Ontario College of Pharmacists
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Agenda

COUNCIL MEETING AGENDA

MONDAY, JUNE 13, 2016 – 9:00 A.M.

COUNCIL CHAMBERS, 483 HURON STREET, TORONTO

1. Noting Members Present

2 Declaration of Conflict

3. Approval of Agenda

4. President's Opening Remarks

4.1 Briefing Note - President's Report to June 2016 Council ..... Appendix 1

4.2 Briefing Note - March 2016 Council Meeting Evaluation ..... Appendix 2

5. Approval of Minutes of Previous Meeting

5.1 Minutes of March 2016 Council Meeting ..... Appendix 3

6. Notice of Motions Intended to be Introduced

7. Motions, Notice of Which Had Previously Been Given

8. Inquiries

9. Matters Arising from Previous Meetings

9.1 Briefing Note – Executive Committee .....Appendix 4
- Approval of proposed amendments to the Pharmacy Act Regulation re Expanded Immunization by Pharmacists

9.2 Briefing Note - Executive Committee .....Appendix 5
- Council Appointed Non-Profession Committee Members

9.3 Briefing Note - Registrar's Report to June 2016 Council ..... Appendix 6
- *Legislative Initiatives*
- *Bill 33 – Patch 4 Patch/Fentanyl*
- *Naloxone*
- *Bill 21, Safeguarding Health Care Integrity Act, 2014*
- *Sexual Abuse Task Force*
- *Bill 119, Health Information Protection Act, 2015*
- *Physician-Assisted Death*
- *Stakeholder Relations*
- *Federation of Health Regulatory Colleges of Ontario*
- *National Association of Pharmacy Regulatory Authorities*
- *District Meetings/Regional Meetings*
- *Operational Plan Update (Includes presentations by Continuing Competence and Registration Programs)*

10. For Decision

10.1 Briefing Note – Finance and Audit Committee .....Appendix 7
Council/Committee Remuneration

11. For Information

11.1 Briefing Note – Executive Committee .....Appendix 8
Physician-Assisted Death/Medical Assistance in Dying (MAiD)

12. Other Matters

12.1 Presentation by Ms. Karen McKibbin, Executive Lead, Health Services Cluster, and Dr. Robin Williams, Associate Chief Medical Officer of Health, Infrastructure and System, Ministry of Health and Long-Term Care
Re: Integrated Access to Patient Drug Profile
Time: 10:30 a.m. to 11:00 a.m.

12.2 Presentation by Dr. David Edwards, Hallman Director and Professor, School of Pharmacy, University of Waterloo
Re: Pharmacy 5 in 5 Initiative and Proposal ..... Appendix 9

12.3 Appointment of Elections Committee

13. Unfinished Business

14. Motion of Adjournment

As a courtesy to other Council Members, you are requested to please turn off your cell phones/pagers/blackberries and other hand-held devices that may cause disruption during the Council Meeting. There are breaks scheduled throughout the day in order to allow members the opportunity to retrieve and respond to messages.

Please note: *The College is a scent free environment. Scented products such as hairsprays, perfume, and scented deodorants may trigger reactions such as respiratory distress and headaches. In consideration of others, people attending the College are asked to limit or refrain from using scented products. Your co-operation is appreciated.*

Thank you.

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COUNCIL BRIEFING NOTE
MEETING DATE: June 2016

FOR DECISION	FOR INFORMATION	X

INITIATED BY: Esmail Merani, President

TOPIC: President's Report to June 2016 Council

ISSUE: As set out in the Governance Manual, the President is required to submit a report of activities at each Council meeting.

BACKGROUND: I respectfully submit a report on my activities since the March 2016 Council Meeting. In addition to regular meetings and phone calls with the Registrar and the Vice President, listed below are the meetings, conferences or presentations I attended on behalf of the College during the reporting period. Where applicable, meetings have been categorized into general topics or groups.

Other Stakeholder Meetings:
April 26th – Golf Organizing Committee of Ottawa Carleton Pharmacy Association - Annual Golf Tournament
April 27th - CE event presented by Dr. Zubin Austin and Ms. Anita Arzoomanian - "Decisions, Decisions: Addressing Challenging Pharmacy Practice Situations and Understanding OCP's New Practice Assessment"
May 4th - Executive meeting of the Ottawa -Carleton Pharmacists Association
June 9th - OPA Conference, Toronto

College Meetings:

