that the kinds of minor ailments under consideration are the same ones for which pharmacists are currently counselling patients in their day-to-day practice. The OCP notes in its submission to HPRAC that none of the changes recommended are intended to obligate an individual pharmacist to perform any activity he or she feels is outside of their training or competence.

Meeting New Requirements

The OPA states that although prescribing for minor ailments is an entry-to-practice competence, a review of the pertinent therapeutics should be available for those pharmacists who feel they would benefit.³¹ For those acts that are a progression of pharmacists' current scope of practice, such as prescribing Schedule I products as part of a minor ailment protocol, the OPA believes that continuing education or, when necessary, certification programs will mitigate any perceived risk of harm.³² For other aspects of prescribing the OPA has indicated that pharmacists would need to undertake additional education to ensure that high standards are consistently maintained, as patient safety is paramount.³³

Before pharmacists can prescribe, new standards of practice will need to be developed which take into account the different types of prescribing and the accountabilities and liabilities associated with each.³⁴ Furthermore, the OPA proposes a mandatory orientation for all pharmacists willing to practice within an expanded scope to provide awareness of the new roles, responsibilities, and accountabilities associated with the ability to prescribe, while making certain that pharmacists only engage in those activities they have the knowledge and skills to perform safely.³⁵

The OCP has said that in a minor ailments program, the OCP would consider three levels of competency, including entry level where all pharmacists are competent, a level where only certified pharmacists have competence, and a level where only Pharm D graduates have competence; protocols and standards of practice for each level would be developed in collaboration with physicians.³⁶

What Other Jurisdictions Are Doing

In Quebec, pharmacists currently need a prescription or protocol to initiate therapy for minor ailments. Saskatchewan and Manitoba are considering changes to allow pharmacists expanded authority under a minor ailments scheme.

In Alberta, a clinical pharmacist is authorized to prescribe Schedule I drug and blood products if it is not reasonably possible for the patient to see a health professional to obtain the prescription and if there is an immediate

³¹ OPA Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 19.

³² Ibid. 10.

³³ Ibid. 19.

³⁴ Ibid. 18.

³⁵ Ibid. 16.

³⁶ Pharmacy Meeting Notes: 8.

need for the drug or blood product, in accordance with the Pharmacists' Standards of Practice.³⁷ There are no lists of drugs; instead, pharmacists are expected to limit their prescribing to situations where they have an adequate understanding of the condition being treated, the drug being prescribed and adequate knowledge about the specific patient.³⁸

HPRAC's Conclusions

HPRAC continues to be satisfied that pharmacists have the necessary training to participate in a minor ailments program, and to support the development of a minor ailments program in Ontario, where pharmacists would be authorized to prescribe drugs from a limited formulary. However, HPRAC is of the opinion that it is premature to adopt a minor ailments protocol at this time, and recommends that this issue be referred to a minor ailments working group, led by the OCP and the OPA, as recommended in the scope of practice review of the pharmacy profession.

Request 3: An Advanced Class of Pharmacist

The OCP is requesting regulatory amendments to the *Pharmacy Act, 1991* to allow the flexibility to establish an advanced class of pharmacist practitioner when appropriate to accommodate the changing education and training of new pharmacists.³⁹

Proponents' Rationale

The proponents note that plans are underway to implement significant enhancements to the pharmacy education programs both at the University of Toronto and University of Waterloo.

Provided government approval is received for Pharm D programs, and with the addition of clinical rotations, pharmacists will graduate from the University of Toronto with Pharm D degrees in 2014 and 2008 program entrants at the School of Pharmacy, University of Waterloo could be awarded Pharm D degrees in 2012 or 2013. The new programs will graduate pharmacists from a more robust, enhanced curriculum, expecting to practice in an expanded role that may include, among other activities, administering drugs by injection and initiating drug therapy in collaborative practice environments under certain conditions.⁴⁰

The University of Toronto Leslie Dan Faculty of Pharmacy will also offer an educational bridging program to Bachelor of Science degree pharmacists wishing to upgrade their knowledge, skills and ability to the Doctor of Pharmacy (Pharm D) level.

³⁷ Pharmacists Profession Regulation, AR 129/2006, s. 16.

³⁸ HPRAC. *Prescribing and Use of Drugs by Non-Physician Health Professionals: A Jurisdictional Review of the Profession of Pharmacy*. November 2008.

³⁹ OCP Submission to the HPRAC Review of Non-Physician Prescribing and Administration of Drugs: 35.

⁴⁰ Ibid. 36.

HPRAC's Conclusions

HPRAC understands that pharmacists currently holding a Pharm D have extensive knowledge and very specialized skill sets. It is not yet clear whether this same level of skill set will be acquired by graduates from the new Pharm D programs. HPRAC has therefore concluded that this issue needs further consideration and examination, and is outside the scope of this review.

Recommendations

1: Medication Therapy Management

That pharmacists be authorized to prescribe Schedule I, II or III drugs, blood products and oxygen for the purpose of medication therapy management, in accordance with the standards of practice of the OCP.

That regulations under the *Pharmacy Act, 1991* designate therapeutic classes of drugs.

That pharmacists be expected to limit prescribing to situations where they have an adequate understanding of the condition being treated, the drug being prescribed and adequate knowledge about the specific patient.

2: Minor Ailments Program

HPRAC recommended in the scope of practice review of pharmacy that steps be taken towards the introduction of a minor ailments program in Ontario. To that end:

- That the OCP and the OPA, in collaboration with the Ontario Medical Association, the College of Physicians and Surgeons of Ontario, the College of Nurses of Ontario, the Registered Nurses' Association of Ontario, the Nurse Practitioners' Association of Ontario, other health professions, facilities, educators and Ministry representatives develop the details of a program that would be suitable in Ontario, including: the list of minor ailments that pharmacists could treat; an agreed formulary including Schedule I, II and III drugs; protocols for referral to and communication with other health professionals, obtaining patient consent, and record-keeping; options for reimbursement for professional services; and educational and competency requirements and quality assurance, among other matters. The working group should also outline an implementation plan, including any pilot projects that might be required, along with communications elements to advise patients of the program.
- That the OCP develop standards of practice, through an interprofessional standards committee, for a minor ailments program.

HPRAC has concluded that it is premature to develop a minor ailments protocol at this time, and recommends that this issue be referred to the minor ailments working group.

3: Travel Prophylaxis

As recommended in HPRAC's scope of practice review, HPRAC continues to recommend that pharmacists not be authorized to independently initiate therapy for travel prophylaxis.

4: Advanced Class of Pharmacist

That this question should be considered in a separate review.

5. Designated Drug Regulation

HPRAC recommends that the following therapeutic classes of drugs be included in the designated drugs regulation under the *Pharmacy Act, 1991*. The specific agents and any terms, limitations or conditions attached to the authority to prescribe drugs would be developed through a new drug approvals framework. In the first instance, the condition "For the purpose of medication therapy management" would be attached to the drug classes for pharmacy.

The following are the proposed therapeutic classes for pharmacist prescribing. All classes are listed except anti-neoplastics and narcotics. Other exceptions include: a select number of classes listed in AHFS formulary such as "enzymes", "gold compounds" (advanced treatment of arthritis), "local anaesthetics", "oxytocics", "radioactive agents", "serums, toxoids and vaccines" and "heavy metal antagonists".

Class
Class: Antihistamine Drugs
Class: Anti-infective Agents
Class: Autonomic Drugs
Class: Blood formation, coagulation, and thrombosis agents
Class: Cardiovascular Drugs
Class: CNS Agents Sub-class: Analgesics and Antipyretics Sub-sub-class: NSAIDs
Class: CNS Agents Sub-class: Anticonvulsants

Class
Class: CNS Agents Sub-class: Psychotherapeutic Agents
Class: CNS Agents Sub-class: Anorexigenic Agents and Respiratory and Cerebral Stimulants
Class: CNS Agents Sub-class: Anxiolytics, Sedatives, and Hypnotics
Class: CNS Agents Sub-class: Antimanic Agents
Class: CNS Agents Sub-class: Antimigraine Agents
Class: CNS Agents Sub-class: Antiparkinsonian Agents
Class: Electrolytic, Caloric, and Water Balance
Class: Respiratory Tract Agents
Class: Eye, Ear, Nose, and Throat Preparations
Class: Gastrointestinal Drugs
Class: Hormones and Synthetic Substitutes
Class: Skin and Mucous Membrane Agents
Class: Vitamins
Class: Miscellaneous Therapeutic Agents

Implementation Proposals

The following recommendations incorporate both HPRAC's recommendations in this project and the recommendations made in HPRAC's scope of practice review of the pharmacy profession. As a result of HPRAC's recommendations for a new drug approval process, some of the statutory and regulatory changes recommended in the earlier report have been modified.

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That section 3 of the *Pharmacy Act, 1991* be repealed and the following substituted:

Scope of practice

3. The practice of pharmacy is the promotion of health and the prevention and treatment of diseases, disorders and dysfunction through the monitoring and management of medication therapy; the custody, prescribing, compounding and dispensing of drugs; and the provision of health care aids and devices and education related to their use.
2. That section 4 of the *Pharmacy Act, 1991* be repealed and the following substituted:

Authorized acts

4. In the course of engaging in the practice of pharmacy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:
 1. Dispensing, selling or compounding a drug or supervising the part of a pharmacy where drugs are kept.
 2. Skin pricking for the purpose of educating patients on the use of health care aids and devices and for the purpose of monitoring chronic diseases.
 3. Administering, by injection or inhalation, a substance for the purpose of patient education or demonstration.
 4. Prescribing a drug that the member may prescribe under the regulations.
3. That the *Pharmacy Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts

- 4.1 A member shall perform a procedure under the authority of paragraphs 2, 3 or 4 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.
- 4.2 A member shall not perform a procedure under the authority of paragraph 3 of section 4 unless the substance is prescribed by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the prescription.

Individual scope of practice for pharmacists

4.3 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

4. That the *Pharmacy Act, 1991* be amended by adding the following section:

Regulations

14. Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,

- (a) regulating the prescribing of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing of drugs; and
- (b) specifying requirements for the performance of procedures under the authority of paragraphs 2 or 3 of section 4.

5. That section 28 of PART IV of Ontario Regulation 202/94 under the *Pharmacy Act, 1991* (General) be amended by adding the following:

- (4)** It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 3 or 4 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.
- (5)** It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 2, 3 or 4 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.
- (6) (a)** For the purposes of this section, “Drug List” has the meaning given to it in the *Regulated Health Professions Act, 1991*.
- (b)** A member may prescribe the following classes of drugs:
 - i) antihistamine drugs,
 - ii) anti-infective agents,
 - iii) autonomic drugs,
 - iv) blood formation, coagulation and thrombosis agents,

- v) cardiovascular drugs,
- vi) CNS agents – analgesics and antipyretics - NSAIDs, anticonvulsants, psychotherapeutic agents, anorexigenic agents and respiratory and cerebral stimulants, anxiolytics, sedatives and hypnotics, antimanic agents, antimigraine agents, antiparkinsonian agents,
- vii) electrolytic, caloric and water balance,
- viii) respiratory tract agents,
- ix) eye, ear, nose and throat preparations,
- x) gastrointestinal drugs,
- xi) hormones and synthetic substitutes,
- xii) skin and mucous membrane agents,
- xiii) vitamins, and
- xiv) miscellaneous therapeutic agents.

(c) A member may only prescribe drugs under the authority of paragraph 4 of section 4 of the Act:

- (a) for the purposes of either medication therapy management, smoking cessation therapy or as otherwise prescribed in the regulations; and
- (b) only those drugs with the classes designated in subsection 6(b) that are listed in the Drug List and must prescribe those listed drugs in accordance with the terms, limitations and conditions contained in the Drug List.

(7) For the purposes of clause 28(6)(c),

“medication therapy management” means professional activities and responsibilities of the member designed to optimize therapeutic outcomes for a patient according to the needs of the individuals being treated as set out in detail in the standards of practice established and published by the College from time to time; and

“smoking cessation therapy” means professional activities and responsibilities of the member designed to assess, initiate and monitor the most appropriate therapy for smoking cessation, including the prescribing of designated drugs as set out in regulation and in the standards of practice established and published by the College from time to time.

6. That section 29.1(a) of Ontario Regulation 202/94 under the *Pharmacy Act, 1991* (General) be repealed and the following substituted:

29.1 (a) prescribe, dispense, sell or compound drugs;

7. That section 38(1) of Ontario Regulation 202/94 under the *Pharmacy Act, 1991* (General) be repealed and the following substituted:

38. (1) In this section,

“advertisement” includes an announcement, directory listing or other form of communication similar to an advertisement; and

“prescription services” means the prescribing, compounding, dispensing or sale by retail of drugs and the provision of information or advice with respect to those drugs.

8. That paragraphs 12, 13 and 15 of section 38(3) of Ontario Regulation 202/94 under the *Pharmacy Act, 1991* (General) be repealed.
9. That Ontario Regulation 202/94 under the *Pharmacy Act, 1991* (General) be amended by adding the following:

PART IX STANDARDS OF PRACTICE

- 52.** The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 2, 3 and 4 of section 4 of the Act.
- 53.** The standards of practice referred to in section 52 shall be developed on the recommendation of the Pharmacy Standards Committee.
- 54.** For the purposes of section 53, the College shall establish the Pharmacy Standards Committee referred to in section 53 and shall appoint the membership of the Pharmacy Standards Committee, which shall include, at a minimum, one or more:
- a) members of the Council;
 - b) members of the College (including practitioners and educators);
 - c) persons who are not and have not been members of the College or of the Council;
 - d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario, who practice family medicine;
 - e) members of the College of Nurses of Ontario, approved by the College of Nurses of Ontario; and
 - f) members of the College of Medical Laboratory Technologists of Ontario, approved by the College of Medical Laboratory Technologists of Ontario.

55. The College shall post the following on its website:

- a) the standards of practice referred to in section 52; and
 - b) a list of those members, who are authorized to perform a procedure under the authority of paragraphs 2, 3 and 4 of section 4 of the Act.
10. That Ontario Regulation 681/93 under the *Pharmacy Act, 1991* (Professional Misconduct) be amended by adding the following section:
- 1.1** Exceeding the scope of practice of the profession.
11. That section 1.2 of Ontario Regulation 681/93 under the *Pharmacy Act, 1991* (Professional Misconduct) be repealed and the following substituted:
- 1.2** Contravening or failing to maintain a standard of practice of the profession.
12. That section 1.5 of Ontario Regulation 681/93 under the *Pharmacy Act, 1991* (Professional Misconduct) be repealed and the following substituted:
- 1.5** Prescribing, dispensing, selling, compounding or administering a drug or substance for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell, compound or administer drugs or substances.
13. That section 1.22 of Ontario Regulation 681/93 under the *Pharmacy Act, 1991* (Professional Misconduct) be repealed and the following substituted:
- 1.22** Contravening, while engaged in the practice of pharmacy, any federal or provincial law or municipal by-law with respect to the distribution, sale, prescribing or dispensing of any drug or mixture of drug.
14. That section 1 of Ontario Regulation 681/93 under the *Pharmacy Act, 1991* (Professional Misconduct) be amended by adding the following sections:
- 1.2.1** Failing to advise a patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such consultation to ensure the proper care of the patient.
- 1.2.2** Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.

- 1.5.1** Being subjected to the withdrawal or restriction of rights or privileges under the *Controlled Drugs and Substances Act* (Canada) or the *Food and Drugs Act* (Canada) or the regulations under either of those Acts, unless by the member's own request.
- 1.9.1** Recommending or providing unnecessary services.
- 1.31** Delegating an act set out in paragraph 1, 2 or 3 of section 4 of the Act except as permitted by the *Regulated Health Professions Act, 1991* or the regulations made thereunder or under the Act, or delegating an act set out in paragraph 4 of section 4 of the Act.
15. That section 3(1) of Ontario Regulation 297/96 under the *Drug and Pharmacies Regulation Act* (General) be repealed and the following substituted:
- 3(1)** In this section,
- “advertisement” includes an announcement, directory listing or other form of communication similar to an advertisement;
- “prescription services” means the prescribing, compounding, dispensing or sale by retail of drugs and the provision of information or advice with respect to those drugs.
16. That paragraphs 3(4)12, 13 and 15 of 297/96 under the *Drug and Pharmacies Regulation Act* (General) be repealed.
17. That paragraph 9(1)(a) of Ontario Regulation 682 under the *Laboratory and Specimen Collection Centre Licensing Act* (Laboratories) be amended by adding the following:
- (iv.3)** at the request of a pharmacist, in respect of a test specified in Appendix F.
18. That Ontario Regulation 682 under the *Laboratory and Specimen Collection Centre Licensing Act* (Laboratories) be amended by adding Appendix F.
19. That paragraph 4(2)(b) of Ontario Regulation 683 under the *Laboratory and Specimen Collection Centre Licensing Act* (Specimen Collection Centres) be amended by adding the following:
- (iv.3)** a pharmacist,
20. That PART III – PERSONS PRESCRIBED TO ORDER TESTS of Ontario Regulation 207/94 under the *Medical Laboratory Technology Act, 1991* (General) be amended by adding the following:
- 5.** A member of the Ontario College of Pharmacists.

21. That section 2(1) of the *Health Care Consent Act, 1996* be amended by adding the following:

(s.1) a member of the Ontario College of Pharmacists,

22. That the Minister of Health and Long-Term Care, with consultation with the College of Pharmacists, amend sections 30, 31 and 32 of PART IV Ontario Regulation 202/94 under the *Pharmacy Act, 1991* to recognize University of Waterloo students and interns in addition to those from University of Toronto.

THE PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF PHYSIOTHERAPY

The College of Physiotherapists of Ontario (CPO) and the Ontario Physiotherapy Association (OPA) made a joint submission to HPRAC requesting that physiotherapists be granted the authority to administer, by inhalation, oxygen or drugs that have been prescribed by a health professional with prescribing authority.

Review of Physiotherapy Scope of Practice

HPRAC recently reviewed the scope of practice for the profession of physiotherapy. In that review, the CPO and the OPA partnered with the academic community to submit a joint response to HPRAC's scope of practice questionnaire.

The profession requested a number of changes including amendments to its scope of practice statement and authorized acts in the *Physiotherapy Act, 1991*. One of the requests was specific to the controlled act of administration of a substance by inhalation, and proposed that physiotherapists should be authorized to administer oxygen or other substances when the order or prescription has been made by a person who is authorized to do so.¹ HPRAC's recommendations included:

That physiotherapists be authorized to administer oxygen or an inhaled drug or substance that has been ordered by a person authorized to do so.²

HPRAC also recommended that the scope of practice statement for physiotherapy be amended to read:

The practice of physiotherapy is the assessment of neuromuscular, musculoskeletal and cardiorespiratory systems, the diagnosis of diseases or disorders that are associated with physical dysfunction, injury or pain to develop, maintain, rehabilitate or augment function, to relieve pain or to promote mobility.

HPRAC was also asked by the Minister to consider the prescribing and use of drugs by non-physicians, and determined that scope of practice reviews were an essential first step in making recommendations on whether a profession should be authorized to prescribe, dispense, compound or sell drugs, and under what conditions. The administration of drugs is an essential component of the Minister's question about the "use" of drugs. HPRAC therefore considered the question of drug regulations under the *Physiotherapy Act, 1991* as a matter to be considered as the second phase of its examination, following the review of the scope of practice of the profession.³

¹ College of Physiotherapists of Ontario and Ontario Physiotherapy Association. Joint submission to HPRAC on Interprofessional Collaboration: 4.