April 1st – Call with Registrar Marshall Moleschi and Past President Mark Scanlon re progress on Public Appointments.
April 4th - New Council Member Orientation with Mr. Ravil Veli, Public Member, North Bay
April 29th – Call with Registrar Moleschi re Various College Updates
May 11th - Finance and Audit Committee Meeting
May 11th – Meeting with Registrar Moleschi re Executive Committee Meeting Agenda and New Council Member Orientation (Mr. James MacLaggan).
May 26th - Executive Committee Meeting

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COUNCIL BRIEFING NOTE
MEETING DATE: June 2016

FOR DECISION	FOR INFORMATION	X

INITIATED BY: Esmail Merani, President

TOPIC: March 2016 Council Evaluation Report to June 2016 Council

ISSUE: As set out in the Governance Manual, after each Council meeting, Council performs an evaluation of the effectiveness of the meeting and provides suggestions for improvement.

BACKGROUND: At the March 2016 Council meeting, we again provided Council members with the opportunity to provide their feedback via electronic survey. 14 Council members responded to the survey. A summary of the input is being provided to Council for information.

1. Governance philosophy Council and staff work collaboratively, each in distinct roles, to carry out self-regulation of the pharmacy profession in the interest of the public and in the context of our mission statement and legislated mandate. How would you evaluate the meeting overall?

Answer Options	Always	Frequently	Often	Occasionally	Never	Response Count
1. In accordance with the governance philosophy, topics were related to the interest of the public and the purpose of OCP	9	3	1	0	0	13
2. Members were well prepared to participate effectively in discussion and decision making	6	7	0	0	0	13
3. In accordance with the governance philosophy, Council worked interdependently with staff	10	1	2	0	0	13
4. There was effective use of time	5	6	2	0	0	13
5. There was an appropriate level of discussion of issues	6	5	1	1	0	13
6. The discussion was focused, clear, concise, and on topic	3	7	2	1	0	13

2. Did the meeting further the public interest?

YES = 12 = 92.31%
NO = 1 = 7.69%

- The presentation on public members was not in greater public interest and within scope of control of the college.

3. Identify the issue for which you felt the discussion and decision-making process worked best, and why.

- For most items on the agenda the council process was effective and worked well. This was a result, generally, of the detail and clarity of the information presented.
- Discussion on the limit of the number of public members mandated to serve on committees as a result of the lengthy delay for appointments by the government. This has been an ongoing concern of the College. Council members were made aware of the discontent of its public members regarding the low reimbursement rate provided by government and the lengthy delay in time for payments. All of which may lead to the early retirement of current members and the continuing availability of the high caliber of public members who now or may wish to serve on College Council. An innovative resolution was presented at the meeting but I believe the tabling of the motion presented was appropriate at the time.
- During the debate on the need for added positions for public members
- There was good discussion in regards to No Committee non professional members
- The vaccine proposal.
- Non professional members on committees; clearly the board was not yet ready to make a decision.
- The registrar's report, many issues were handled well and decisions made, exception the appointment of past public members.
- Travel vaccines. Not much discussion though

4. Identify the issue(s) for which you have felt the discussion and decision-making process was not effective, and why. Note any areas where the distinction between governance and operations was unclear

- The item related to the appointment of non-government public members could have gone better then it did. Looking back on the situation this is what I have learned: it would have been beneficial to allow the initial discussion to continue longer without interruption; materials presented could have been more detailed, more clear and better explained the rationale for proposing this change.
- Discussion on non professional council members- lack of understanding of need for this parallel process
- None
- During the presentation about appointments. There should never be personal questions (billing) or agendas. It should be about the public as a whole
- I was disappointed in the tabling of the motion related to using non-appointed public members on committees. It seemed that the appointed public members felt that they were entitled to support the work of the College more than the group of public members that the College was seeking to appoint. In the end, this did not serve the public interest.
- The by law changes. There was some confusion
- As mentioned the appointment of past public members was not well presented nor understood, often discussion branched out into other issues
- There was confusion about the voting process around the college appointed public members. It was not clear and I would have voted differently. Also please make Members wait their turn to speak. Interruptions are unproductive. Perhaps make everyone stand when addressing council again? That would reintroduce decorum?

5. Using the Code of Conduct and Procedures for Council and Committee Members as your guide, in general, how satisfied are you with Council members' ability to demonstrate the principles of accountability, respect, integrity and openness?