² HPRAC. *Interim Report to the Minister*. September 2008: 175.

³ Ibid./

In this current review of prescribing and use of drugs by health professions, the CPO and the OPA are consistent with their recommendation that physiotherapists have demonstrated their competencies to administer certain drugs and substances by inhalation.⁴

HPRAC's Central Response

HPRAC concluded in its review of the scope of practice of physiotherapy that members have the knowledge, skill and judgment as entry to practise competencies, to administer oxygen or other drugs or substances by inhalation. The procedure must be ordered by persons authorized to do so and can be undertaken within the practice of physiotherapy interventions to maintain or improve cardiopulmonary function.

Physiotherapy in Ontario

The practice of physiotherapy has evolved significantly over the last 20 years, as practitioners' skills are being maximized in new models of collaborative care.⁵ The current scope of practice of physiotherapy is "the assessment of physical function and the treatment, rehabilitation and prevention of physical dysfunction, injury or pain, to develop, maintain, rehabilitate or augment function or to relieve pain".⁶ The profession is seeking, and HPRAC recommended in its recent review of the scope of practice of physiotherapy, a broadened scope of practice to reflect the full competencies of members of the profession.

Physiotherapy is governed through the *Regulated Health Professions Act, 1991 (RHPA)* and the *Physiotherapy Act, 1991*. The CPO is the regulatory body for the profession and ensures safe, effective physiotherapy care through regulations, by-laws and standards of practice to which all members must adhere. The CPO sets standards for entry into the profession and develops programs to enhance the practice of physiotherapists in Ontario. The OPA is the voluntary professional association representing physiotherapists throughout the province. There are approximately 6,400 registered physiotherapists in Ontario.⁷

There are five accredited graduate degree programs in physiotherapy in Ontario.

⁴ College of Physiotherapists of Ontario and Ontario Physiotherapy Association. Joint submission to HPRAC on Interprofessional Collaboration: 4

⁵ HPRAC. Interprofessional Collaboration Phase II, Part 1: 163.

⁶ *Physiotherapy Act, 1991*, c. 37, s.3.

⁷ CPO. <http://www.collegept.org> retrieved Jan 4/09.

Authorized Acts

In the course of engaging in the practice of physiotherapy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Moving the joints of the spine beyond a person's usual physiological range of motion using a fast, low amplitude thrust.
2. Tracheal suctioning.⁸

Currently, the administration of a drug or substance by inhalation by a physiotherapist is performed under medical directive, order or delegation from a physician or other health professional.

Delegation of a controlled act is authorized by the *RHPA*. It is a process whereby a regulated health professional who is authorized to perform a controlled act confers that authority to someone, regulated or unregulated, who is not so authorized.⁹ Delegation may be established in one of two ways: by order or by designation. The accountability for the performance and safety of the controlled act remains with the health professional who has made the delegation.

Education and Continuing Competency

There are five accredited physiotherapy programs at universities in Ontario and eight others in Canada. To practise in Ontario, physiotherapists must have graduated from a university program in physiotherapy and have successfully passed the National Physiotherapy Competency Examination. The programs are accredited by the Accreditation Council for Canadian Physiotherapy Academic Programs.

The entry to practise education and training requirements conform to the curriculum guidelines of the Canadian Universities Physiotherapy Academic Council, the Accreditation Standards for Physiotherapy Education Programs in Canada and the Essential Competency Profile for Physiotherapists in Canada.¹⁰

The physiotherapy entry to practise curricula in all Ontario university programs includes content related to the administration of oxygen, including exercise physiology, the use of oxygen, maintaining oxygen saturation, the technology for measuring oxygen saturation and the interpretation of measured values. Students learn about multiple conditions in which supplemental oxygen is used and in which oxygen saturation is monitored, for example, exercise in post-operative patients or in patients with chronic obstructive pulmonary disease and during suctioning of patients in an intensive care unit. Knowledge of national practice guidelines, including evidence for hyperoxygenation with suctioning, is required.

⁸ *Physiotherapy Act, 1991*, c. 37, s.4.

⁹ Federation of Health Regulatory Colleges of Ontario. *An Interprofessional Guide on the Use of Orders, Directives and Delegation for Regulated Health Professionals in Ontario*. <http://www.mdguide.regulatedhealthprofessions.on.ca/orders/what/default.asp>.

¹⁰ CPO and OPA. Joint submission to HPRAC. 40.

Students are evaluated by written and practical examinations.¹¹ Entry to practise skills include the administration of inhaled drugs for cardiorespiratory conditions. Specifically, the pharmacology and indications for inhaled drugs that affect respiratory status and for which timing of dosage is relevant to secretion clearance and exercise are included in the curricula.¹²

Competency Evaluation

At the entry to practise level, administration of oxygen and other inhaled drugs is evaluated in the national Physiotherapy Competency Examination. In the examination blueprint, one of the elements listed under interventions is “administer oxygen as prescribed.”¹³

For therapists practicing in hospitals under medical directive, evaluation of competency is specific to the institution. The process for this evaluation is most frequently through a self-study examination. Other hospital personnel who are authorized to perform this act must be engaged in physiotherapy educational reviews and competency evaluation sessions.¹⁴ Proficiency is demonstrated through practical application, following which the medical directive is signed by a respiratory therapist.

There is sufficient evidence that the administration of oxygen and other inhaled substances is an entry-level competency held by physiotherapists.

Request for Change: Administering Drugs and Substances by Inhalation¹⁵

The CPO and the OPA submit that physiotherapists have the education and competencies to be granted the authority to administer, by inhalation:

- i) Oxygen, or
- ii) A drug or substance that has been ordered by a person who is authorized to do so by the *Chiropody Act, 1991*, the *Dentistry Act, 1991*, the *Medicine Act, 1991*, the *Nursing Act, 1991* or the *Midwifery Act, 1991*.

Granting this act to the physiotherapy profession will give physiotherapists the authority to administer oxygen and substances such as Ventolin® when required as part of a physiotherapy intervention.¹⁶

¹¹ Ibid: Appendix B, 3.

¹² Ibid: Appendix A, 8.

¹³ Ibid: Appendix A, 9.

¹⁴ Ibid: 24.

¹⁵ Ibid: 14.

¹⁶ Ibid: 16.

Proponents' Rationale

The profession maintains that access to this authority will bring regulation into closer alignment with physiotherapists' current knowledge, competence and practice realities.

Prior to the *RHPA*, physiotherapists routinely administered oxygen to maintain saturation during interventions such as exercise, training, endurance assessment, tracheal suctioning and treatments related to the mobilization of secretions.¹⁷ Since oxygen de-saturation can often occur with these interventions, the authority to administer oxygen during physiotherapy treatment is critical to care. Currently, if a patient needs oxygen, or needs to have oxygen levels adjusted to maintain the blood oxygen saturation level at a prescribed level while performing exercises under the supervision of a physiotherapist, another health professional must be present to administer the oxygen or to adjust the levels.¹⁸

In Ontario, physiotherapists have the authority to perform tracheal suctioning of intubated patients but do not have the independent authority to administer oxygen, which is a normal adjunct to this procedure.¹⁹ Oxygen levels often decrease when tracheal suctioning is performed. Oxygen must then be adjusted to maintain the patient's appropriate blood oxygen saturation level. Standing orders or medical directives often do not authorize the adjustment of oxygen by a physiotherapist, and another health professional, such as a nurse or a respiratory therapist, must perform the procedure.

Without the authority to administer oxygen, the hospitals in which physiotherapists work must engage in lengthy processes to develop medical directives to allow physiotherapists to perform an act which is an entry-level qualification. The expanded administrative burden medical directives place on institutions and authorized providers perpetuates the underutilization of competent health professionals and undermines responsiveness to patient needs and system efficiency.

Outside hospitals, many home care and long-term care patients undergoing physiotherapy treatments experience a decrease in blood saturation levels for which the administration of oxygen is required.²⁰ Authorizing physiotherapists to perform the act would eliminate the need to schedule the services of a health professional whose specialized skills could be better used elsewhere. This would result in more timely access to care for all patients, reduced complications for home-bound patients and fewer admissions to hospital.

¹⁷ Ibid: 24.

¹⁸ Ibid: 8.

¹⁹ Ibid: 16.

²⁰ Ibid: Appendix A, 8.

What HPRAC Found

During HPRAC's review of scope of practice for physiotherapists, HPRAC heard reports from educators that the CPO's requests correspond to what is permitted in other parts of Canada.²¹ In other provinces and territories, physiotherapists are authorized to perform a number of the proposed acts submitted by the CPO and the OPA in the scope of practice review, including the administration of oxygen by inhalation.

The act of administering oxygen is integral to tracheal suctioning because oxygen levels often decrease when tracheal suctioning is performed to clear secretions. Best practice around the management of ventilated patients suggests that patients should receive additional oxygenation prior to suctioning. Oxygen is required in order to maintain optimum blood oxygen saturation levels.²²

HPRAC met with physiotherapy educators who stressed that, with a few minor adjustments, existing academic programs would cover all of the procedures requested.²³ Furthermore, other colleges and associations whose members work closely with physiotherapists indicated broad agreement with the proposals put forth by the CPO and the OPA. In some cases, professions who currently perform some of the functions that physiotherapists are requesting be added to their scope, such as respiratory therapists, were also supportive of the expansion of physiotherapists' roles.

The College of Respiratory Therapists of Ontario stated, "it would make a lot of sense for physiotherapists to be able to administer oxygen," since this is an entry to practise competency. It is a duplication of efforts to delegate to physiotherapists in clinical practice. The Ontario Society of Occupational Therapists was supportive of an expansion of the scope of practice of physiotherapists in that it would lend "flexibility for systemic growth and evolution of practice."²⁴

Consultations with Local Health Integration Networks, community care access centres (CCACs) and long-term care homes indicated that physiotherapists help to provide timely, effective patient care and reduce emergency visits.²⁵

In subsequent meetings with the proponents following the release of HPRAC's scope of practice review of physiotherapy, HPRAC clarified an issue regarding the administration of oxygen during physiotherapy treatment: whether it can involve mechanically and non-mechanically ventilated patients. HPRAC heard from the OPA that "mechanical ventilation is used when the body cannot support breathing on its own". This can be in an acute situation such as we see in intensive care, in subacute situations

²¹ HPRAC. Interprofessional collaboration, Phase II, Part 1: 165.

²² Ibid: 174.

²³ Ibid: 166.

²⁴ Ibid: 166.

²⁵ Ibid: 164.

on hospital wards or in chronic situations in complex continuing care hospitals, long-term care homes or in an individual's residence. Physiotherapists treat in all these situations and are taught and tested on the use of oxygen for these cases. Mechanical ventilation and implications for physiotherapy treatment including oxygen administration are part of the entry-level curriculum for physiotherapists in Canada. The presence of mechanical ventilation does not mean a barrier to physiotherapists and their use of oxygen".²⁶

Conclusions

During its scope of practice review of physiotherapy, HPRAC found little concern with this request, other than that it be clarified that the profession was seeking the administration of oxygen or drugs, and not the initiation of orders or prescriptions. HPRAC is satisfied that this act can be authorized to the profession, as an entry to practise competency, within physiotherapy interventions to maintain or improve cardiopulmonary function. As in its previous recommendations, the prescribing or ordering of oxygen, drug or substance would be done by a health professional authorized to do so by his or her own professional scope.

Recommendations

1. That physiotherapists be authorized to administer oxygen or an inhaled drug or substance that has been ordered by a person authorized to do so.

Implementation Proposals

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That section 3 of the *Physiotherapy Act, 1991* be repealed and the following substituted:

Scope of practice

3. The practice of physiotherapy is the assessment of neuromuscular, musculoskeletal and cardiorespiratory systems, the diagnosis of diseases or disorders that cause or are associated with physical dysfunction, injury or pain, and the treatment, rehabilitation and prevention of physical dysfunction, injury or pain to develop, maintain, rehabilitate or augment function, relieve pain or promote mobility.
2. That section 4 of the *Physiotherapy Act, 1991* be repealed and the following substituted:

²⁶ Consultation with Dorianne Sauvé, President OPA. January 2008.

Authorized acts

4. In the course of engaging in the practice of physiotherapy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:
 1. Communicating a diagnosis identifying, as the cause of an individual's symptoms, a disease, disorder or dysfunction that may be identified through a physiotherapy assessment.
 2. Treating a wound by cleansing, soaking, irrigating, probing, debriding, packing or dressing the wound.
 3. Moving the joints of the spine beyond a person's usual physiological range of motion using a fast, low amplitude thrust.
 4. Administering by inhalation oxygen, a drug or substance for the purpose of maintaining or improving cardiopulmonary function during physiotherapy interventions.
 5. Tracheal suctioning.
 6. Putting an instrument, hand or finger beyond the labia majora or the anal verge for the purpose of manipulating the tailbone and for the purpose of assessing or rehabilitating pelvic musculature associated with urinary or fecal incontinence.
 7. Ordering the application of a prescribed form of energy.
3. That the *Physiotherapy Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts

- 4.1 A member shall perform a procedure under the authority of paragraph 1, 2, 4, 6 or 7 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.
- 4.2 A member shall not perform a procedure under the authority of paragraph 4 of section 4 unless the procedure is ordered, or the oxygen, drug or substance is prescribed, by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the order or prescription.

Individual scope of practice for physiotherapists

4.3 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health professionals.

4. That the *Physiotherapy Act, 1991* be amended by adding the following section:

Regulations

11(b) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations:

- (i) specifying requirements for the performance of procedures under the authority of paragraph 1, 2, 4, 6 or 7 of section 4; and
- (ii) prescribing the forms of energy that a member may order for the purpose of paragraph 7 of section 4 of the Act and prescribing the purpose for which, or the circumstances in which, the form of energy may be ordered.

5. That Ontario Regulation 532/98 under the *Physiotherapy Act, 1991* (General) be amended by adding the following:

6(6) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 1, 2, 6 or 7 of section 4 must: (a) provide satisfactory evidence of successful completion of a post-graduate program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

(7) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 1, 2, 4, 6 or 7 of section 4 must ensure the procedure is performed in accordance with any standards of practice established by the College from time to time.

(8) For the purposes of paragraph 7 of section 4 of the Act, a member may order the application of electromagnetism for magnetic resonance imaging and the application of sound waves for diagnostic ultrasound.

6. That Ontario Regulation 532/98 under the *Physiotherapy Act, 1991* (General) be amended by adding the following:

PART IV
STANDARDS OF PRACTICE

- 27.** The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 1, 2, 4, 6 and 7 of section 4 of the Act.
- 28.** The standards of practice referred to in section 27 shall be developed, established and maintained on the recommendation of the Physiotherapy Standards Committee.
- 29.** For the purposes of section 28, the College shall establish the Physiotherapy Standards Committee referred to in section 28 and shall appoint the membership of the Physiotherapy Standards Committee, which shall include, at a minimum, one or more:
- a) members of the Council;
 - b) members of the College (including practitioners and educators);
 - c) persons who are not and have not been members of the College or of the Council;
 - d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario;
 - e) members of the College of Nurses of Ontario, approved by the College of Nurses of Ontario;
 - f) members of the College of Medical Laboratory Technologists, approved by the College of Medical Laboratory Technologists; and
 - g) members of the College of Medical Radiation Technologists of Ontario, approved by the College of Medical Radiation Technologists of Ontario.
- 30.** The College shall post the following on its website:
- a) the standards of practice referred to in section 27; and
 - b) a list of those members, who are authorized to perform a procedure under the authority of paragraph 2 of section 4.
- 7.** That Ontario Regulation 388/08 under the *Physiotherapy Act, 1991* (Professional Misconduct) be amended by adding the following sections:
- 1.1** Exceeding the scope of practice of the profession.
 - 9.1** Administering oxygen, a drug or substance for an improper

purpose, or otherwise using improperly the authority to administer oxygen, drugs and substances.

42.1 Failing to advise the patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such consultation to ensure the proper care of the patient.

42.2 Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.

43. Recommending or providing unnecessary services.

- 8.** That Ontario Regulation 107/96 under the *Regulated Health Professions Act, 1991* be amended by deleting the word “or” after paragraph 7.1(2)(b), by inserting the word “or” after paragraph 7.1(2)(c) and by adding a new paragraph (d) as follows:

A member of the College of Physiotherapists of Ontario, with respect to ordering the application of soundwaves for diagnostic ultrasound.

- 9.** That subsection 6(1) the *Healing Arts Radiation Protection Act* be amended by adding the following paragraph (g), so that it reads:

6(1) No person shall operate an X-ray machine for the irradiation of a human being unless the irradiation has been prescribed by, ... (g) a member of the College of Physiotherapists of Ontario.

- 10.** That paragraph 9(1)(a) of Ontario Regulation 682 under the *Laboratory and Specimen Collection Centre Licensing Act* be amended by adding the following:

(iv.2) at the request of a physiotherapist, in respect of a test specified in Appendix E, ...

- 11.** That Ontario Regulation 682 under the *Laboratory and Specimen Collection Centre Licensing Act* be amended by adding Appendix E.

- 12.** That paragraph 4(2)(b) of Ontario Regulation 683 under the *Laboratory and Specimen Collection Centre Licensing Act* be amended by adding the following:

(vi) a physiotherapist,

- 13.** That PART III – PERSONS PRESCRIBED TO ORDER TESTS of Ontario Regulation 207/94 under the *Medical Laboratory Technology Act, 1991* be amended by adding the following:

4. A member of the College of Physiotherapy of Ontario.

THE PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF RESPIRATORY THERAPY

The College of Respiratory Therapists of Ontario (CRTO) has proposed that Respiratory Therapists (RTs) be granted the authority to prescribe oxygen. HPRAC carefully considered this request, including an extensive review of the protocols associated with the prescribing and administration of oxygen in various care settings, as well as findings from research and consultations with other health professionals and institutions where oxygen therapy is provided.

HPRAC's Central Response

Providing RTs with the authority to prescribe oxygen will enable members of the profession to practise to the full extent of their recognized competencies and to independently initiate and adjust oxygen therapy according to patient needs. This will provide patients with appropriate care with no increased risk of harm, recognize the knowledge, skills and judgment of members of the profession and reduce unnecessary wait times for discharge from hospitals to home care or long-term care facilities.

Respiratory Therapy in Ontario

The Profession

The practice of respiratory therapy is the provision of oxygen therapy, cardio-respiratory equipment monitoring and the assessment and treatment of cardio-respiratory and associated disorders to maintain or restore ventilation. RTs are health professionals who monitor, evaluate and treat individuals with respiratory and cardio-respiratory disorders.¹

RTs provide patient care for adults, children and newborns for the following purposes:

- Critical care, including emergency, intensive care and trauma services;
- Anaesthesia support;
- Non-critical patient assessment and treatments;
- Support for patients in their residences;
- Diagnostic testing services, including analysis of blood for oxygen and carbon dioxide levels (arterial blood gas analysis) and various other blood values;
- Analysis of pulmonary function (volumes in/out of lungs; amount of oxygen and carbon dioxide moving between the lungs and the blood, ability to move volumes in/out of lungs);

¹ College of Respiratory Therapists of Ontario. *What is a Respiratory Therapist?*
www.crto.on.ca/html/whatistrt.htm.