Answer Choices	Responses
Completely Satisfied	6
Mostly Satisfied	7
Neither Satisfied Nor Dissatisfied	0
Mostly Dissatisfied	0
Completely Dissatisfied	0
Total Responses	13

6. Suggestions for improvement and General Comments (name of respondent - optional)

- Generally the meeting was fine. A small suggestion to smooth the Council's decision making process is, to ensure sufficient, detailed and easily understood information is provided and effectively communicated to allow Council to make informed decisions; regardless of what those decisions are. Sylvia Moustacalis
- I would suggest that a speaker list be taken so that members may speak in an orderly fashion and that members get to speak before someone else gets a second chance. Wes Vickers
- Council should be more welcoming place to speak.
- The need to break for lunch before finishing the discussion on non-appointed public members was odd.
- Work with public members to present solutions to government on the problem of appointing and especially retaining LGIC appointees. Ron Farrell
- I think the discussion over the appointment of non-professional committee members was the beginning of a much more fulsome discussion. I'm glad the group was open to parking it for further debate. I think our public members (as always) made highly valuable comments and fulfilled their role of protecting the public interest. D. Stewart
- Presentation and speakers really great. Especially liked Kelly Grinrod UofWaterloo presentation and support David Edwards in partnering with OCP this special project

Respectfully submitted,

Esmail Merani, President

Ontario College of Pharmacists

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MINUTES OF MEETING

OF COUNCIL

MARCH 29, 2016

Page

TUESDAY, MARCH 29, 2016 – 9:00 A.M.

COUNCIL CHAMBERS, ONTARIO COLLEGE OF PHARMACISTS

Elected Members

District H	Dr. Regis Vaillancourt, Ottawa
District H	Ms. Christine Donaldson, Windsor
District K	Dr. Esmail Merani, Carleton Place
District K	Mr. Mark F. Scanlon, Peterborough
District L	**VACANT**
District L	Dr. Michael Nashat, Brampton
District L	Mr. Farid Wassef, Stouffville
District M	Mr. Fayez Kosa, Toronto **- Regrets**
District M	Mr. Don Organ, Toronto
District M	Ms. Laura Weyland, Toronto
District N	Mr. Gerry Cook, London
District N	Mr. Chris Leung, Windsor
District N	Dr. Karen Riley, Sarnia
District P	Mr. Jon MacDonald, Sault Ste. Marie
District P	Mr. Douglas Stewart, Sudbury
District T	Ms. Michelle Filo, Sudbury
District TH	Mr. Goran Petrovic, Kitchener

Dr. Heather Boon, Dean, Leslie Dan Faculty of Pharmacy, University of Toronto
Dr. David Edwards, Hallman Director, School of Pharmacy, University of Waterloo

Members Appointed by the Lieutenant-Governor-in-Council

Ms. Kathleen Al-Zand, Ottawa
Ms. Linda Bracken, Marmora **- Regrets**
Mr. Ronald Farrell, Sundridge
Mr. Javaid Khan, Markham
Mr. John Laframboise, Ottawa
Mr. Lewis Lederman, Ottawa
Ms. Sylvia Moustacalis, Toronto
Mr. Shahid Rashdi, Mississauga **- Regrets**
Ms. Joy Sommerfreund, London **- Regrets**
Mr. Wes Vickers, LaSalle

Staff present

Ms. Connie Campbell, Director, Finance and Administration
Ms. Susan James, Director, Competence
Mr. Marshall Moleschi, CEO and Registrar
Ms. Ushma Rajdev, Council and Executive Liaison
Ms. Anne Resnick, Deputy Registrar/Director, Conduct

Invited Guests

Mr. John Amodeo, Director, Corporate Management Branch and Mr. Tom Boyd, Manager, Agency Liaison and Public Appointments Unit, Corporate Services Division, Ministry of Health and Long Term Care
Dr. Kelly Grindrod, University of Waterloo

1. Noting Members Present

Member attendance was noted.

2 Declaration of Conflict

There were no conflicts declared.

3. Approval of Agenda

It was moved and seconded that the Agenda be approved. CARRIED.

4. President's Opening Remarks

President Merani welcomed Mr. Wes Vickers, Public Member from LaSalle, who was appointed to College Council on February 10th. Mr. Vickers has been appointed to serve on the Discipline, Inquiries Complaints and Reports, and the Registration Committees of the College and the President added that Ms. Moustacalis had been appointed as his mentor. Mr. Vickers was invited to briefly introduce himself to Council.

It was noted that on February 11th, Ms. Jillian Grocholsky from District L tendered her resignation. Elections will be held in that District later this year. Ms. Grocholsky has been appointed to the Discipline and Registration Committees as a Non-Council Committee member until September 2016.

4.1 Briefing Note - President's Report to Council

The President referred to his report which summarized his activities since the previous Council meeting. These included attending various committee meetings at the College and various phone calls and meetings with the Registrar and the Vice President.

4.2 Briefing Note – December 2015 Council Meeting Evaluation

Referring to the December 2015 Council Meeting Evaluation, President Merani advised that, in response to the comment that having Council members stand when addressing Council (resulting in the speaker being further away from the microphone which can sometimes make it difficult to hear/understand the speaker), going forward, the requirement to stand will be removed. He further noted that the number of respondents to the meeting evaluation had dropped and Council members were encouraged to provide feedback which will serve to ensure efficiency and enhance Council members' participation at these meetings.

5. Approval of Minutes of Previous Meeting

5.1 Minutes of December 2015 Council Meeting

It was moved and seconded that the Minutes of the December 2015 meeting be approved. CARRIED.

6. Notice of Motions Intended to be Introduced

There were none.

7. Motions, Notice of Which Had Previously Been Given

There were none.

8. Inquiries

There were none.

9. Matters Arising from Previous Meetings

9.1 Briefing Note - Registrar's Report to Council

Mr. Moleschi highlighted the salient points from his report and responded to questions from the floor.

In response to a request from the floor, the Registrar provided an update on the Quality Assurance Program re-design. He explained that as has been reported in the Operation Plan Update (attached to his Briefing Note), one goal of the re-design was to find ways to reach more members than we do currently by building on the existing program through consideration of practices in other jurisdictions and professions. He added that at the September Council meeting, Ms. Winkelbauer (Manager, Continuing Competence), will be providing an in-depth explanation of the re-design project, together with the proposed activities and timelines.

Referring to his Briefing Note, the Registrar advised that the Minister of Health and Long-Term Care recently launched a stakeholder consultation on a proposal to strengthen patient-centered health care in Ontario. He noted that the various service model options presented in the consultation paper would result in enhancing and strengthening the role of Local Health Integrated Networks (LHINs) and reducing the role of Community Care Access Centres (CCACs).

Also noted was the "Immunization 2020" initiative, which calls for amendments to legislation that, if passed, will require parents to participate in an education session delivered by their local public health unit in order to obtain a vaccine exemption for non-medical reasons. As well, during the announcement of the "Immunization 2020" plan, the government reiterated its commitment to make access to travel vaccines as convenient as possible to the public by exploring ways for pharmacists to give travel vaccines in local pharmacies. Registrar Moleschi added that a Briefing Note on the expansion of immunization by pharmacists was on today's agenda and will be discussed later in the day.

It was noted for information that Ms. Christine Elliott, the former Conservative Member of Provincial Parliament, was appointed as the first ever Patient Ombudsman. Ms. Elliott's mandate includes helping meet the needs of patients who have not had their concerns resolved through existing complaint mechanisms. In response to a question from the floor, Registrar Moleschi advised that Ms. Elliott will be invited to attend a meeting of the Federation of Health Regulatory Colleges (FHRCO) and address the members regarding structure and processes with regard to complaints received by her office. He agreed that if warranted, Ms. Elliott could also be invited to address this Council at a future meeting.

The Registrar also informed Council that following the meetings held by federal, provincial and territorial Ministers of Health towards the end of January 2016, there was agreement that there would be movement on various priorities including enhancing the affordability, accessibility and appropriate use of prescription drugs.

Referring to the section on the Transparency and Openness Strategy for Health Regulatory Colleges, Mr. Moleschi advised that the College has worked hard towards making many of its processes more transparent and that currently, we are participating on the government's working group to determine how best to make more information publicly available.

It was noted that the proposed amendments to regulations to the *Drug and Pharmacies Regulation Act* are anticipated to be approved by spring of 2016. In early March, hospital pharmacies were invited to submit applications for certificates of accreditation in anticipation of proclamation and the Registrar advised that many hospitals have already submitted their applications.

Mr. Moleschi next advised Council that the Ministry has commenced work on modernizing the province's health regulatory framework. Parliamentary Assistant (PA) John Fraser has, as part of his mandate, the responsibility for "…leading work that will help the minister ensure that nurses, pharmacists and other health professionals can make their full contribution to the health care system. In response to a question from the floor, the Registrar advised that no specific timelines had been given with regard to this initiative and agreed with the suggestion that Ms. Denise Cole, Assistant Deputy Minister, Health Workforce Planning and Regulatory Affairs Division, should be invited to address College Council at a future meeting to provide an update.

Regarding Bill 33 (*An Act to Reduce the Abuse of Fentanyl Patches and Other Controlled Substance Patches*) Mr. Moleschi explained that the Bill requires the prescriber of the fentanyl patches to record on the prescription, the name and location of the pharmacy that will fill the prescription, and to notify the pharmacy about the prescription. He added that the development of regulations is proceeding, with both this College and the College of Physicians and Surgeons providing input on operational considerations and that an OCP clinical advisory group has been established to provide further guidance.