- Analysis of the body's response to stress (exercise), cardiac electrical activity electrocardiogram (ECG); sleep studies (polysomnography);
- Transporting patients to the hospital and between hospitals; and Cardiopulmonary resuscitation (CPR); controlling and supplying medical gases; patient, family and caregiver education; and health promotion.²

RTs work collaboratively with other health professionals in both hospital and community-based settings, including public hospitals, asthma centres, community health centres, long-term care homes and rehabilitation facilities. People with conditions such as asthma, chronic bronchitis, emphysema, occupational lung disease and cystic fibrosis, may use oxygen therapy at home, with routine assessments provided by RTs who are employed by oxygen suppliers.

CERTO reports a 2007/2008 total membership of 2,516 regulated RTs (including 179 inactive members).³ This is an increase of 129 new general members over 2006/2007.⁴

Legislative and Regulatory Framework for the Practice of Respiratory Therapy

The scope of practice for respiratory therapy is defined in the *Respiratory Therapy Act, 1991* as follows:

The practice of respiratory therapy is the providing of oxygen therapy, cardio-respiratory equipment monitoring and the assessment and treatment of cardio-respiratory and associated disorders to maintain or restore ventilation.⁵

The *Respiratory Therapy Act, 1991* defines the controlled acts authorized to RTs as follows:

In the course of engaging in the practice of respiratory therapy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Performing a prescribed procedure below the dermis.
2. Intubation beyond the point in the nasal passages where they normally narrow or beyond the larynx.
3. Suctioning beyond the point in the nasal passages where they normally narrow or beyond the larynx.
4. Administering a substance by injection or inhalation.⁶

² College of Respiratory Therapists of Ontario. www.crto.on.ca.

³ College of Respiratory Therapists of Ontario. Annual Report 2007/2008:13.

⁴ Ibid.

⁵ *Respiratory Therapy Act, 1991, S.O. 1991, c. 39, s.3.*

⁶ Ibid: s.4.

Additional Requirements for Authorized Acts

To perform these authorized acts, a member must receive an order for the procedure from a member of the College of Physicians and Surgeons of Ontario, the College of Midwives of Ontario or the Royal College of Dental Surgeons of Ontario, an extended class nurse (Nurse Practitioner) or a member of a health profession that is prescribed by regulation.⁷ Under current authorities, a member of the CRTO cannot order oxygen or adjust oxygen concentration for a patient.

How the College Regulates its Members

A respiratory therapist is a self-regulated professional in Ontario who performs a variety of roles including diagnostic, therapeutic, research, health promotion and education in a variety of settings. CRTO regulates the practice of respiratory therapy in the public interest. All respiratory therapists practise in accordance with the profession's scope of practice: the provision of oxygen therapy, cardio-respiratory equipment monitoring and the assessment and treatment of cardio-respiratory and associated disorders to maintain or restore ventilation.⁸

Education and Continuing Competency

RTs in Ontario complete a three-year diploma program at a community college in the province or an approved program outside of the province. The CRTO approves schools accredited by the Council on Accreditation for Respiratory Therapy Education (CoARTE). Graduates from approved programs are eligible to register in the Graduate Class of Registration, and are eligible to write the Canadian Board for Respiratory Care (CBRC) National Certification Examination. Upon successful completion of the examination, candidates receive the General Certificate of Registration, provided they meet all eligibility requirements.

Entry to practise clinical competencies include: anatomy and physiology (cardiorespiratory system, central nervous system, renal system and other body systems); pathophysiology; pharmacology; wellness and safety; basic sciences related to respiratory therapy; medical gases; infection control; diagnostic and therapeutic modalities and equipment (including airway management; anaesthesia; blood, cardiac, hemodynamic, physical and pulmonary assessment); bronchial hygiene and chest care; medical gas therapy; suction and drainage; humidity and aerosol therapy; patient transport; imaging; and patient education and ventilator support.

⁷ Ibid, s.5.1.

⁸ Ibid: s.3.

⁹ College of Respiratory Therapists of Ontario. *Entry to Practice Competencies*. January 1999: 3 – 23.

Mandatory Professional Liability Insurance

Under the CRTO's registration regulation, it is a condition of every certificate of registration that members provide the College with satisfactory evidence of professional liability insurance coverage in the amounts and coverage set out in CRTO policies. Currently, the CRTO requires that active members carry minimum liability insurance coverage of \$2 million for each occurrence.

Quality Assurance

CRTO has developed a number of documents to support RTs in their professional practice, including papers on the eleven fields of minimum knowledge, skills and judgment required for entry to practise. A Standards of Practice document outlines the requirements for meeting and maintaining the CRTO's ethical and legal requirements of professional practice. Professional practice guidelines define appropriate professional standards of practice for respiratory therapy in Ontario, including certification programs for advanced prescribed procedures below the dermis, conflict of interest, interpretation of authorized acts, delegation of controlled acts, orders for medical care, responsibilities under consent legislation and other matters.

Position statements have been released by CRTO on bloodborne pathogens, French-language services, medical directives and the ordering of controlled acts, RTs as anaesthesia assistants, and skills development. The CRTO requires skills development for members who have limitations placed on their certificate of registration or who have determined they are not competent to perform a specific procedure. The development opportunities may be included in in-service education through a supervised training process provided by a regulated health professional competent to perform the procedure.

CRTO requires members to complete an annual four-step Professional Portfolio to document continuous quality improvement including twelve learning activities each year. A random selection of members must submit portfolios for assessment by reviewers who present reports to the Quality Assurance Committee. A recently introduced Professional Standards Assessment (PSA) is the main tool under the Assessment module of the Quality Assurance Program. It is an online (web-based) open-book assessment consisting of 50 multiple-choice questions requiring members to apply their knowledge of College legislation, regulations, standards and guidelines.

What the CRTO has Proposed

Currently RTs are permitted to administer oxygen as part of the controlled act of administering a substance by injection or inhalation. However, with the exception of suctioning, RTs are not authorized to administer medication, including oxygen, without an order from an authorized professional. They are also not authorized to prescribe drugs, including oxygen.

The CRTO has proposed that RTs be authorized to prescribe oxygen under the *Respiratory Therapy Act, 1991*, and that the Hospital Management Regulation 965 under the *Public Hospitals Act* be amended to remove the requirement for a physician order for this procedure in a hospital setting.¹⁰

The CRTO indicates that the inability to independently prescribe oxygen means RTs face a number of barriers in providing the best care to patients in hospital and home care settings.

Often, the CRTO states, the need to have a pre-existing order for oxygen settings or saturation levels is overlooked in a clinical setting, including in hospitals. If a patient's condition changes and oxygen requirements increase or decrease, there is often no order to permit an RT to adjust or titrate the rate of oxygen flow. This may result at best in significant patient distress and at worst in an acute deterioration in the patient's condition.

When standing orders for oxygen are present, RTs indicate that these orders are most often "static", not allowing for titration or changes in oxygen therapy. Under "static" orders, RTs can administer a constant dosage of oxygen, but when the patient's condition changes or deteriorates, altering the prescription to ensure appropriate oxygen dosage is not addressed, and a new prescription or order must be obtained. RTs maintain that it is inappropriate care for all patient populations to receive commonly prescribed oxygen levels, as indicated in a standing order. Elderly patients or clients who have a predisposition to CO₂ narcosis, an abnormal sensitivity to supplemental oxygen, may be harmed under such standing orders.¹¹

The CRTO said that there can be serious consequences to delays in initiating and titrating oxygen. Hypoxemia is a condition in which there is an inadequate supply of oxygen in arterial blood, which can lead to multiple organ systems damage, especially in those systems with high oxygen utilization rates such as the central nervous system. A patient's oxygen requirements can be monitored non-invasively with the use of oxygen saturation monitors. However, under current legislation, if an RT were to note a critical desaturation (oxygen saturation below optimal range), other than in an emergency situation, a valid order from an authorized prescriber would be required before oxygen therapy could be initiated or altered, usually resulting in an unsatisfactory delay in treatment.¹²

Conversely, patients who no longer require oxygen may remain on inappropriate levels of oxygen for significant periods of time, waiting for an order to discontinue oxygen use. Unnecessary oxygen use limits a patient's mobility and can interfere with rehabilitation. According to the CRTO, this scenario can also lead to a longer than required length of stay in a hospital and can disrupt the discharge planning process.

¹⁰ CRTO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 11, 2008: 2-3.

¹¹ Ibid: 4.

¹² Ibid: 3.

The CRTO notes that within a hospital the RT is considered to be one of the most knowledgeable health professionals regarding oxygen therapy and an integral part of the health care team. It is routinely the RT who assesses the patient to determine the need for oxygen therapy or its adjustment. As such, RTs view the requirement for a physician order as an unnecessary step causing undue delay, or care that is not reflective of best practices.

These observations are supported by a study undertaken at London Health Sciences Centre (LHSC) on the utilization of oxygen, entitled: *Breathing Easier: An Inter-disciplinary Goal Oriented Approach to Oxygen Therapy Administration*¹³ that outlines LHSC's efforts to move from a process where physician orders are static to a dynamic customer focused model, where the needs of the patient drive oxygen therapy care. The report found that moving to this new process meant that the number of patients on excessive amounts of oxygen was reduced by 60 percent, the length of patient days on oxygen was reduced by 40 percent and oxygen therapy supplies were reduced by 12 percent.

The CRTO submission indicates that there is significant variation in physicians' approaches to ordering oxygen. Saturation criteria and procedures guiding oxygen administration can potentially result in reduction of oxygen use, decreases in patient length of stays as well as unnecessary application of oxygen.¹⁴

Ontario's Home Oxygen Program

The Ministry of Health and Long-Term Care's Home Oxygen Program, operated under the Assistive Devices Program (ADP) provides funding for long-term oxygen therapy and related equipment and supplies for eligible Ontario residents living with a chronic illness or dysfunction. Patients aged 65 or older, and those who receive benefits from Ontario's Disability Support Program, Ontario Works, Assistance to Children with Severe Disabilities programs, who receive professional services through a Community Care Access Centre, or who live in a long-term care facility receive full coverage for the monthly costs of a basic oxygen system. The costs covered include basic disposable supplies such as masks, nasal cannula and bubble humidifiers.

To qualify for the program, a physician registered with the College of Physicians and Surgeons of Ontario must apply on behalf of a patient, after having made use of all available treatments to stabilize the patient's condition. Initial assessments are required, along with routine reassessments of oxygen need.¹⁵

¹³ London Health Sciences Centre. *Breathing Easier: An Inter-disciplinary Goal Oriented Approach to Oxygen Therapy Administration*. www.lhsc.on.ca/respthrapy/breathe/index.htm.

¹⁴ CRTO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 11, 2008: 10.

¹⁵ Ministry of Health and Long-Term Care. Home Oxygen Program. www.health.gov.on.ca/english/public/pub/adp/oxygen.html.

In home care, the evaluation of the patient who requires home oxygen is most often performed by RTs, who are the health professionals most often employed by home care providers or oxygen suppliers to routinely assess and reassess the patient's oxygen needs. Currently, information concerning the patient's oxygen requirements must be relayed to the ordering physician for the initial prescription for oxygen therapy, and when as a result of assessments a change is required to respond to immediate needs, that assessment must also be referred to the physician, often creating a delay in the patient receiving optimal oxygen therapy.

The CRTO indicates that if RTs were authorized to prescribe oxygen for patients in the community, a change to the Home Oxygen Program application process to accept applications from RTs would be needed.

Public Hospitals Act Regulation 965

CRTO has indicated that a change to Regulation 965 under the *Public Hospitals Act* would also be required for procedures ordered by RTs in a hospital setting. The regulation requires that orders for treatment must be made by physicians, dentists, midwives or extended class nurses (nurse practitioners).

What HPRAC Heard

In addition to carefully considering the submission of the CRTO, HPRAC held several consultation meetings, invited written responses to the submission by interested individuals and organizations and undertook a literature review and a jurisdictional review of RTs outside of Ontario.

Epidemiological Trends

Epidemiological trends in illness and disease indicate that Canada is facing a substantial increase in the incidence of chronic respiratory disease due to a number of factors including: Chronic Obstructive Pulmonary Disease (COPD), lung cancer, tuberculosis, cystic fibrosis, asthma, obstructive sleep apnea, respiratory influenza, and those caused by poor indoor/outdoor air quality. These factors have a major impact on care delivery systems.¹⁶ Canada's increasing aging population is expected to lead to an increased demand for health services related to respiratory diseases and conditions.

There has been an increased prevalence of hospitalization rates among women with respiratory ailments. Since 2000, female mortality due to COPD has risen at double the rate of breast cancer.¹⁷ Patients with COPD typically require oxygen therapy on an ongoing basis and the demand for such services will continue to increase in the coming years. This will impact both in-hospital and home care services.

¹⁶ Public Health Agency of Canada. *Life & Breath: Respiratory Disease in Canada, 2007*.

¹⁷ Canadian Lung Association/Thoracic Society of Canada. *Women and COPD: A National Report*. 2004.

Health human resources, access to care and coordination of care

RTs, along with nurse practitioners and physiotherapists, have noted that difficulties in accessing physicians in underserviced areas of the province pose significant barriers in obtaining orders for oxygen therapy. According to the CRTO, the authority for RTs to write hospital orders for home oxygen would potentially eliminate delays in discharging medically stable patients requiring home oxygen therapy, and in monitoring the therapy when it is established.¹⁸

The Profession's Readiness for Change

HPRAC has confirmed that RTs are well trained in the administration and titration of oxygen and are considered experts in oxygen therapy. HPRAC has concluded that members of the profession generally have the necessary education and competencies both to prescribe and administer oxygen, and that limited educational bridging programs are required respecting the professional responsibilities associated with the prescribing authority.

RTs are taught basic pharmacotherapy and are examined in the entry-to-practice CBRC National Certification Examination. Both the educational programs and the CBRC examination are based on the National Competency Profile (NCP).¹⁹ In the 2003 version of the NCP, 98 percent of the RTs in Ontario reported that they performed oxygen therapy as part of their clinical practice.

During 2000-2005, the Canadian Society of Respiratory Therapists (CSRT) developed an Occupational Profile based on a national job analysis that was used as a blueprint for curriculum development, educational program evaluation and the national examination. The profile outlines the skills and knowledge required of a RT and describes in detail the competencies required for safe application of oxygen therapy.²⁰

The CSRT national accreditation program is provided through the Council on Accreditation for Respiratory Therapy Education (CoARTE). CoARTE accreditation provides a tool to assist respiratory therapy schools and regulatory bodies in assuring the public that the national educational standards for entry-level respiratory therapy have been met.

Oxygen Administration

Oxygen administration is taught extensively in the educational programs under "Medical Gases Therapy". The Occupational Profile outlines the knowledge component of oxygen therapy and is "used as a blueprint for curriculum development, educational program evaluation and the national examination. The profile outlines the skills and knowledge required of a

¹⁸ CRTO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 11, 2008: 10.

¹⁹ National Alliance of Respiratory Therapy Regulatory Bodies. *National Competency Profile*. 2003.

²⁰ Canadian Society of Respiratory Therapists. *Occupational Profile*. 2000: 67-69.

Respiratory Therapist and describes in detail the competencies required for safe application of oxygen therapy.”²¹ The RT is required to demonstrate an understanding and analysis of both the equipment used in the practice of respiratory care and the various medical gas systems. They are also required to maintain the competencies for the activities/procedures that they perform.

As part of the core competency for the CSRT National Competency profile, RTs are required to know the physical and chemical properties of oxygen, safety standards, delivery systems and devices, as well as the medical indications and hazards.²²

The administration of oxygen therapy is a core competency for RTs and...no further education would be required.²³

It is an expectation outlined in the CRTO Standards of Practice that CRTO members demonstrate an understanding and analysis of both the equipment used in the practice of respiratory care and the various medical gas systems. Members are also required to maintain the competencies for the activities and procedures that are performed.²⁴

The CRTO's Quality Assurance (QA) Program is outlined in detail in the Quality Assurance Regulation 596/94 Part VI.²⁵ The QA Program is divided into two main components: the Continuous Quality Improvement module, and the Assessment module. Members are required to participate in the CRTO's QA program on an ongoing basis. They are selected at random for assessment on a yearly basis and their knowledge of the application of legislative and regulatory requirements is tested at that time. Members are required to keep a professional portfolio which monitors their day-to-day learning and enables them to track at least one major learning objective each year.

Prescribing

The profession is in support of the new role of prescribing oxygen. The CRTO noted that the proposal related to the ordering and prescribing of oxygen was discussed and approved in principle at the Annual General Meeting of the Respiratory Therapy Society of Ontario (RTSO), the provincial voluntary professional association.

In interviews with members of other health professions, HPRAC heard that RTs are respected for their knowledge of cardiorespiratory disease therapy, medical gas therapy, and knowledge of therapeutic modalities and equipment. They are relied on for arterial blood gas (ABG) analysis to

²¹ CRTO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 11, 2008: 6.

²² Ibid. 7.

²³ Ibid. 7.

²⁴ College of Respiratory Therapists of Ontario. *Standards of Practice*. 2004.

²⁵ Ontario Regulation 596/94, Part VI – Quality Assurance under the *Respiratory Therapy Act, 1991*, S.O. 1991, c.39.

measure the levels of oxygen and carbon dioxide in the arterial blood, and to determine the acidity (pH) of the blood. Other professionals rely on advice from RTs, working with them as part of a team, in assessing changes in the patient and the consequent appropriate adjustment in therapy.

Physicians indicated, in meetings with HPRAC, some surprise at the barriers to optimal care that were created by “static” orders and the inability of RTs to adjust oxygen concentrations without additional and separate prescriptions or orders. Hospitals indicated that new procedures might be needed to provide new authorities for RTs to prescribe oxygen, but that efficiencies could be increased and team-based care would be impacted positively.

Upgrading to ensure Readiness for the New Controlled Act of Prescribing

The CRTO said it would initiate appropriate consultations with other health professions, including the College of Physicians and Surgeons of Ontario, College of Nurses of Ontario and the College of Physiotherapists of Ontario, to discuss how best to assess current members’ competencies and implement any educational bridging program required.²⁶

The CRTO has agreed to address any needed upgrades to training for RTs to ensure that they are ready to accept this new role. Measures would include:

- Education and guidance for [RTs] relevant to the responsibilities of prescribing and for those new members coming from jurisdictions where prescribing of oxygen is not part of the scope of practice of the profession.²⁷
- Provision of additional information of the rights and responsibilities around prescribing/ordering oxygen. The CRTO indicates that in view of members’ existing knowledge and skills, very little additional education would be required related to prescribing of oxygen.²⁸

The CRTO said it would develop relevant guidelines and continuing education processes to specifically address the prescribing function.²⁹

The Professional Standards Assessment (PSA) portion of the QA program would be revised to include questions on prescribing and a practice guideline on prescribing and ordering oxygen would be developed to address standards of practice related to prescribing.³⁰

Education on the responsibilities related to prescribing and ordering would be provided both to the students through educational programs and to existing RTs through the CRTO.³¹ According to the CRTO, while practice guidelines are already in place, additional requirements relating to

²⁶ CRTO. Submission to HPRAC: *Review of Non-Physician Prescribing and Administration of Drugs Under the Regulated Health Professions Act*. November 11, 2008: 12.

²⁷ Ibid: 7-8.

²⁸ Ibid.

²⁹ Ibid.

³⁰ Ibid.

³¹ Ibid.

prescribing oxygen therapy would be developed, consistent with standards and guidelines regarding ordering, responsibilities, professional standards, patient choice and communicating with physicians and other health professionals. The CRTO intends to review educational programs of other health care providers and develop modules for current members. The CRTO indicates that in keeping with an interprofessional collaborative approach, practice guidelines could be developed with other health professions.³²

What Leading Jurisdictions Do

If RTs are granted the authority to prescribe oxygen, Ontario will be the first jurisdiction to do so. In Canada, respiratory therapy is regulated in Alberta, Manitoba, Ontario, Quebec and Nova Scotia. Alberta, Manitoba and Nova Scotia provide authority to RTs to administer oxygen. Quebec provides authority to RTs to administer and adjust prescribed medications and substances.

In the U.S., RTs are licenced in 48 states. The only two states that currently do not regulate respiratory therapy practice are Alaska and Hawaii. All the licensed states use the NBRC CRT examination as the state licensure examination. RTs provide their services either under medical direction or the medical supervision of a licensed physician. In general, RTs cannot prescribe. They carry out the orders of a physician.

The respiratory therapy scope of practice statements for the states all include the phrase “administering medications to the cardio pulmonary system”, or similar words. Essentially, if the drug (medication) is related to cardio-respiratory practice, and prescribed by a physician, the RT can administer it. The laws are not specific as to the drugs respiratory therapists can administer, but it is understood that these would be cardio-respiratory drugs or medications that are U.S. Food and Drug Administration (FDA) approved. Oxygen, for example, is an FDA approved drug.

North Carolina authorizes the “administering and application” of oxygen and substances, while Illinois provides the authority for “administration”, with differing authorities for Respiratory Therapists and Respiratory Care Practitioners. Michigan, Colorado, New York and Oklahoma allow RTs to “administer” the therapies.

Managing the Risk of Harm

The CRTO has made the case that granting the controlled act of prescribing to RTs should improve patient safety both in hospitals and at home. As a result of delays in obtaining an order from a physician for oxygen, patients might not receive optimal treatment in a timely fashion or might not have an order for the correct saturation level (written orders frequently do not anticipate changes that may be required to patients’

³² Summary Notes from December 2, 2008 meeting between HPRAC & key intervenors.

oxygen requirements). Both instances potentially result in adverse consequences for patients or longer hospital stays. This is of particular importance in remote and rural facilities where there are fewer physicians and access to care is often more challenging.

The literature supports this case. For example, a retrospective review of patients with Chronic Obstructive Pulmonary Disease (COPD) discharged from an academic hospital showed inconsistencies or gaps in hospital care for the application and titration of oxygen, and the ongoing monitoring of saturation and arterial blood gases were associated with inpatient adverse events.³³

The CRTO has described the risk of the application of high levels of oxygen as follows:

[The] greatest risk to adults would be oxygen toxicity, which can result in pulmonary tissue damage. However, the results of most studies indicate that adults can breathe up to 50 percent for extended periods without major lung injury.³⁴ This can be avoided by limiting the adult client's exposure to 100 percent oxygen to less than 24 hours and closely monitoring the partial pressure of oxygen in the client's arterial blood (PaO₂). According to human and animal studies, high concentrations of inspired oxygen can cause a spectrum of lung injury, ranging from mild tracheobronchitis (inflammation of the trachea and bronchi) to diffuse alveolar damage.³⁵ Absorption atelectasis (where oxygen over 50 percent can reduce the nitrogen levels in the lungs and cause areas to collapse) can also occur with concentrations greater than 50 percent, particularly in clients who are breathing at a low tidal volume (e.g., sedation, surgical pain). CO₂ narcosis can result in a depression in ventilation in clients predisposed to the disorder due to chronic hypercapnia (e.g., COPD). Retinopathy of prematurity (ROP) is an abnormal eye condition that occurs in some premature or low-birth-weight infants (up to approximately one month of age) who receive supplemental oxygen. Currently resuscitation standards recommend keeping an infant's arterial PO₂ below 80mmHg as the best way of minimizing the risk of ROP. All of the above precautions and potential hazards could be managed through close monitoring that the RT would provide in collaboration with the rest of the health care team. RTs routinely perform arterial saturation monitoring and arterial blood gas sampling as part of their clinical practice and these are the best methods of assessing the adequacy of oxygen administration. In current clinical practice patients sometimes remain on higher levels of oxygen than necessary because there is no order for titration.

³³ Choi, P., Day, A., Etchells, E. "Gaps in care in patients admitted to hospital with exacerbation of chronic obstructive pulmonary disease." *Canadian Medical Association Journal*. 170(9):1409-1413. 2004.

³⁴ Yao, F., Malhotra, V., Fontes, M. *Anesthesiology: Problem-Oriented Patient Management*. 6th edition. Lippincott, Williams & Wilkins. 2007.

³⁵ Malhotra, A., Schwartz, D., Schwartzstein, R. *Oxygen Toxicity*. 2007.

An Enabling Regulatory Framework

In its previous reports to the Minister of Health and Long-Term Care,³⁶ HPRAC has made recommendations for an enabling regulatory framework for health professions. It is within this framework that HPRAC is making recommendations for the regulation of RTs. The proposed enabling framework will:

- Maintain a broad professional scope of practice for RTs under the *Respiratory Therapy Act, 1991* and regulations;
- Place responsibility for setting appropriate and rigorous standards, limitations and conditions on practice, that could be changed over time, with the CRTO, and
- Require interprofessional collaboration among professions in establishing standards, limitations and conditions on the performance of controlled acts, where professions share the same or similar controlled acts.

In particular, the Minister asked HPRAC to take into account, when controlled acts are shared, public expectations for high quality services no matter which health profession is responsible for delivering care or treatment. In this case, HPRAC has compared the expertise of the professions who are authorized to prescribe oxygen therapy with that of RTs, and how they participate in collaborative health care teams in providing safe and effective health care.

A key element of HPRAC's approach is the creation of a new Respiratory Therapy Standards Committee. This mechanism would allow the CRTO to collaborate with other health professions whose members prescribe oxygen in determining standards, limitations and conditions on the performance of this authorized act by RTs, based on best practices and with a focus on patient safety.

HPRAC's Conclusions

In reviewing the proposal to authorize RTs to prescribe oxygen, HPRAC was struck by the recognition of the technical expertise of members of the profession and their place as central members of health care teams in hospitals and in community settings. HPRAC also noted, however, that the request for independent prescribing authority was occasioned by RTs' frustration with inadequate or "static" orders from physicians or other authorized professionals who prescribe oxygen, which often lead to suboptimal patient care. Their experience with "chasing orders" has advanced this request.

³⁶ HPRAC, *A Report to the Minister of Health and Long-Term Care on the Review of the Scope of Practice for Registered Nurses in the Extended Class (Nurse Practitioners)*, March 2008, and an *Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals: Phase II, Part I*, September 2008.

HPRAC reviewed the Quebec alternative, which provides authority for RTs to administer and adjust prescribed medications and substances; however, in the Ontario framework, an adjustment of medication is considered a prescription; alternatively, the initial prescription would need to specifically reference the performance of both procedures. Given the tendency by prescribers to write static orders, HPRAC does not consider the latter a realistic probability.

Under the *Public Hospitals Act*, Regulation 965 would need to be modified in order to authorize an RT to order a treatment. With that authority, HPRAC has concluded that a reporting relation must exist between RTs and the patient's most responsible physician. Requirements must also be in place for any treatment orders to be recorded in the patient's health record.

HPRAC has also reviewed the CRTO QA program and has concluded that additional rigour is required to accommodate new prescribing authorities. HPRAC notes that the CRTO has indicated that it is eager to proceed in a collaborative approach with other health professions to expand its continuing quality improvement and assurance programs.

It is HPRAC's view that CRTO should engage in discussions with the Ontario Hospital Association and the Council of Academic Hospitals of Ontario to ensure that adequate protocols are in place for the implementation of a new authority to make orders in the hospital setting. In the community, HPRAC expects that referral protocols and extensive sharing of patient care information between the RT and the patient's primary health care professional would be a necessary part of the prescribing authority. This would be part of a collaborative development of standards of practice. RTs do not see themselves as separate and distinct from other health professionals who provide care to a patient, but rather as part of a team that coordinates and communicates with other members of the patient's health team. Nonetheless, with additional authority for RTs to prescribe oxygen, it is important that there be clear understandings about how the initiation of or adjustments to oxygen therapy affect other aspects of patient care and what information must be communicated to other health professionals.

HPRAC has concluded that RTs, with independent prescribing authority, will be well positioned to effect efficient, timely and competent patient care within interprofessional care teams, both in the hospital and the community.

Recommendations

- 1:** That RTs be authorized to prescribe oxygen.
- 2:** That complementary amendments be made to section 24 (1) of regulation 965 of the *Public Hospitals Act* to authorize RTs to make orders for oxygen therapy in hospitals.
- 3:** That RTs be required to advise the attending physician of the order or prescription in a hospital, or the attending health professional in the community, and cause the order or prescription to be recorded in the patient health record.

- 4: That the CRTO engage in discussions with the Home Oxygen Program of the Ministry of Health and Long-Term Care's Assistive Devices Program concerning applications from registered RTs on behalf of patients who are eligible for home oxygen therapy and respiratory equipment.

Implementation proposals

To implement these recommendations, the following changes to statutes and regulations are proposed:

1. That section 4(1) of the *Respiratory Therapy Act, 1991* be amended by adding the following paragraph:
 5. Prescribing oxygen.
2. That section 5(2) of the *Respiratory Therapy Act, 1991* be repealed and the following substituted:

Additional requirements for authorized acts

- 5(2)** A member shall perform a procedure under the authority of paragraph 5 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.

Individual scope of practice for respiratory therapists

- 5(3)** A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

Grounds for misconduct

- 5(4)** In addition to the grounds set out in subsection 51(1) of the Health Professions Procedural Code, a panel of the Discipline Committee shall find that a member has committed an act of professional misconduct if the member contravenes subsection (1), (2) or (3).
3. That the *Respiratory Therapy Act, 1991* be amended by adding the following section:

Regulations

- 12.** Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,
- (a) prescribing procedures for the purpose of paragraph 1 of section 4, and
 - (b) regulating the prescribing of oxygen by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing of oxygen.

4. That Ontario Regulation 596/94 under the Respiratory Therapy Act, 1991 (General) be amended by adding the following sections:

57.1 (1) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 5 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

(2) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 5 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

5. That sections 1(4) and 1(7) of Ontario Regulation 753/93 under the *Respiratory Therapy Act, 1991* (Professional Misconduct) be repealed and the following substituted:

4. Delegating a controlled act set out in subsection 27(2) of the *Regulated Health Professions Act, 1991*, in contravention of the regulations, or delegating an act set out in paragraph 5 of section 4 of the Act.

7. Recommending, prescribing, dispensing or selling medical gases or equipment for an improper purpose or otherwise using improperly the authority to recommend, prescribe, dispense or sell medical gases or equipment.

6. That section 1 of Ontario Regulation 753/93 under the *Respiratory Therapy Act, 1991* (Professional Misconduct) be amended by adding the following paragraphs:

1.1 Exceeding the scope of practice of the profession.

31. Failing to advise the patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such consultation to ensure the proper care of the patient.

32. Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.

33. Practicing the profession while the member is in a conflict of interest.

34. Recommending or providing unnecessary services.

CONCLUSIONS

CRITICAL LINKS: TRANSFORMING AND SUPPORTING PATIENT CARE

This document presents HPRAC's third report to the Minister on interprofessional collaboration between health colleges and their members, as well as its full report on non-physician prescribing and use of drugs. The findings and recommendations in these reports are intertwined, calling for far-reaching measures to modernize the regulatory framework and restructure the health regulatory system. Together, these reports call for the creation of critical links, among health colleges at the regulatory level and among their members at the clinical level, to transform and support patient care.

The proposed reforms will drive continuous improvement in the way health professions are regulated, so Ontarians derive the maximum benefit from health human resources. As a result, health professionals will be able to work to the utmost of their knowledge and skill, to collaborate more closely to deliver the best outcomes and to adapt more readily to new medical technologies and rising patient expectations.

In its report on interprofessional collaboration, HPRAC is making two overriding recommendations:

- Establish a **new enabling regulatory framework** to enhance interprofessional collaboration and strengthen the self-regulation of health professions in Ontario. This new way of doing business will give health colleges authority to establish legally enforceable standards of practice, based on interprofessional collaboration where controlled acts are shared, and at the same time provide colleges with the flexibility to adjust these standards in response to changing practices and practice environments.
- Establish a new agency – the **Council on Health Professions Regulatory Excellence** – to facilitate interprofessional collaboration, promote regulatory rigour and excellence and increase accountability within the health profession regulatory system. These aims will be advanced by identifying best practices and by setting new requirements for Colleges to measure and report on their activities and to improve their communication with the public.

These directions represent fundamental reforms designed to bring the regulatory system into step with the evolution of the practice environment and to facilitate sustained quality improvement in the regulation of health professions. They also provide the foundation for HPRAC's approach to a new framework and process for drug regulations under health profession Acts.

An Enabling Regulatory Framework

Standards of practice are critical elements in what health colleges do to regulate their members. The standards of practice under the enabling framework proposed by HPRAC would cover: education; training;

continuing competency; mandatory discussion, consultation and transfer of care; and standards, limitations and conditions relating to the performance of an act authorized to the profession. HPRAC has found that the existing process for developing and approving standards of practice through regulation does not work well. It is cumbersome, frustrating and far too slow. The process creates ongoing challenges for colleges that may end up without standards of practice in place that are current and enforceable.

HPRAC recommends that the *RHPA* be amended to authorize health colleges to adopt standards of practice that would still be enforceable in law but would be developed outside the government's regulation-making process. The clear authority for the implementation of the colleges' standards of practice would be recognized in statute. This flexibility would be coupled with a new requirement for health colleges to establish interprofessional standards committees to take part in developing the standards of practice. The committees would provide a forum for input from other professions that share the authorized acts or have an interest in the quality of their performance.

Council on Health Professions Regulatory Excellence

The increased authority conferred on Colleges to establish standards of practice must, in HPRAC's view, be balanced with increased accountability for effective protection of the public interest. This imperative underpins HPRAC's recommendation for a new agency to play a strong monitoring and advisory role to ensure that colleges fulfill their responsibilities under the *RHPA* and specifically the new objects under the *HSIA* – including enhanced relations between colleges and their members, other colleges, key stakeholders and the public; interprofessional collaboration with other colleges; and response to changes in practice environments, advances in technology and other emerging issues.

Other jurisdictions have struggled to find the right balance between the autonomy of each profession and the shared responsibility for the regulatory system as a whole. Weighing this question, HPRAC has concluded that a new independent agency, the Council on Health Professions Regulatory Excellence, should be established in Ontario to strengthen the self-regulation of health professions. The agency should incorporate HPRAC's existing advisory roles and combine them with new roles to provide strategic direction to the Colleges, monitor standards development and regulatory performance, and report to the public and government on how Colleges are fulfilling their mandates. The new agency will support excellence in the work of the Colleges, whether in quality assurance, patient safety or collaborative relationships, and communicate and guide the adoption of best practices in regulatory functions and ethics.

The reforms HPRAC proposes reflect trends in other jurisdictions where growing attention is being paid to the role of regulators and systems of regulation in promoting collaborative practice among health care professionals. By better aligning regulation with changes underway in clinical practice, these reforms will help to transform the delivery of patient care.

New Drug Approvals Framework

HPRAC believes that the problems with the regulation-making and approval process are of particular concern where drug regulations are at issue. It can take years for a profession to obtain approval to prescribe or use a new drug. These delays create unnecessary risks, as patients may not have access to current pharmaceuticals from their health professionals. As well, non-physician prescribers may be prevented from following best practices by adjusting their patients' medications based on the latest research and clinical practices.

HPRAC concludes that a rigorous two-stage process should be established within a new drug approvals framework.

The first stage of the process would entail a comprehensive review of a profession's request for a new class of drug, or other authorities respecting drugs, to determine whether the request is within a profession's scope of practice, whether a change in scope of practice is needed, and if this change is appropriate. Following a determination that it is in the public interest to add a new class of drugs to a profession's prescribing authority, a recommendation would be made to the Minister to include the class in the health profession's drug regulation. This recommendation would then go through an expedited government regulation-making and approval process.

An infrastructure will be needed for the new drug approvals framework; the new agency would provide it. The proposed agency would oversee the development of recommendations for the addition and removal of drug classes for health professions.

The second stage of the approval process would involve a new interprofessional Drug and Therapeutics Formulary Committee that would provide technical and scientific advice to the agency. The committee would determine the specific drugs or agents that should fall within the classes authorized to a profession under regulation and any conditions or limitations that should be attached to their use. The committee would be comprised of health professionals and other experts in pharmacotherapy. Its recommendations for the drug list would be submitted to the agency for final review and approval and would have the force of law. If a profession sought changes to an existing list of drugs within a class, the request would be reviewed by the agency and directed to the committee for immediate consideration and recommendation.

HPRAC believes that this two-stage process would provide the substantial protections required to ensure patient safety, while increasing efficiency and reflecting best practices.

Profession-Specific Drug Regulation Issues

In its work on non-physician prescribing and use of drugs, HPRAC has addressed issues raised by 12 professions that prescribe or use drugs in the course of practice. In some cases, HPRAC has recommended a regulation to name a therapeutic class or sub-class of drugs, and at the outset has

included a list of specific agents that are included in current regulations, recommendations for some additional agents and limitations and conditions for their use. Subsequently, additions or deletions to the Drug List would be recommended by the new agency on the advice of the Drug and Therapeutics Formulary Committee.

HPRAC is recommending changes to prescribing authorities for a number of professions. It proposes that dental hygienists, naturopaths, pharmacists and respiratory therapists be given access to the controlled act of prescribing, where appropriate for their scope of practice. HPRAC is also recommending that the range of medications that can be prescribed by optometrists, chiropodists, podiatrists, nurses and midwives be expanded. In addition, HPRAC proposes that registered nurses be authorized to dispense, sell and compound drugs, in accordance with standards of practice to be developed by an interprofessional standards committee.

These changes will enable these professions to play more central roles in the care of their patients, particularly in primary care settings. For example, the new authorities will assist dental hygienists to provide care to patients in settings such as long-term care homes or independent clinics according to the profession's scope of practice. And optometrists will be able to manage a wider range of conditions, including some glaucoma cases.

HPRAC is recommending that respiratory therapists be granted the authority to prescribe oxygen. This will reduce unnecessary patient waiting time for discharge from hospital and expand respiratory therapists' ability to provide safe care for patients in the home.

Pharmacists, as one of the most accessible regulated health professionals, will play a larger role in primary health care. The introduction of a broad range of drug classes will give pharmacists the latitude to adapt, modify and extend an existing prescription. HPRAC continues to recommend that the government consider developing a minor ailments program for Ontario, in which pharmacists could treat patients with minor ailments by prescribing drugs from a limited formulary.

Broadening access to the controlled act of prescribing, dispensing, selling or compounding drugs as proposed in this report will allow regulated health professionals in Ontario to work to the full extent of their competencies. In the future all these professions – and their patients – will benefit from a more efficient regulation-making and drug approvals framework that will keep Drug Lists in line with evidence-based practices.

Scopes of Practice Reviewed

As part of its work on interprofessional collaboration, HPRAC has reviewed the scopes of practice of seven professions that are already engaged in interprofessional care and offer high potential for further efforts in this direction. This work focused on authorized acts apart from those pertaining to drugs.

HPRAC is convinced that enabling professionals to perform more tasks independently, consistent with their competence, will encourage new roles as part of collaborative health care teams. In this report, HPRAC is recommending changes in the scope of practice requested by medical radiation technologists, who are valuable technical experts in the safe and effective use of rapidly evolving and highly sophisticated diagnostic and therapeutic equipment. The proposed changes reflect the current daily functions of medical radiation technologists and are supported by their education and training. In addition, HPRAC reviewed the scope of practice of medical laboratory technologists, and while not recommending changes, found systemic issues that present barriers to the efficient and effective provision of health care services, but are not suited to scope of practice responses.

Critical Links to Transform Patient Care

HPRAC contends that the recommendations in this report will not only better position Ontario's health colleges to carry out their regulatory responsibilities, but will also forge critical links between colleges that will support the transformation of patient care. The proposed new advisory and monitoring agency will deliver the strategic impetus for a shared change management agenda, seeking the highest levels of regulatory excellence. Today's array of regulatory silos will be replaced by a true regulatory system, where Colleges are better aligned, learn from each other and work together to develop common structures, processes and standards – all aimed at the shared objective of serving the public interest.

Continued progress in health care depends on enabling all health professionals to contribute to the maximum of their abilities, improving the way they work together, and facilitating their adoption of new knowledge, practices and technologies. Regulatory excellence is one key to achieving these vital goals. HPRAC is striving for a dynamic health profession regulatory system for the 21st century – one that will further the vision of a modern, accessible and sustainable health care system delivering the best care available in the world.

CRITICAL LINKS: SUMMARY OF PROPOSALS FOR IMPLEMENTATION

This chapter provides a summary of changes to legislation and regulation that would be needed to implement HPRAC's recommendations in this report.

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CHAPTER 4: CRITICAL LINKS: PROPOSALS FOR THE ESTABLISHMENT OF A NEW AGENCY TO FACILITATE AND SUPPORT INTERPROFESSIONAL COLLABORATION AND BEST PRACTICES AT THE REGULATORY LEVEL AND TO ESTABLISH A NEW DRUG APPROVALS FRAMEWORK

1. That the definition of “Advisory Council” in section 1(1) of the *Regulated Health Professions Act, 1991* be repealed and the following substituted:

“Agency” means Council for Health Professions Regulatory Excellence;

2. That all references to “Advisory Council” in the *Regulated Health Professions Act, 1991* be replaced with references to “Agency”.

That section 1(1) of the *Regulated Health Professions Act, 1991* be amended by adding the following definitions:

“drug” means a drug as defined in the *Drug and Pharmacies Regulation Act* and includes prescription therapeutic products as defined in the *Food and Drugs Act* or the regulations made thereunder;

“Drug List” means, for each health profession that has the authority to perform the controlled act of administering a substance by injection or inhalation, or prescribing, compounding, dispensing or selling drugs during the course of practice of the profession, other than medicine or dentistry, the list of individual drugs that are designated by the Agency as falling within a class of drugs authorized to the health profession by the regulations made under the health profession Act;

“Formulary Committee” means the Drug and Therapeutics Formulary Committee.

3. That section 6 of the *Regulated Health Professions Act, 1991* be repealed and the following substituted:

Annual report

- 6.(1) Each College shall report annually to the Minister on its activities and financial affairs.

Audited financial statement

- (2) Each College’s annual report shall include an audited financial statement

Content and form

- (3) The Minister may specify the content and form of the annual report submitted by the College and, where the Minister has done so, the annual report shall contain that content and be in that form.

Minister may publish information

- (4) The Minister may, in every year, publish information from the annual reports of the Colleges.

No personal information

- (5) Information from the annual reports published by the Minister shall not include any personal information.

4. That sections 7 through 17 of the *Regulated Health Professions Act, 1991* be repealed and replaced with the following:

Agency**Agency**

The Agency is established under the name Council for Health Professions Regulatory Excellence in English and Conseil de l'excellence de la réglementation des professions de la santé in French.

Composition

The Agency shall be composed of at least five and no more than nine persons who shall be appointed by the Lieutenant Governor in Council on the Minister's recommendation.

Chair and vice-chair

The Lieutenant Governor in Council shall designate one member of the Agency to be the chair and one to be the vice-chair.

Qualification of members

A person may not be appointed as a member of the Agency if the person,

(a) is employed under Part III of the *Public Service of Ontario Act, 2006* or by a Crown agency as defined in the *Crown Agency Act*; or

(b) is or has been a member of a Council or College

Terms of members

The chair and vice-chair shall be appointed for a fixed period not to exceed ten years and the other members for a fixed period not to exceed three years. Members of the Agency are eligible for reappointment. Upon expiry of their term, members of the Agency shall remain in office until reappointed or replaced.

Replacement members

A person appointed to replace a member of the Agency before the member's term expires shall hold office for the remainder of the term.

Initial members

Other than the chair and vice-chair, the initial members of the Agency may be appointed for terms of one, two or three years.

Remuneration and expenses

The members of the Agency shall be paid the remuneration and expenses the Lieutenant Governor in Council determines.

General Functions of Agency

The general functions of the Agency are:

- to see that each College serves and protects the public interest;
- to promote good professional self-regulation and best practices by the Colleges; and
- to promote collaboration between and among Colleges and others.

Powers and Duties of Agency

The Agency shall have the following powers and duties:

- to advise the Minister on,
 - whether unregulated professions should be regulated;
 - whether regulated professions should no longer be regulated;
 - suggested amendments to this Act, a health profession Act or a regulation under any of those Acts and suggested regulations under any of those Acts;
 - the recommended scope of practice of regulated professions;
 - the need for collaboration among the Colleges;
 - any conflicts between and among the Colleges and others;
 - any College that does not fulfill its objects and duties;
 - suggested amendments to any provincial act or regulation affecting health care or health care delivery;
- to promote best practices by Colleges in their:
 - registration, complaints, investigations, discipline, fitness to practice, quality assurance, patient relations, enforcement, record-keeping and reporting functions; and
 - development of regulations, standards of practice and professional practice guidelines for their members;

- to monitor each College's efforts in serving and protecting the public interest and in achieving its objects;
- to inform the public on matters relating to health profession regulation and the public's rights and recourses associated with health profession regulation;
- to establish criteria, rules and procedures that must be followed for the designation of a drug on the Drug List, and to publish those criteria, rules and procedures on its website and in any other format it considers advisable;
- to designate drugs on the Drug List for a regulated health profession, with any terms, limitations and conditions associated with those drugs, and to remove or modify those designations or terms, limitations or conditions from time to time;
- to keep, maintain and publish the Drug List; and
- to bring to the Minister's attention any other matter that requires government action.

Requirement to provide information

For the purposes of fulfilling its general functions and duties under this Act, the Agency may require a Council to provide information other than personal information to the Agency either in response to a specific request, or at regular intervals.

Time and form

The Agency may specify the time at which and the form in which the information must be provided.

Compliance required

The Council shall comply with every requirement to provide information under this section.

Drug List

The Agency shall keep, maintain and publish a Drug List.

The Drug List shall set out,

- (a) the individual list of drugs that a health profession is authorized to administer by injection or inhalation, prescribe, compound, dispense or sell within the class of drugs authorized to the health profession under the regulations made under its health profession Act;
- (b) the terms, limitations and conditions associated with those drugs for the health profession; and
- (c) any other information or material the Agency considers

necessary or advisable.

The Agency shall publish the Drug List on its website.

A drug becomes authorized to a health profession on the effective date of its being designated in the Drug List for that health profession, and ceases to be authorized to a health profession on the effective date of that designation being removed.

The Agency may designate a drug in the Drug List where the Agency considers it to be in the public interest to do so, but shall not do so if its criteria for approval have not been met.

Any modification of a designation takes place on the effective date of its being designated in the Drug List as a modification.

A drug or substance that was authorized to a health profession by regulation made under its health profession Act immediately before •, 2009 is deemed to be designated on the Drug List until it is removed from the Drug List under this section. The terms, limitations and conditions contained in the regulation made under the health profession Act continue to apply until modified under this section.

In deciding whether or not to designate a drug on the Drug List, to remove a drug from the Drug List, or to impose, amend or remove any terms, limitations or conditions associated with a drug, the Agency may consider anything it considers advisable in the public interest, including, without limiting the generality of the foregoing, the education, training, competence or standards of practice of the health profession, the needs of the public, or matters concerning patient safety.

The Agency shall obtain expert advice from the Formulary Committee and may consult with other persons or organizations on matters of concern arising out of the maintenance of the Drug List.

The Agency must accept the recommendations of the Formulary Committee unless doing so is not advisable in the public interest.

A person or organization may request, in writing, that the Agency amend the Drug List but the Agency is not obligated to act on the request.

At least 60 days before the Agency makes an amendment to the Drug List, the Agency shall submit a copy of the proposed amendment to the Minister, to the members of the Formulary Committee and to the affected Council for review.

The Agency shall be entitled to circulate a copy of the proposed amendment to other College Councils, health professionals and expert advisors.

If there is no written objection to a proposed amendment to the Drug List by the Minister within 60 days after it is submitted by the Agency, the Agency shall amend the Drug List in accordance with the proposed amendment.

The Minister shall only object to a proposed amendment to the Drug List if the proposed amendment is not advisable in the public interest.

The Drug List for each health profession established under this section shall be interpreted as if it formed part of a regulation made under the applicable health profession Act.

The *Statutory Powers Procedure Act* does not apply to any decision or action of the Agency under this Act.

The Lieutenant Governor in Council may make regulations,

(a) clarifying, modifying or restricting the functions and powers of the Agency concerning the Drug List; and

(b) providing for additional functions and powers of the Agency concerning the Drug List.

Function is advisory only

Except for the maintenance of the Drug List, the function of the Agency is advisory only.

Procedure

The Agency shall sit in Ontario where and when the chair designates.

Idem

The Agency shall conduct its proceedings in the manner it considers appropriate.

Employees

Such employees as are considered necessary for the proper conduct of the affairs of the Agency may be appointed under Part III of the *Public Service of Ontario Act, 2006*.

Experts

The Agency may engage experts or professional advisors to assist it.

Secretary

The Agency shall appoint one of its employees as the Secretary.

Duties

The Secretary's duties are,

- (a) to have the custody and care of the records and documents of the Agency; and
- (b) to carry out the functions and duties assigned by the Minister or the Agency.

Reports

The Agency shall report annually to the Minister, and the Minister shall submit the report to the Lieutenant Governor in Council and shall then lay the report before the Assembly if it is in session or, if not, at the next session.

Same

The annual report shall include,

- (a) a report on the work of the Agency;
- (b) any information that the Agency considers appropriate concerning the activities of the Colleges in protecting the public interest; and
- (c) any information requested by the Minister.

Same

The first report under subsection • shall be submitted in the first half of 2011 and shall cover the period beginning on the day this Act receives Royal Assent and ending on December 31st, 2010.

Special reports

The Agency may make a special report to the Minister at any time on any matter related to this Act that, in the opinion of the Agency should not be deferred until the annual report, and the Minister shall submit the report to the Lieutenant Governor in Council and shall then lay the report before the Assembly as soon as reasonably possible.

No personal information

The annual reports and special reports made by the Agency shall not include any personal information.

5. That the *Regulated Health Professions Act, 1991* be amended by adding the following after section 17:

Drug and Therapeutics Formulary Committee

Formulary Committee

The Formulary Committee is established under the name Drug and Therapeutics Formulary Committee in English and Comité du formulaire des médicaments et des thérapeutiques in French.

Composition

The Formulary Committee shall be composed of such number of members as may be appointed by the Lieutenant Governor in Council and shall consist of:

- (a) the Chair of the Agency, ex officio;
- (b) equal representation from the College of Physicians and Surgeons of Ontario, and the Ontario College of Pharmacists;
- (c) an expert in pharmacology or pharmacotherapy who may be an educator,
- (d) one member of a College that is not already represented under subsection (b);
- (e) a representative of the Ontario Drug Benefits Program of the Ontario Ministry of Health and Long-Term Care.

The Lieutenant Governor in Council shall appoint the representatives listed in subsections (b) (c) (d) and (e) on the Agency's recommendation.

Chair

The Chair of the Agency shall serve as the chair of the Formulary Committee.

Terms of members

The members listed in subsections (b) (c) and (d) shall be appointed for a fixed period not to exceed three years. Members of the Formulary Committee are eligible for reappointment. Upon expiry of their term, members of the Formulary Committee shall remain in office until reappointed or replaced.

Replacement members

A person appointed to replace a member of the Formulary Committee before the member's term expires shall hold office for the remainder of the term.

Initial members

The initial members of the Formulary Committee listed in subsections (b) (c) and (d) may be appointed for terms of one, two or three years.

Independence

The members of the Formulary Committee listed in subsection (b) and (d) shall perform their functions in an independent manner, and not as representatives of their employers, their Council or their College.

Lobbying

A member of the Formulary Committee shall not, with respect to any matter related to this Act,

- (a) act as a consultant lobbyist within the meaning of subsection 4 (10) of the *Lobbyist Registration Act, 1998*; or
- (b) act as an in-house lobbyist within the meaning of subsection 5 (7) or 6 (5) of the *Lobbyist Registration Act, 1998*.

Remuneration and expenses

The members of the Formulary Committee shall be paid the remuneration and expenses the Lieutenant Governor in Council determines.

Functions of the Formulary Committee

The Formulary Committee shall:

- (a) compile and recommend to the Agency a Drug List for each health profession, other than medicine and dentistry, that the Committee is satisfied the health profession may be competent to administer by injection or inhalation, prescribe, compound, dispense or sell if the Agency confirms their qualifications and they fall within a class of drugs authorized to the health profession under the regulations made under their health profession Act;
- (b) provide expert advice to the Agency on the terms, limitations and conditions that should be imposed on the Drug List authorized for each health profession; and
- (c) provide expert advice to the Agency as requested by the Agency.

Meetings

The Formulary Committee shall meet at least once a year and as requested by the Agency.

Idem

The Formulary Committee shall conduct its proceedings in the manner it considers appropriate.

Other Advisors

The Formulary Committee may, from time to time, seek the advice of other regulated health professionals when the Formulary Committee deems such advice is required.

Provision of Advice

The Formulary Committee shall send a copy of its recommendations to the Minister at the same time it sends its recommendations to the Agency

Best Practices

6. That the Agency facilitate and support the development of a common Code of Ethics by all of the Colleges that is applicable to all regulated health professionals. That, once developed, section 94(1)(k) of the Health Professions Procedural Code be repealed and the common Code of Ethics be passed as a regulation made under the *Regulated Health Professions Act, 1991*.
7. That the Agency facilitate and support the development of common conflict of interest rules by all of the Colleges that are applicable to all regulated health professionals. That, once developed, section 95(1)(i) of the Health Professions Procedural Code be repealed and the common conflict of interest rules be passed as a regulation made under the *Regulated Health Professions Act, 1991*.
8. That the Agency facilitate and support the development of common advertising rules by all of the Colleges that are applicable to all regulated health professionals. That, once developed, section 95(1)(l) of Schedule 2, Health Professions Procedural Code be repealed and the common advertising rules be passed as a regulation made under the *Regulated Health Professions Act, 1991*.

Standards of Practice

9. That section 95(1)(n) of Schedule 2, Health Professions Procedural Code be repealed and the following substituted:

95(1) Subject to the approval of the Lieutenant Governor in Council and with prior review of the Minister, the Council may make regulations prohibiting members from acting beyond the scope of practice of the

profession in the course of practicing the profession.

That sections 95(1.4), (1.5), (1.6) and (1.7) be moved to follow section 95(1).

10. That sections 95(1.1) through (1.3) be repealed and the following substituted:
 - 1) The Council may establish standards of practice of the profession relating to required education, training, continuing competency, mandatory discussion, consultation and transfer of care, and standards, limitations and conditions relating to the performance of an act authorized to the profession.
 - 2) Without limiting the generality of subsection (1.1), a standard of practice may be limited in its application to specified classes of members or certificates.
 - 3) At least 60 days before a standard of practice is established by the Council under subsection (1.1), the Council shall submit a copy of the proposed standard of practice to the Minister, to the Agency and to every member for review
 - 4) The Agency shall be entitled to circulate a copy of the proposed standard of practice to other Colleges, health professionals and expert advisors.
 - 5) If there is no written objection to a standard of practice by the Minister or by the Agency within 60 days after it is submitted by the Council, the standard is deemed to be established by the Council.
 - 6) The Council shall send a copy of each standard of practice made under subsection (1.1) to each member, the Agency and the Ministry.
 - 7) The Council shall publish all established standards of practice on the Internet at a publicly accessible and freely available website and shall make them available as a document or in any other format, on request and at cost, to members of the public.
 - 8) The standards of practice of a profession established under this section shall be interpreted as if they formed part of a regulation made under the applicable health profession Act.
 - 9) Without limiting the generality of subsection (1.1), the Council's power to establish standards of practice may be exercised by adopting by reference, in whole or in part and with such changes as the Council considers necessary, any code, standard or guideline relating to standards of practice of the profession and require compliance with the code, standard or guideline as adopted.
 - 10) If a standard of practice so provides, a scientific, administrative or technical document adopted by reference shall be a reference to it,

- as amended from time to time, and whether the amendment was made before or after the standard of practice was established.
- 11) A document adopted under subsection 1.10 must be a document created by a recognized body and must not be a document created by the College.
 - 12) A copy of every code, standard or guideline adopted by reference under subsection 1.9 and every scientific, administrative or technical document adopted by reference under subsection 1.10 shall be available for public inspection during normal business hours in the office of the College and shall be posted on the College's website or be available through a hyperlink at the College's website.
 - 13) The Minister may, on written notice, require that the Council establish, amend or revoke a standard of practice that the Council has the authority to make, amend or revoke, as described in subsection (1.1).
 - 14) If the Council does not establish, amend or revoke the standard of practice as required by the Minister within 30 days after receiving notice from the Minister, the Minister may establish a standard of practice that carries out the intent of the Minister's requirement.
11. That as the Agency conducts scope of practice reviews or otherwise participates in conflict resolution between and among Colleges, that the Agency identifies to the Minister other instances when it would be appropriate for the regulations under one or more health profession acts to be amended to require interprofessional standards committees to be established and mandated to develop enforceable standards of practice on an interprofessional basis.

Professional Liability Protection

12. That all regulated health professionals be required to have and maintain professional liability insurance, or belong to a specified association that provides protection against professional liability, or be covered by their employers' insurance policies. That all regulated health professionals be required to give proof of the insurance or membership to the Registrar upon their registration or otherwise when requested by the Registrar. That this requirement be effected by an amendment to the Registration provisions under the Health Professions Procedural Code as follows:

That section 22.4 of Schedule 2, Health Professions Procedural Code be amended by adding the following subsection:

Each application for registration must be accompanied by evidence of professional liability insurance, or membership in a specified association that provides protection against professional liability, or an employer's insurance coverage of the applicant. Each registrant shall provide the Registrar with evidence of the maintenance of such

coverage following registration and when requested by the Registrar from time to time. Such coverage shall satisfy the requirements specified in the standards of practice developed by the College.

That once this is effected, section 94(1)(y) of the Health Professions Procedural Code be repealed.

Addressing Transparency, Accountability and the Public Interest

13. That the Minister make a regulation under section 43(1)(h.2) of the *Regulated Health Professions Act, 1991* requiring each College to publish on its website on the Internet, without password protection, as contemplated under section 3.1(1) of the Health Professions Procedural Code, general information including, but not limited to:
 - a. its role, responsibilities and accountabilities;
 - b. its functions, programs and processes;
 - c. the scope of practice of the health profession(s) it governs;
 - d. the use of titles by its members;
 - e. what constitutes professional misconduct for its members;
 - f. how to access the public portion of the register;
 - g. its audited financial statements;
 - h. general and statistical information on its registration reviews and hearings, complaints reviews and hearings, discipline hearings, fitness to practise assessments, quality assurance assessments; and
 - i. other information that the Minister specifies.

CHAPTER 6.

REVIEW OF THE SCOPE OF PRACTICE OF MEDICAL RADIATION TECHNOLOGY

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That section 3 of the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

Scope of practice

3. The practice of medical radiation technology is the use of ionizing radiation, electromagnetism and other prescribed forms of energy to produce diagnostic images and data and to perform therapeutic procedures as prescribed in the regulations, and the evaluation of the technical sufficiency of the diagnostic images and data.

2. That section 4 of the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

Authorized acts

4. In the course of engaging in the practice of medical radiation technology, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Administering substances by injection or inhalation.
2. Performing a prescribed procedure on tissue below the dermis.
3. Putting an instrument, hand or finger:
 - (a) into an artificial opening of the body for the purpose of tracheal suctioning or for the purpose of administering contrast media;
 - (b) beyond the labia majora;
 - (c) beyond the urethra;
 - (d) beyond the anal verge.
4. Applying a prescribed form of energy.

3. That section 5 of the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

Additional requirements for authorized acts

5.(1) A member shall not perform a procedure under the authority of section 4 unless the procedure is ordered by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the order.

(2) A member shall perform a procedure under the authority of section 4 in accordance with any requirements prescribed in the regulations.

Grounds for misconduct

(3) In addition to the grounds set out in subsection 51(1) of the Health Professions Procedural Code, a panel of the Discipline Committee shall find that a member has committed an act of professional misconduct if the member contravenes subsection (1) or (2).

Individual scope of practice for medical radiation technologists

5.1 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

4. That section 12 (2) of the *Medical Radiation Technology Act, 1991* be repealed, and that a new section 12(2.1) be added to the Medical Radiation Technology Act, 1991 as follows:

Regulations

12 (2.1) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,

(a) designating the procedures that a member may perform on tissue below the dermis; and

(b) specifying requirements for the performance of procedures under the authority of paragraph 3 of section 4.

(2.2) Subject to the approval of the Lieutenant Governor in Council, the Minister may make regulations prescribing forms of energy, other than ionizing radiation, for the purposes of paragraph 4 of section 4.

5. That a new section 7.1 be added to Ontario Regulation 866/93 under the *Medical Radiation Technology Act, 1991* as follows:

7.1(1) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 3 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

(2) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the

authority of paragraph 3 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

6. That Ontario Regulation 866/93 under the *Medical Radiation Technology Act, 1991* be amended by adding the following:

STANDARDS OF PRACTICE

7.2. The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 3 of section 4 of the Act.

7.3. The standards of practice referred to in section 7.2 shall be developed on the recommendation of the Medical Radiation Technology Standards Committee.

7.4. For the purposes of section 7.3, the College shall establish the Medical Radiation Technology Standards Committee referred to in section 10 and shall appoint the membership of the Medical Radiation Technology Standards Committee, which shall include, at a minimum, one or more:

- a) members of the Council;
- b) members of the College (including practitioners and educators);
- c) persons who are not and have not been members of the College or of the Council; and
- d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario.

7.5. The College shall post the following on its website:

- a) the standards of practice referred to in section 7.2; and
- b) a list of those members who are authorized to perform a procedure under the authority of paragraph 3 of section 4 of the Act.

7. That the title of Ontario Regulation 226/03 under the *Medical Radiation Technology Act, 1991* be changed to **PRESCRIBED FORMS OF ENERGY AND PRESCRIBED PROCEDURES**

8. That section 1 of Ontario Regulation 226/03 under the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

Prescribed Forms of Energy

1. Electromagnetism is a prescribed form of energy for the purposes of paragraph 4 of section 4 of the Act.

9. That section 2 be added to Ontario Regulation 226/03 under the *Medical Radiation Technology Act, 1991* as follows:

Prescribed Procedures

2. The following are prescribed procedures below the dermis for the purposes of paragraph 3 of section 4 of the Act:

- a) Taking blood samples from veins.
- b) Tattooing.
- c) Administering a substance by injection.

10. That section 3.1 of Ontario Regulation 107/96 under the *Regulated Health Professions Act, 1991* be repealed.

11. That section 1. 1. of Ontario Regulation 855/93 under the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

1. (a) Contravening a term, condition or limitation imposed on the member's certificate of registration.

12. That a new section 1. 1. (b) of Ontario Regulation 855/93 under the *Medical Radiation Technology Act, 1991* be added as follows:

1. (b) Exceeding the scope of practice of the profession.

13. That section 1. 5. of Ontario Regulation 855/93 under the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

5. Practicing the profession while the member is in a conflict of interest.

14. That section 1. 11. of Ontario Regulation 855/93 under the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

11. Carelessly, negligently or unskillfully using ionizing radiation, electromagnetism or a prescribed form of energy.

15. That section 1. 12. of Ontario Regulation 855/93 under the *Medical Radiation Technology Act, 1991* be repealed and the following substituted:

12. Contravening or failing to maintain a standard of practice of the profession.

CHAPTER 7.

PRESCRIBING AND USE OF DRUGS IN THE PROFESSIONS OF CHIROPODY AND PODIATRY

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That paragraph 2 and 3 of subsection 5(1) of the *Chiroprody Act, 1991* be repealed and the following substituted:

Authorized acts

5(1) In the course of engaging in the practice of chiroprody, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

2. Administering by inhalation, or injection into feet, a substance designated in the regulations.
3. Prescribing, dispensing and selling a drug that the member may prescribe, dispense and sell under the regulations.

2. That paragraph 3 and 4 of subsection 5(2) of the *Chiroprody Act, 1991* be repealed and the following substituted:

5(2) In the course of engaging in the practice of chiroprody, a member who is a podiatrist is authorized, subject to the terms, conditions and limitation imposed on his or her certificate of registration, to perform the following:

3. Administering by inhalation, or injection into feet, a substance designated in the regulations.
4. Prescribing, dispensing and selling a drug that the member may prescribe, dispense and sell under the regulations.

3. That the *Chiroprody Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts for chiroprodists

5.1 A member shall perform a procedure under the authority of paragraph 2 or 3 of subsection 5(1) in accordance with any requirements prescribed in the regulations.

Additional requirements for authorized acts for podiatrists

5.2 A member who is a podiatrist shall perform a procedure under the authority of paragraph 3 or 4 of subsection 5(2) in accordance with any requirements prescribed in the regulations.

Individual scope of practice for podiatrists

5.3 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health professionals.

4. That section 13 of the *Chiropody Act, 1991* be repealed and the following substituted:

Regulations

13. Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations regulating the prescribing, dispensing and sale of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing, dispensing and sale of drugs.

5. That sections 1 through 4 of Ontario Regulation 203/94 under the *Chiropody Act, 1991* (General) be repealed and replaced by the following:

PART I

CONTROLLED ACTS AND STANDARDS OF PRACTICE

1.(1) The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 2 and 3 of subsection 5(1) and paragraph 3 and 4 of subsection 5(2) of the Act.

(2) The standards of practice referred to in subsection (1) shall be developed on the recommendation of the Chiropody Standards Committee.

(3) The College shall establish the Chiropody Standards Committee referred to in subsection (2) and shall appoint the membership of the Chiropody Standards Committee, which shall include, at a minimum, one or more:

- (a) members of the Council;
- (b) members of the College (including practitioners and educators);
- (c) persons who are not and have not been members of the College or of the Council;
- (d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario;

(e) members of the College of Respiratory Therapists of Ontario, approved by the College of Respiratory Therapists of Ontario; and

(f) members of the Ontario College of Pharmacists, approved by the Ontario College of Pharmacists.

(4) The College shall post the following on its website:

(a) the standards of practice referred to in subsection (1); and

(b) a list of those members, who are authorized to perform a procedure under the authority of paragraph 2 and 3 of subsection 5(1) and paragraph 3 and 4 of subsection 5(2).

6. That Schedule 1, Schedule 2, Schedule 3 and Schedule 4 of Ontario Regulation 203/94 under the *Chiropractic Act, 1991* (General) be repealed.
7. That section 7 of Ontario Regulation 830/93 under the *Chiropractic Act, 1991* (Registration) be amended by adding the following paragraph:

GENERAL TERMS, LIMITATIONS AND CONDITIONS

4. (1) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of either paragraph 2 or 3 of subsection section 5(1) or paragraph 3 or 4 of subsection 5(2) of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

(2) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of either paragraph 2 of subsection 5(1) or paragraph 3 of subsection 5(2) of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

(3) For the purposes of this section, “Drug List” has the meaning given to it in the *Regulated Health Professions Act, 1991*.

(4) A member holding a general or academic class certificate may prescribe, dispense, or sell the following classes of drugs:

(a) antihistamines

(b) anti-infective agents: antibacterials, antifungals, antivirals

- (c) CNS agents: general anaesthetics, analgesics and antipyretics, anxiolytics, sedatives, and hypnotics
- (d) emergency medications
- (e) hormones and synthetic substitutes: adrenals
- (f) local anaesthetics
- (g) sclerosing agents
- (h) skin and mucous membrane agents
- (i) vitamins

(5) A member may only prescribe, dispense or sell those drugs within the classes designated in subsection that are listed in the Drug List and must prescribe, dispense or use those listed drugs in accordance with the terms, limitations and conditions contained in the Drug List.

8. That section 1(4) of Ontario Regulation 750/93 under the *Chiropody Act, 1991* (Professional Misconduct) be repealed and the following substituted:
 4. Delegating an act set out in paragraph 1 or 2 of subsection 5(1) of the Act or paragraph 1, 2 or 3 of subsection 5(2) of the Act except as permitted by the *Regulated Health Professions Act, 1991* or the regulations made thereunder or under the Act, or delegating an act set out in paragraph 3 of subsection 5(1) or paragraph 1 or 4 of subsection 5(2) of the Act.
9. That section 1(7) of Ontario Regulation 750/93 under the *Chiropody Act, 1991* (Professional Misconduct) be repealed and the following substituted:
 7. Prescribing, dispensing, selling or administering a drug or substance for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell or administer drugs or substances.
10. That Ontario Regulation 750/93 under the *Chiropody Act, 1991* (Professional Misconduct) be amended by adding the following sections:
 - 1.1 Exceeding the scope of practice of the profession.
 - 8.1 Recommending or providing unnecessary services.
 - 15.1 Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.

31.1 Contravening, while engaged in the practice of chiropody, any federal or provincial law or municipal by-law with respect to the prescribing or dispensing of any drug or substance or mixture of drugs and substances.

CHAPTER 8.

PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF DENTAL HYGIENE

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That the *Dental Hygiene Act, 1991* be amended by adding the following sections:

Authorized acts

4.3 Prescribing, dispensing, selling or compounding a drug that the member may prescribe, dispense, sell or compound under the regulations.

Additional requirements for authorized acts

5(2.1) A member shall perform a procedure under the authority of paragraph 3 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.

Individual scope of practice for dental hygienists

5(4) A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

2. That section 5(3) of the *Dental Hygiene Act, 1991* be repealed and the following substituted:

Grounds for misconduct

(3) In addition to the grounds set out in subsection 51(1) of the Health Professions Procedural Code, a panel of the Discipline Committee shall find that a member has committed an act of professional misconduct if the member contravenes subsection (1), (2) or (2.1).

3. That section 12 of the *Dental Hygiene Act, 1991* be repealed and the following substituted:

Regulations

12. Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,

(a) regulating the prescribing, dispensing, selling or compounding of drugs by members, requiring members to keep prescribed records

and to provide to the Minister reports containing prescribed information respecting the prescribing, dispensing, selling or compounding of drugs;

(b) prescribing requirements for performing scaling teeth and root planing, including curetting surrounding tissue, which requirements may include the educational and experiential qualifications that must be obtained in order for a member to undertake those procedures on the member's own initiative; and

(c) prescribing contraindications to a member performing or continuing to perform on the member's own initiative the procedures of scaling teeth and root planing, including curetting surrounding tissue.

4. That Ontario Regulation 218/94 under the *Dental Hygiene Act, 1991* (General) be amended by adding the following sections:

12.1(k.1) any drug prescribed, dispensed, sold or compounded for the client.

39.(a) For the purposes of this section, "Drug List" has the meaning given to it in the *Regulated Health Professions Act, 1991*.

(b) A member may prescribe, dispense, sell or compound the following classes of drugs:

- i. Anti-infectives— miscellaneous
- ii. Miscellaneous therapeutic agents – cariostatic agents.

(c) A member may only prescribe, dispense, sell, compound or use those drugs within the classes designated in subsection 39(b) that are listed in the Drug List and must prescribe, dispense, sell, compound or use those listed drugs in accordance with the terms, limitations and conditions contained in the Drug List.

40. (1) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 3 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

(2) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 3 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

41. The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 3 of section 4 of the Act.

42. The standards of practice referred to in section 41 shall be developed on the recommendation of the Dental Hygiene Standards Committee.

43. For the purposes of section 42, the College shall establish the Dental Hygiene Standards Committee referred to in section 42 and shall appoint the membership of the Dental Hygiene Standards Committee, which shall include, at a minimum, one or more:

- a) members of the Council;
- b) members of the College (including practitioners and educators);
- c) persons who are not and have not been members of the College or of the Council;
- d) members of the Royal College of Dental Surgeons of Ontario, approved by the Royal College of Dental Surgeons of Ontario; and
- e) members of the Ontario College of Pharmacists, approved by the Ontario College of Pharmacists.

44. The College shall post the following on its website:

- a) the standards of practice referred to in section 41; and
- b) a list of those members, who are authorized to perform a procedure under the authority of paragraph 3 of section 4 of the Act.

5. That section 15 of Ontario Regulation 218/94 under the *Dental Hygiene Act, 1991* (General) be amended by adding the following paragraphs:

1.1 Exceeding the scope of practice of the profession.

48. Prescribing, dispensing, selling, compounding or using a drug or substance for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell, compound or use drugs or substances.

49. Contravening, while engaged in the practice of dental hygiene, any federal or provincial law or municipal by-law with respect to the distribution, sale, prescribing or dispensing of any drug or mixture of drugs.

- 51.** Delegating an act set out in paragraph 1 or 2 of section 4 of the Act except as permitted by the *Regulated Health Professions Act, 1991* or the regulations made thereunder or under the Act, or delegating an act set out in paragraph 3 of section 4 of the Act.
6. That section 50 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act* (Dentistry) be repealed and made a regulation under Ontario Regulation 218/94 under the *Dental Hygiene Act, 1991* (General).

CHAPTER 9.

PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF DENTISTRY

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That paragraph 7 of section 4 of the *Dentistry Act, 1991* be repealed and the following substituted:

7. Prescribing, dispensing, selling or compounding a drug.

2. That the *Dentistry Act, 1991* be amended by adding the following section:

Additional requirements for authorized acts

4.1 A member shall perform a procedure under the authority of paragraph 7 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the Regulated Health Professions Act, 1991.

3. That section 12 of the *Dentistry Act, 1991* be repealed and the following substituted:

Regulations

12. Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations regulating the prescribing, dispensing, selling or compounding of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing, dispensing, selling or compounding of drugs.

4. That Part IV (Registration) of Ontario Regulation 205/94 under the *Dentistry Act, 1991* (General) be amended by adding the following section:

15.1 It is a condition of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 7 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

5. That Ontario Regulation 205/94 under the *Dentistry Act, 1991* (General) be amended by adding the following:

PART V

STANDARDS OF PRACTICE

32. The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 7 of section 4 of the Act.

33. The standards of practice referred to in section 32 shall be developed on the recommendation of the Dentistry Standards Committee.

34. For the purposes of section 33, the College shall establish the Dentistry Standards Committee referred to in section 33 and shall appoint the membership of the Dentistry Standards Committee, which shall include, at a minimum, one or more:

- a) members of the Council;
- b) members of the College (including practitioners and educators);
- c) persons who are not and have not been members of the College or of the Council;
- d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario, who practice family medicine;
- e) members of the College of Nurses of Ontario, approved by the College of Nurses of Ontario; and
- f) members of the Ontario College of Pharmacists, approved by the Ontario College of Pharmacists.

35. The College shall post the standards of practice referred to in section 32 on its website.

6. That section 2 of Ontario Regulation 853/93 under the *Dentistry Act, 1991* (Professional Misconduct) be amended by adding the following section:

5.1 Failing to advise the patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such consultation to ensure the proper care of the patient.

7. That section 2(10) of Ontario Regulation 853/93 under the *Dentistry Act, 1991* (Professional Misconduct) be repealed and the following substituted:

10. Prescribing, dispensing, selling or compounding a drug for an improper purpose, or otherwise using improperly the authority to

prescribe, dispense, sell or compound drugs.

8. That section 2 of Ontario Regulation 853/93 under the *Dentistry Act, 1991* (Professional Misconduct) be amended by adding the following sections:

10.1 Being subjected to the withdrawal or restriction of rights or privileges under the *Controlled Drugs and Substances Act* (Canada) or the *Food and Drugs Act* (Canada) or the regulations under either of those Acts, unless by the member's own request.

10.2 Contravening, while engaged in the practice of dentistry, any federal or provincial law or municipal by-law with respect to the prescribing, dispensing, distribution or sale of any drug or mixture of drug.

9. That sections 1 to 36, 38 to 49, 51 to 60 and Forms 1, 2 and 3 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act* (Dentistry) be repealed and made a regulation under the *Dentistry Act, 1991*.
10. That section 50 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act* (Dentistry) be repealed and made a regulation under the *Dental Hygiene Act, 1991*.
11. That section 37 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act* (Dentistry) be repealed.

That all references to drugs listed in Schedules A, B, C, D, E, F, G and N found in sections 39, 41, 44, 45 of Ontario Regulation 547 under the *Drug and Pharmacies Regulation Act* (Dentistry) be amended to refer to the corresponding drugs listed in Schedules I, II, III or U of the *Drug and Pharmacies Regulation Act* when enacted as a new regulation under the *Dentistry Act, 1991*.

CHAPTER 10.

PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF MIDWIFERY

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That section 4 of the *Midwifery Act, 1991* be repealed and the following substituted:

Authorized acts

4. In the course of engaging in the practice of midwifery, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Communicating a diagnosis of a disease, disorder or dysfunction that may be identified through a midwifery assessment.
2. Managing labour and conducting spontaneous normal vaginal deliveries.
3. Performing episiotomies and amniotomies and repairing episiotomies and lacerations, not involving the anus, anal sphincter, rectum, urethra and periurethral area.
4. Administering, by injection or inhalation, a substance that the member may administer under the regulations.
5. Putting an instrument, hand or finger beyond the labia majora during pregnancy, labour and the postpartum period.
6. Putting an instrument, hand or finger beyond the anal verge for the purpose of administering suppository drugs that the member may administer under the regulations.
7. Taking blood samples from newborns by skin pricking or from women, fathers or sperm donors from veins or by skin pricking.
8. Inserting urinary catheters into women.
9. Prescribing a drug that the member may prescribe under the regulations.

2. That the *Midwifery Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts

4.1 A member shall perform a procedure under the authority of section 4 in accordance with any requirements prescribed in the regulations.

Individual scope of practice for midwives

4.2 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving

situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

3. That sections 11(1) and 11(2) of the *Midwifery Act, 1991* be repealed and the following substituted:

Regulations

11. (1) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,

(a) requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing of drugs; and

(b) specifying requirements for the performance of procedures under the authority of section 4.

4. That the title of Ontario Regulation 884/93 (Designated Drugs) be renamed Drugs and Substances.
5. That sections 1 to 5 of Ontario Regulation 884/93 (Designated Drugs) be repealed and the following substituted:

1. For the purposes of paragraph 4 and paragraph 9 of section 4 of the Act,

(a) a member may prescribe or administer, on the member's own responsibility, the following classes of drugs and substances:

- i. antihistamines,
- ii. anti-infective agents – antibacterials, antifungals, antivirals,
- iii. blood derivatives,
- iv. galactagogues,
- v. CNS agents: general anaesthetics, analgesics and antipyretics, opiate antagonists, anxiolytics, sedatives and hypnotics,
- vi. hormones and synthetic substitutes – adrenals,
- vii. local anaesthetics,
- viii. uterotonics,
- ix. serums, toxoids and vaccines,
- x. vitamins, and
- xi. emergency medications.

(b) a member may prescribe or administer by injection or inhalation, on order of a member of the College of Physicians and Surgeons of Ontario, any drug or substance.

2. A member may use, on order of a member of the College of Physicians and Surgeons of Ontario, any drug.

3. A member may prescribe, administer or order any drug or substance that may lawfully be purchased or acquired without a prescription.
 4. For the purposes of subsection 1(a), a member may only prescribe or administer, on the member's own responsibility, those drugs and substances within the classes designated in subsection 1(a) that are listed in the Drug List and must prescribe or administer those listed drugs and substances in accordance with the terms, limitations and conditions contained in the Drug List. For the purposes of this section, "Drug List" has the meaning given to it in the *Regulated Health Professions Act, 1991*.
6. That Ontario Regulation 867/93 (Registration) under the *Midwifery Act, 1991* be amended by adding the following:
- 3.1 It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.
 - 3.2 It is a term, condition and limitation of a certificate of registration of any class that the holder must comply with the standards, limitations and conditions set out in the publication of the College entitled, "*Indications for Mandatory Discussion, Consultation and Transfer of Care Guideline*," as that publication is amended by the College from time to time.
7. That Ontario Regulation 858/93 (Professional Misconduct) under the *Midwifery Act, 1991* be amended by adding the following:
- 1.1 Exceeding the scope of practice of the profession.
8. That section 1(2) of Ontario Regulation 858/93 under the *Midwifery Act, 1991* be repealed and the following substituted:
- 1(2) Contravening or failing to maintain a standard of practice of the profession.
25. That section 1(4) of Ontario Regulation 858/93 (Professional Misconduct) under the *Midwifery Act, 1991* be repealed and the following substituted:
4. Delegating an act set out in paragraph 2, 3, 4, 5, 6, 7 or 8 of section 4 of the Act except as permitted by the *Regulated Health Professions Act, 1991* or the regulations made thereunder or under the Act, or delegating an act set out in paragraph 1 or 9 of section 4 of the Act.

10. That section 1(7) of Ontario Regulation 858/93 (Professional Misconduct) under the *Midwifery Act, 1991* be repealed and the following substituted:

7. Prescribing or administering drugs or substances for an improper purpose, or otherwise using improperly the authority to prescribe or administer drugs or substances.

11. That Ontario Regulation 858/93 (Professional Misconduct) under the *Midwifery Act, 1991* be amended by adding the following sections:

16.1 Failing to advise a patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such a consultation to ensure the proper care of the patient.

16.2 Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.

16.3 Recommending or providing unnecessary services.

33. Being subjected to the withdrawal or restriction of rights or privileges under the *Controlled Drugs and Substances Act* (Canada) or the *Food and Drugs Act* (Canada) or the regulations under either of those Acts, unless by the member's own request.

34. Contravening, while engaged in the practice of midwifery, any federal or provincial law or municipal by-law with respect to the prescribing of any drug or mixture of drugs.

CHAPTER 11.

PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF NATUROPATHY

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That subsection 1(1) of the *Naturopathy Act, 2007* be amended to add the following:

“Prescription therapeutic product” has the same meaning as in the Food and Drugs Act (Canada).

2. That paragraph 5 of section 4(1) of the *Naturopathy Act, 2007* be repealed and the following substituted:

Authorized acts

5. Communicating a diagnosis made by the member identifying, as the cause of an individual's symptoms, a disease, disorder or dysfunction that can be identified from,

- i. the individual's health history,
- ii. the findings of a comprehensive health examination, or
- iii. the results of any prescribed naturopathic examinations.

3. That section 4(1) of the *Naturopathy Act, 2007* be amended by adding the following section:

7. Prescribing, dispensing, selling or compounding a prescription therapeutic product or drug that the member may prescribe, dispense, sell or compound under the regulations.

4. That sections 4(2) and 4(3) of the *Naturopathy Act, 2007* be repealed and the following substituted:

Additional requirements for authorized acts

4(2) A member shall perform a procedure under the authority of paragraph 3, 5 or 7 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.

Individual scope of practice for naturopaths

4(3) A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring individuals to other health care professionals.

Grounds for misconduct

4(4) In addition to the grounds set out in subsection 51(1) of the Health Professions Procedural Code, a panel of the Discipline Committee shall find that a member has committed an act of professional misconduct if the member contravenes subsections (2) or (3).

5. That section 11(d) of the *Naturopathy Act, 2007* be repealed.
6. That section 11 of the *Naturopathy Act, 2007* be amended by adding the following section:

Regulations

(f) regulating the prescribing, dispensing, selling or compounding of prescription therapeutic products or drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing, dispensing, selling or compounding of prescription therapeutic products or drugs.

7. That the regulations to be made under the *Naturopathy Act, 2007* (General) include the following provisions:
 - For the purposes of this section, “Designated Drug List” has the meaning given to it in the *Regulated Health Professions Act, 1991*.
 - A member may prescribe, dispense, sell or compound the following classes of prescription therapeutic products as defined under the *Food and Drugs Act* (Canada):
 - Amino acids,
 - Botanical extracts and their derivatives,
 - Chelating agents,
 - Electrolyte and fluid replacement,
 - Enzymes, digestive and proteolytic preparations,
 - Homeopathic preparations,
 - Bioidentical hormones,
 - Glandular and organ preparations,
 - Minerals, trace minerals and their derivatives, and
 - Vitamins and vitamin preparations and derivatives.
 - A member may prescribe the following classes of drugs:
 - Anti-infectives: antibiotics, antifungals, antiparasitics, antivirals,
 - Skin and mucous membrane agents,
 - CSN agents: analgesics and antipyretics: NSAIDs.
 - A member may only prescribe, dispense, sell, compound or use those prescription therapeutic products and drugs within the classes designated in the foregoing sections that are listed in the Drug List and must prescribe, dispense, sell, compound or use those listed prescription therapeutic products and drugs in

accordance with the terms, limitations and conditions contained in the Drug List.

- It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 3, 5 or 7 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.
 - It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 3, 5 or 7 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.
 - The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 3, 5 and 7 of section 4 of the Act.
 - The standards of practice referred to above shall be developed on the recommendation of the Naturopathy Standards Committee.
 - For the purposes of the foregoing section, the College shall establish the Naturopathy Standards Committee referred to in section • and shall appoint the membership of the Naturopathy Standards Committee, which shall include, at a minimum, one or more a) members of the Council; b) members of the College (including practitioners and educators); c) persons who are not and have not been members of the College or of the Council; d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario; and e) members of the Ontario College of Pharmacists, approved by the Ontario College of Pharmacists.
 - The College shall post the following on its website:
 - The standards of practice referred to in the foregoing section; and
 - A list of those members, who are authorized to perform a procedure under the authority of paragraph 3, 5 and 7 of section 4 of the Act.
8. That the regulations to be made under the *Naturopathy Act, 2007* (Professional Misconduct) including the following acts of professional misconduct for the purposes of clause 51 (1) (c) of the Health Professions Procedural Code:
- Contravening a term, condition or limitation imposed on the member's certificate of registration.

- Exceeding the scope of practice of the profession.
 - Contravening or failing to maintain a standard of practice of the profession.
 - Failing to advise an individual to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such consultation to ensure the proper care of the individual.
 - Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.
 - Practising the profession while the member is in a conflict of interest.
 - Recommending or providing unnecessary services.
 - Prescribing, dispensing, selling, compounding or using a prescription therapeutic product or drug for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell, compound or use prescription therapeutic products or drugs.
 - Being subjected to the withdrawal or restriction of rights or privileges under the Food and Drugs Act (Canada) or the regulations under either of those Acts, unless by the member's own request.
 - Contravening, while engaged in the practice of naturopathy, any federal or provincial law or municipal by-law with respect to the distribution, sale, prescribing or dispensing of any prescription therapeutic product or drug or mixture of prescription therapeutic products or drugs.
 - Delegating an act set out in paragraph 3, 5 or 7 of section 4 of the Act.
9. That section 10 of Ontario Regulation 107/96 under the *Regulated Health Professions Act, 1991* (Controlled Acts) be repealed.

CHAPTER 12.

PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF NURSING

To implement HPRAC's recommendations, the following changes to legislation and regulations are proposed:

1. That section 4 of the *Nursing Act, 1991* be amended by adding the following section:

Authorized Acts

4. In the course of engaging in the practice of nursing, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

5. Dispensing a drug that has been prescribed by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the prescription.

2. That section 5 of the *Nursing Act, 1991* be repealed and the following substituted:

Additional requirements for authorized acts

5. (1) A member shall not perform a procedure under the authority of paragraph 1, 2, 3 or 4 of section 4 unless,

(a) the performance of the procedure by the member is permitted by the regulations and the member performs the procedure in accordance with the regulations; or

(b) the procedure is ordered by a person who is authorized to do the procedure by section 5.1 of this Act or by the *Chiropody Act, 1991*, the *Dentistry Act, 1991*, the *Medicine Act, 1991* or the *Midwifery Act, 1991*.

(1.1) A member shall perform a procedure under the authority of paragraph 5 of section 4 in accordance with any requirements prescribed in the regulations.

Individual scope of practice for nurses

(1.2) A member is responsible for identifying the limits of his or her education preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

Grounds for misconduct

(2) In addition to the grounds set out in subsection 51 (1) of the Health Professions Procedural Code, a panel of the Discipline Committee shall find that a member has committed an act of professional misconduct if the member contravenes subsection (1), (1.1) or (1.2).

3. That paragraph 3 of section 5.1 of the *Nursing Act, 1991* be repealed and the following substituted:

Authorized acts by certain registered nurses

5.1(1) In the course of engaging in the practice of nursing, a member who is a registered nurse and who holds an extended certificate of registration in accordance with the regulations is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following acts in addition to those the member is authorized to perform under section 4:

3. Prescribing a drug that the member may prescribe under the regulations.

3.1 Selling or compounding a drug that has been prescribed by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the prescription.

4. That section 5.1 of the *Nursing Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts

5.1(1.1) A member shall perform a procedure under the authority of paragraph 3 or 3.1 of section 5.1 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.

5.2 A nurse practitioner is responsible for identifying the limits of his or her education preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

5. That section 14 of the *Nursing Act, 1991* be repealed and the following substituted:

Regulations

14. (1) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,

(a) prescribing procedures for the purpose of paragraph 1 of section 4;

(b) permitting a member to perform a procedure under clause 5(1)(a) and governing the performance of the procedure including, without limiting the foregoing, prescribing the class of members that can perform the procedure and providing that the procedure may only be performed under the authority of a prescribed member or a member of a prescribed class;

(b.1) regulating the prescribing, compounding, dispensing or selling of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing, compounding, dispensing or selling of drugs; and

(c) prescribing the forms of energy that a member may order for the purpose of paragraph 2 of subsection 5.1(1) and prescribing the purpose for which, or the circumstances in which, the form of energy may be applied.

6. That Ontario Regulation 275/94 under the *Nursing Act, 1991* (General) be amended by adding the following section:

5(4) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 5 of section 4 of the Act or paragraph 3.1 of section 5.1 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

7. That section 16 of PART III (Controlled Acts) of Ontario Regulation 275/94 under the *Nursing Act, 1991* (General) be repealed and the following substituted:

16(a) For the purposes of this section, “Drug List” has the meaning given to it in the *Regulated Health Professions Act, 1991*.

(b) A member may prescribe the following classes of drugs under the authority of paragraph 3 of section 5.1:

1. antihistamine drugs,
2. anti-infective agents,
3. autonomic drugs,
4. blood formation, coagulation and thrombosis agents – antithrombotic drugs,
5. cardiovascular drugs,
6. CNS agents – analgesics and antipyretics – NSAIDs, anticonvulsants, psychotherapeutic agents, antimigraine agents, miscellaneous,
7. electrolytic, caloric and water balance,
8. enzymes,
9. respiratory tract agents,
10. eye, ear, nose and throat preparations – anti-infectives, anti-inflammatory agents,

11. gastrointestinal drugs,
12. hormones and synthetic substitutes – adrenals, contraceptives, estrogens, antidiabetic agents, progestins, thyroid and antithyroid agents,
13. local anaesthetics,
14. serums, toxoids and vaccines,
15. skin and mucous membrane agents,
16. vitamins,
17. bone resorption inhibitors, and
18. emergency medications.

(c) A member may only prescribe those drugs within the classes designated in subsection 16(b) that are listed in the Drug List and must prescribe or use those listed drugs in accordance with the terms, limitations and conditions contained in the Drug List.

(d) A member may prescribe or administer any drug or substance that may lawfully be purchased or acquired without a prescription.

8. That section 19 of PART III (Controlled Acts) and Schedules 2 and 3 of Ontario Regulation 275/94 under the *Nursing Act, 1991* (General) be repealed.
9. That Ontario Regulation 275/94 under the *Nursing Act, 1991* (General) be amended by adding the following sections:

PART V

STANDARDS OF PRACTICE

30. The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 5 of section 4 of the Act or paragraph 3.1 of section 5.1 of the Act.

31. The standards of practice referred to in section 30 shall be developed on the recommendation of the Nursing Standards Committee.

32. For the purposes of section 31, the College shall establish the Nursing Standards Committee referred to in section 31 and shall appoint the membership of the Nursing Standards Committee, which shall include, at a minimum, one or more:

- a) members of the Council;
- b) members of the College (including practitioners and educators);
- c) persons who are not and have not been members of the College or of the Council;
- d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario, who practice family medicine; and

- e) members of the Ontario College of Pharmacists, approved by the Ontario College of Pharmacists.

33. The College shall post the following on its website:

- a) the standards of practice referred to in section 30; and
- b) a list of those members, who are authorized to perform a procedure under the authority of paragraph 5 of section 4 of the Act or paragraph 3.1 of section 5.1 of the Act.

10. That Ontario Regulation 799/93 under the *Nursing Act, 1991* (Professional Misconduct) be amended by adding the following sections:

1.1 Exceeding the scope of practice of the profession.

11.1 Recommending or providing unnecessary services.

11.2 Prescribing, dispensing, selling, compounding or administering a drug or substance for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell, compound or administer drugs and substances.

11.3 Being subjected to the withdrawal or restriction of rights or privileges under the Controlled Drugs and Substances Act (Canada) or the Food and Drugs Act (Canada) or the regulations under either of those Acts, unless by the member's own request.

11.4 Contravening, while engaged in the practice of nursing, any federal or provincial law or municipal by-law with respect to the distribution, sale, prescribing or dispensing of any drugs or mixture of drugs.

12.1 Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.

11. That sections 1, 2, 12, 18 of Ontario Regulation 799/93 under the *Nursing Act, 1991* (Professional Misconduct) be repealed and the following substituted:

1. Contravening or failing to maintain a standard of practice of the profession.

2. Delegating an act set out in section 4 or 5.1 of the Act in contravention of section 5 of the Act, or delegating an act set out in paragraph 3.1 of section 5.1 of the Act.

12. Failing to advise a client to consult with a physician or other regulated health professional where the member recognizes, or

ought to recognize, a condition that is beyond the competence or experience of the member or that requires such a consultation to ensure the proper care of the client.

18. Contravening a term, condition or limitation imposed on the member's certificate of registration.

CHAPTER 13.

PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF OPTOMETRY

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That paragraph 2.1 of section 4 of the *Optometry Act, 1991* be repealed and the following substituted:

2.1 Prescribing a drug that the member may prescribe under the regulations.

2. That the *Optometry Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts

4.1 A member shall perform a procedure under the authority of paragraph 2.1 of section 4 in accordance with any requirements prescribed in the regulations.

Individual scope of practice for optometrists

4.2 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

3. That section 12(1) of the *Optometry Act, 1991* be repealed and the following substituted:

Regulations

12. (1) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,

(a) regulating the prescribing of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing of drugs; and

(b) designating the diseases for which a member may communicate a diagnosis for the purposes of paragraph 1 of section 4.

4. That section 12(2) of the *Optometry Act, 1991* be repealed.

5. That section 10(2) of Part IV (Records) of Ontario Regulation 119/94 under the *Optometry Act, 1991* (General) be amended by adding the following section:

13. The drugs prescribed.

6. That Part VIII of Ontario Regulation 119/94 under the *Optometry Act, 1991* (General) be renamed Prescribed Diseases and Drugs.
7. That sections 21 and 22 of Part VIII (Prescribed Diseases) of Ontario Regulation 119/94 under the *Optometry Act, 1991* (General) be repealed and the following substituted:

21. For the purposes of subsection 3(c) and paragraph 1 of section 4 of the *Optometry Act, 1991*, a “prescribed disease” is any disease limited to and manifested in the eye and vision system that can be determined by the findings from an oculo-visual assessment.

22.(a) For the purposes of this section, “Drug List” has the meaning given to it in the .

(b) A member may prescribe the following classes of drugs:

- i) anti-infectives – antibiotics and antivirals, and
- ii) eye, ear, nose and throat preparations – antiallergic agents, anti-infectives, anti-inflammatory agents, mydriatics, vasoconstrictors, anti-glaucoma agents and miscellaneous.

(c) A member may use the following classes of drugs:

- i) topical anaesthetics, and
- ii) eye, ear, nose and throat preparations - mydriatics.

24. A member may only prescribe or use those drugs within the classes designated in section 22 that are listed in the Drug List and must prescribe or use those listed drugs in accordance with the terms, limitations and conditions contained in the Drug List.

8. That Ontario Regulation 837/93 under the *Optometry Act, 1991* be amended by adding the following sections:

GENERAL TERMS, LIMITATIONS AND CONDITIONS

16. (1) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 2.1 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

- (2) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 2.1 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.
9. That Ontario Regulation 550 under the *Drug and Pharmacies Regulation Act (Optometry)* be repealed and/or made a regulation under the Optometry Act, 1991, as appropriate.
10. That section 1(1)13 of Ontario Regulation 859/93 under the *Optometry Act, 1991* (Professional Misconduct) be repealed and the following substituted:
- 13.** Failing to advise a patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition of the eye or vision system that is beyond the competence or experience of the member or that requires such a consultation to ensure the proper care of the patient.
11. That section 1(1)17 of Ontario Regulation 859/93 under the *Optometry Act, 1991* (Professional Misconduct) be repealed and the following substituted:
- 17.** Contravening or failing to maintain the standards of practice of the profession.
12. That section 1(1)18 of Ontario Regulation 859/93 under the *Optometry Act, 1991* (Professional Misconduct) be repealed and the following substituted:
- 18.** Delegating an act set out in paragraph 2 or 4 of section 4 of the Act except as permitted by the *Regulated Health Professions Act, 1991* or the regulations made thereunder or under the Act, or delegating an act set out in paragraph 1 or 2.1 of the Act.
13. That Ontario Regulation 859/93 under the *Optometry Act, 1991* (Professional Misconduct) be amended by adding the following sections:
- 21.1** Prescribing drugs for an improper purpose, or otherwise using improperly the authority to prescribe drugs.
- 21.2** Contravening, while engaged in the practice of optometry, any federal or provincial law or municipal by-law with respect to the prescribing of any drug or mixture of drugs.
14. That paragraph 2 of Section 21 of Part VIII of Regulation 119/94 made under the *Optometry Act, 1991* be repealed.

CHAPTER 14.

PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF PHARMACY

To implement HPRAC's recommendations, the following changes to legislation and regulations are proposed:

1. That section 3 of the *Pharmacy Act, 1991* be repealed and the following substituted:

Scope of practice

3. The practice of pharmacy is the promotion of health and the prevention and treatment of diseases, disorders and dysfunction through the monitoring and management of medication therapy; the custody, prescribing, compounding and dispensing of drugs; and the provision of health care aids and devices and education related to their use.
2. That section 4 of the *Pharmacy Act, 1991* be repealed and the following substituted:

Authorized acts

4. In the course of engaging in the practice of pharmacy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:
 1. Dispensing, selling or compounding a drug or supervising the part of a pharmacy where drugs are kept.
 2. Skin pricking for the purpose of educating patients on the use of health care aids and devices and for the purpose of monitoring chronic diseases.
 3. Administering, by injection or inhalation, a substance for the purpose of patient education or demonstration.
 4. Prescribing a drug that the member may prescribe under the regulations.
3. That the *Pharmacy Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts

4.1 A member shall perform a procedure under the authority of paragraphs 2, 3 or 4 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.

4.2 A member shall not perform a procedure under the authority of paragraph 3 of section 4 unless the substance is prescribed by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the prescription.

Individual scope of practice for pharmacists

4.3 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

4. That the *Pharmacy Act, 1991* be amended by adding the following section:

Regulations

14. Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,

(a) regulating the prescribing of drugs by members, requiring members to keep prescribed records and to provide to the Minister reports containing prescribed information respecting the prescribing of drugs; and

(b) specifying requirements for the performance of procedures under the authority of paragraphs 2 or 3 of section 4.

5. That section 28 of PART IV of Ontario Regulation 202/94 under the *Pharmacy Act, 1991* (General) be amended by adding the following:

(4) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 3 or 4 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

(5) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 2, 3 or 4 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

(6)(a) For the purposes of this section, “Drug List” has the meaning given to it in the *Regulated Health Professions Act, 1991*.

(b) A member may prescribe the following classes of drugs:

- i. antihistamine drugs,
- ii. anti-infective agents,
- iii. autonomic drugs,

- iv. blood formation, coagulation and thrombosis agents,
- v. cardiovascular drugs,
- vi. CNS agents – analgesics and antipyretics - NSAIDs, anticonvulsants, psychotherapeutic agents, anorexigenic agents and respiratory and cerebral stimulants, anxiolytics, sedatives and hypnotics, antimanic agents, antimigraine agents, antiparkinsonian agents,
- vii. electrolytic, caloric and water balance,
- viii. respiratory tract agents,
- ix. eye, ear, nose and throat preparations,
- x. gastrointestinal drugs,
- xi. hormones and synthetic substitutes,
- xii. skin and mucous membrane agents,
- xiii. vitamins, and
- xiv. miscellaneous therapeutic agents.

(c) A member may only prescribe drugs under the authority of paragraph 4 of section 4 of the Act:

(a) for the purposes of either medication therapy management, smoking cessation therapy or as otherwise prescribed in the regulations; and

(b) only those drugs with the classes designated in subsection 6(b) that are listed in the Drug List and must prescribe those listed drugs in accordance with the terms, limitations and conditions contained in the Drug List.

(7) For the purposes of clause 28(6)(c),

“medication therapy management” means professional activities and responsibilities of the member designed to optimize therapeutic outcomes for a patient according to the needs of the individuals being treated as set out in detail in the standards of practice established and published by the College from time to time; and

“smoking cessation therapy” means professional activities and responsibilities of the member designed to assess, initiate and monitor the most appropriate therapy for smoking cessation, including the prescribing of designated drugs as set out in regulation and in the standards of practice established and published by the College from time to time.

6. That section 29.1(a) of Ontario Regulation 202/94 under the *Pharmacy Act, 1991* (General) be repealed and the following substituted:

29.1 (a) prescribe, dispense, sell or compound drugs;

7. That section 38(1) of Ontario Regulation 202/94 under the *Pharmacy Act, 1991* (General) be repealed and the following substituted:

38. (1) In this section,

“advertisement” includes an announcement, directory listing or other form of communication similar to an advertisement; and

“prescription services” means the prescribing, compounding, dispensing or sale by retail of drugs and the provision of information or advice with respect to those drugs.

8. That paragraphs 12, 13 and 15 of section 38(3) of Ontario Regulation 202/94 under the *Pharmacy Act, 1991* (General) be repealed.
9. That Ontario Regulation 202/94 under the *Pharmacy Act, 1991* (General) be amended by adding the following:

PART IX

STANDARDS OF PRACTICE

52. The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 2, 3 and 4 of section 4 of the Act.

53. The standards of practice referred to in section 52 shall be developed on the recommendation of the Pharmacy Standards Committee.

54. For the purposes of section 53, the College shall establish the Pharmacy Standards Committee referred to in section 53 and shall appoint the membership of the Pharmacy Standards Committee, which shall include, at a minimum, one or more:

- a) members of the Council;
- b) members of the College (including practitioners and educators);
- c) persons who are not and have not been members of the College or of the Council;
- d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario, who practice family medicine;
- e) members of the College of Nurses of Ontario, approved by the College of Nurses of Ontario; and
- f) members of the College of Medical Laboratory Technologists of Ontario, approved by the College of Medical Laboratory Technologists of Ontario.

55. The College shall post the following on its website:

- a) the standards of practice referred to in section 52; and

- b) a list of those members, who are authorized to perform a procedure under the authority of paragraphs 2, 3 and 4 of section 4 of the Act.
10. That Ontario Regulation 681/93 under the *Pharmacy Act, 1991* (Professional Misconduct) be amended by adding the following section:
- 1.1** Exceeding the scope of practice of the profession.
11. That section 1.2 of Ontario Regulation 681/93 under the *Pharmacy Act, 1991* (Professional Misconduct) be repealed and the following substituted:
- 1.2** Contravening or failing to maintain a standard of practice of the profession.
12. That section 1.5 of Ontario Regulation 681/93 under the *Pharmacy Act, 1991* (Professional Misconduct) be repealed and the following substituted:
- 1.5** Prescribing, dispensing, selling, compounding or administering a drug or substance for an improper purpose, or otherwise using improperly the authority to prescribe, dispense, sell, compound or administer drugs or substances.
13. That section 1.22 of Ontario Regulation 681/93 under the *Pharmacy Act, 1991* (Professional Misconduct) be repealed and the following substituted:
- 1.22** Contravening, while engaged in the practice of pharmacy, any federal or provincial law or municipal by-law with respect to the distribution, sale, prescribing or dispensing of any drug or mixture of drug.
14. That section 1 of Ontario Regulation 681/93 under the *Pharmacy Act, 1991* (Professional Misconduct) be amended by adding the following sections:
- 1.2.1** Failing to advise a patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such consultation to ensure the proper care of the patient.
- 1.2.2** Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.
- 1.5.1** Being subjected to the withdrawal or restriction of rights or privileges under the *Controlled Drugs and Substances Act* (Canada) or the *Food and Drugs Act* (Canada) or the regulations under either of those Acts, unless by the member's own request.

1.9.1 Recommending or providing unnecessary services.

1.31 Delegating an act set out in paragraph 1, 2 or 3 of section 4 of the Act except as permitted by the *Regulated Health Professions Act, 1991* or the regulations made thereunder or under the Act, or delegating an act set out in paragraph 4 of section 4 of the Act.

15. That section 3(1) of Ontario Regulation 297/96 under the *Drug and Pharmacies Regulation Act (General)* be repealed and the following substituted:

3(1) In this section,

“advertisement” includes an announcement, directory listing or other form of communication similar to an advertisement;

“prescription services” means the prescribing, compounding, dispensing or sale by retail of drugs and the provision of information or advice with respect to those drugs.

16. That paragraphs 3(4)12, 13 and 15 of 297/96 under the *Drug and Pharmacies Regulation Act (General)* be repealed.
17. That paragraph 9(1)(a) of Ontario Regulation 682 under the *Laboratory and Specimen Collection Centre Licensing Act (Laboratories)* be amended by adding the following:

(iv.3) at the request of a pharmacist, in respect of a test specified in Appendix F.

18. That Ontario Regulation 682 under the *Laboratory and Specimen Collection Centre Licensing Act (Laboratories)* be amended by adding Appendix F.
19. That paragraph 4(2)(b) of Ontario Regulation 683 under the *Laboratory and Specimen Collection Centre Licensing Act (Specimen Collection Centres)* be amended by adding the following:

(iv.3) a pharmacist,

20. That PART III – PERSONS PRESCRIBED TO ORDER TESTS of Ontario Regulation 207/94 under the *Medical Laboratory Technology Act, 1991 (General)* be amended by adding the following:

5. A member of the Ontario College of Pharmacists.

21. That section 2(1) of the *Health Care Consent Act, 1996* be amended by adding the following:

(s.1) a member of the Ontario College of Pharmacists,

22. That the Minister of Health and Long-Term Care, with consultation with the Ontario College of Pharmacists, amend sections 30, 31 and 32 of PART IV Ontario Regulation 202/94 under the *Pharmacy Act, 1991* to recognize University of Waterloo students and interns in addition to those from University of Toronto.

CHAPTER 15.

PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF PHYSIOTHERAPY

To implement HPRAC's recommendations, the following changes to statutes and regulations are proposed:

1. That section 3 of the *Physiotherapy Act, 1991* be repealed and the following substituted:

Scope of practice

3. The practice of physiotherapy is the assessment of neuromuscular, musculoskeletal and cardiorespiratory systems, the diagnosis of diseases or disorders that cause or are associated with physical dysfunction, injury or pain, and the treatment, rehabilitation and prevention of physical dysfunction, injury or pain to develop, maintain, rehabilitate or augment function, relieve pain or promote mobility.

2. That section 4 of the *Physiotherapy Act, 1991* be repealed and the following substituted:

Authorized acts

4. In the course of engaging in the practice of physiotherapy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. Communicating a diagnosis identifying, as the cause of an individual's symptoms, a disease, disorder or dysfunction that may be identified through a physiotherapy assessment.
2. Treating a wound by cleansing, soaking, irrigating, probing, debriding, packing or dressing the wound.
3. Moving the joints of the spine beyond a person's usual physiological range of motion using a fast, low amplitude thrust.
4. Administering by inhalation oxygen, a drug or substance for the purpose of maintaining or improving cardiopulmonary function during physiotherapy interventions.
5. Tracheal suctioning.
6. Putting an instrument, hand or finger beyond the labia majora or the anal verge for the purpose of manipulating the tailbone and for the purpose of assessing or rehabilitating pelvic musculature associated with urinary or fecal incontinence.
7. Ordering the application of a prescribed form of energy.

3. That the *Physiotherapy Act, 1991* be amended by adding the following sections:

Additional requirements for authorized acts

4.1 A member shall perform a procedure under the authority of paragraph 1, 2, 4, 6 or 7 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.

4.2 A member shall not perform a procedure under the authority of paragraph 4 of section 4 unless the procedure is ordered, or the oxygen, drug or substance is prescribed, by a member of a College as defined in the *Regulated Health Professions Act, 1991* who has the authority to make the order or prescription.

Individual scope of practice for physiotherapists

4.3 A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

4. That the *Physiotherapy Act, 1991* be amended by adding the following section:

Regulations

11(b) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations:

(i) specifying requirements for the performance of procedures under the authority of paragraph 1, 2, 4, 6 or 7 of section 4; and

(ii) prescribing the forms of energy that a member may order for the purpose of paragraph 7 of section 4 of the Act and prescribing the purpose for which, or the circumstances in which, the form of energy may be ordered.

5. That Ontario Regulation 532/98 under the *Physiotherapy Act, 1991* (General) be amended by adding the following:

6(6) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure under the authority of paragraph 1, 2, 6 or 7 of section 4 must: (a) provide satisfactory evidence of successful completion of a post-graduate program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

(7) It is a term, condition and limitation of a certificate of registration of any class that the holder who performs a procedure

under the authority of paragraph 1, 2, 4, 6 or 7 of section 4 must ensure the procedure is performed in accordance with any standards of practice established by the College from time to time.

(8) For the purposes of paragraph 7 of section 4 of the Act, a member may order the application of electromagnetism for magnetic resonance imaging and the application of sound waves for diagnostic ultrasound.

6. That Ontario Regulation 532/98 under the *Physiotherapy Act, 1991* (General) be amended by adding the following:

PART IV

STANDARDS OF PRACTICE

27. The College shall develop, establish and maintain standards of practice for those procedures performed under the authority of paragraph 1, 2, 4, 6 and 7 of section 4 of the Act.

28. The standards of practice referred to in section 27 shall be developed, established and maintained on the recommendation of the Physiotherapy Standards Committee.

29. For the purposes of section 28, the College shall establish the Physiotherapy Standards Committee referred to in section 28 and shall appoint the membership of the Physiotherapy Standards Committee, which shall include, at a minimum, one or more:

- a) members of the Council;
- b) members of the College (including practitioners and educators);
- c) persons who are not and have not been members of the College or of the Council;
- d) members of the College of Physicians and Surgeons of Ontario, approved by the College of Physicians and Surgeons of Ontario;
- e) members of the College of Nurses of Ontario, approved by the College of Nurses of Ontario;
- f) members of the College of Medical Laboratory Technologists, approved by the College of Medical Laboratory Technologists; and
- g) members of the College of Medical Radiation Technologists of Ontario, approved by the College of Medical Radiation Technologists of Ontario.

30. The College shall post the following on its website:

- a) the standards of practice referred to in section 27; and

- b) a list of those members, who are authorized to perform a procedure under the authority of paragraph 2 of section 4.
7. That Ontario Regulation 388/08 under the *Physiotherapy Act, 1991* (Professional Misconduct) be amended by adding the following sections:
- 1.1** Exceeding the scope of practice of the profession.
- 9.1** Administering oxygen, a drug or substance for an improper purpose, or otherwise using improperly the authority to administer oxygen, drugs and substances.
- 42.1** Failing to advise the patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such consultation to ensure the proper care of the patient.
- 42.2** Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.
- 43.** Recommending or providing unnecessary services.
8. That Ontario Regulation 107/96 under the *Regulated Health Professions Act, 1991* be amended by deleting the word “or” after paragraph 7.1(2)(b), by inserting the word “or” after paragraph 7.1(2)(c) and by adding a new paragraph (d) as follows:
- A member of the College of Physiotherapists of Ontario, with respect to ordering the application of sound waves for diagnostic ultrasound.
9. That subsection 6(1) the *Healing Arts Radiation Protection Act* be amended by adding the following paragraph (g), so that it reads:
- 6(1)** No person shall operate an X-ray machine for the irradiation of a human being unless the irradiation has been prescribed by, ... (g) a member of the College of Physiotherapists of Ontario.
10. That paragraph 9(1)(a) of Ontario Regulation 682 under the *Laboratory and Specimen Collection Centre Licensing Act* be amended by adding the following:
- (iv.2)** at the request of a physiotherapist, in respect of a test specified in Appendix E, ...
11. That Ontario Regulation 682 under the *Laboratory and Specimen Collection Centre Licensing Act* be amended by adding Appendix E.

12. That paragraph 4(2)(b) of Ontario Regulation 683 under the *Laboratory and Specimen Collection Centre Licensing Act* be amended by adding the following:

(vi) a physiotherapist,

13. That PART III – PERSONS PRESCRIBED TO ORDER TESTS of Ontario Regulation 207/94 under the *Medical Laboratory Technology Act, 1991* be amended by adding the following:

4. A member of the College of Physiotherapy of Ontario.

CHAPTER 16.

PRESCRIBING AND USE OF DRUGS IN THE PROFESSION OF RESPIRATORY THERAPY

To implement these recommendations, the following changes to statutes and regulations are proposed:

1. That section 4(1) of the *Respiratory Therapy Act, 1991* be amended by adding the following paragraph:

5. Prescribing oxygen.

2. That section 5(2) of the *Respiratory Therapy Act, 1991* be repealed and the following substituted:

Additional requirements for authorized acts

5(2) A member shall perform a procedure under the authority of paragraph 5 of section 4 in accordance with any requirements prescribed in the regulations made under this Act or under the *Regulated Health Professions Act, 1991*.

Individual scope of practice for respiratory therapists

5(3) A member is responsible for identifying the limits of his or her educational preparation and competencies, and for resolving situations beyond his or her expertise by consulting with or referring patients to other health care professionals.

Grounds for misconduct

5(4) In addition to the grounds set out in subsection 51(1) of the Health Professions Procedural Code, a panel of the Discipline Committee shall find that a member has committed an act of professional misconduct if the member contravenes subsection (1), (2) or (3).

3. That the *Respiratory Therapy Act, 1991* be amended by adding the following section:

Regulations

12. Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council may make regulations,
 - (a) prescribing procedures for the purpose of paragraph 1 of section 4, and
 - (b) regulating the prescribing of oxygen by members, requiring members to keep prescribed records and

to provide to the Minister reports containing prescribed information respecting the prescribing of oxygen.

4. That Ontario Regulation 596/94 under the *Respiratory Therapy Act, 1991* (General) be amended by adding the following sections:

57.1 (1) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 5 of section 4 of the Act must: (a) provide satisfactory evidence of successful completion of a program that meets approved criteria; and (b) ensure the procedure performed does not exceed the level of training completed.

(2) It is a term, condition and limitation of a certificate of registration of any class that the member who performs a procedure under the authority of paragraph 5 of section 4 of the Act must ensure the procedure is performed in accordance with any standards of practice established and published by the College from time to time.

5. That sections 1(4) and 1(7) of Ontario Regulation 753/93 under the *Respiratory Therapy Act, 1991* (Professional Misconduct) be repealed and the following substituted:

4. Delegating a controlled act set out in subsection 27(2) of the *Regulated Health Professions Act, 1991*, in contravention of the regulations, or delegating an act set out in paragraph 5 of section 4 of the Act.

7. Recommending, prescribing, dispensing or selling medical gases or equipment for an improper purpose or otherwise using improperly the authority to recommend, prescribe, dispense or sell medical gases or equipment.

6. That section 1 of Ontario Regulation 753/93 under the *Respiratory Therapy Act, 1991* (Professional Misconduct) be amended by adding the following paragraphs:

1.1 Exceeding the scope of practice of the profession.

31. Failing to advise the patient to consult with a physician or other regulated health professional where the member recognizes, or ought to recognize, a condition that is beyond the competence or experience of the member or that requires such consultation to ensure the proper care of the patient.

32. Treating or attempting to treat a condition that the member knew or ought to have known was beyond his or her expertise or competence.

33. Practicing the profession while the member is in a conflict of interest.

34. Recommending or providing unnecessary services.

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ISBN 978-1-4249-8646-0 (PDF)

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