Next, the Registrar referred to the issue of Physician-Assisted Death (now known as Medical Aid in Dying). Council noted that the College developed a guidance document intended to provide interim guidance in the absence of federal and provincial legislation to support the profession when assisting patients who have qualified and consented to physician-assisted death. The guidance is intended to help pharmacy professionals comply with the Code of Ethics and Standards of Practice in a manner that is consistent with the decision of the Supreme Court of Canada.

Also noted for information was the production of video segments by the Federation of Health Regulatory Colleges of Ontario (FHRCO) for Council member training. The Registrar advised that the videos will be available to FHRCO member Colleges online as part of their orientation or ongoing education programs.

The Registrar also provided an update on NAPRA's (National Association of Pharmacy Regulatory Authorities) initiatives. He noted that NAPRA's Registrars' Group, at a recent meeting, addressed many of the issues identified in his Briefing Note to Council today. He also noted that Ms. Carole Bouchard, the current Executive Director of NAPRA, had recently announced her intention to step down from her position at the end of the summer.

It was noted that the remainder of the Registrar's Report to Council would continue after a guest presentation.

12. Other Matters

12.1 Presentation by Mr. John Amodeo, Director, Corporate Management Branch, Corporate Services Division, Ministry of Health and Long-Term Care

Referring to the agenda, and noting that the presentation by Mr. Amodeo was scheduled next, President Merani requested the Registrar perform introductions after which, Mr. Amodeo was invited to make his presentation. From 10:05 a.m. to 10:50 a.m., Council received an overview

of the Corporate Management Branch's responsibilities, with specific focus on public appointments.

9. Matters Arising from Previous Meetings *(continued)*

9.1 Briefing Note - Registrar's Report to Council *(continued)*

Mr. Moleschi referred Council members to the Operational Plan update which was attached to his Report. Mr. Moleschi reminded Council that in addition to providing an opportunity for Council to assess progress of all directional policies, the update should also be considered a reflection of his performance since he is responsible for the implementation outcomes of the plan. He further advised Council that as outlined in the Governance Manual, the Registrar is to develop a risk management program and report on risk management activities to inform Council on how risks that may impact the College's ability to achieve their public protection goals are being managed. The Risk Management Plan, he continued, was also attached to his Briefing Note to Council.

10. For Discussion and Decision

10.1 Briefing Note – Finance and Audit Committee

Mr. Khan, Chair of the Finance and Audit Committee was invited to present the Briefing Note to Council. **A motion to receive the Briefing Note from the Finance and Audit Committee was moved and seconded. CARRIED.**

Mr. Vinay Raja, Audit Partner at Clarke Henning, was introduced to Council and invited to present the Audited Financial Statements to Council. Mr. Raja provided detailed information on Clarke Henning's role and expectations as the College's auditor. He explained that prior to commencing the audit, they met with the Finance and Audit Committee to outline the auditor's role and also to provide guidance regarding the Committee's own role and responsibilities. Council noted that as is common practice, the Finance and Audit Committee also held an in-camera meeting with the auditors (i.e. no staff were present). In summary, the auditor advised Council of a clean audit with no issues to report.

Together with Ms. Campbell, Mr. Khan answered questions from the floor and provided clarification on some line items. The deficit of approximately $500,000 was noted (a significant portion of which is related to an increase in and complexity of cases being heard by the Discipline Committee). The Chair of the Discipline Committee, Mr. Stewart, added that one reason for the increased volume was increased referrals from ICRC due to elimination of the backlog. Mr. Moleschi explained that the increase in the number of registrants (both pharmacists and pharmacy technicians), as well as the expectations around standards of practice and processes, could also have contributed towards an increase in such hearings. A suggestion was made that the College may want to consider the use of in-house counsels to offset future costs.

In response to a question from the floor, explanation was also provided on the defined contribution pension plan for College employees, including its audit process, use of financial

advisors and the existence of an employee-driven Pension Committee. Ms. Campbell further explained that the increase in this area was a reflection of increased number of participants as well as the performance of the investments.

Following discussion, **it was moved and seconded that Council approve the Audited Financial Statements and Summary Statements for the operations of the Ontario College of Pharmacists for 2015 as prepared by management and audited by Clarke Henning LLP, Chartered Accountants.**

Council members voted in favour of the motion. There were no negative votes or abstentions. The motion **CARRIED.**

10.2 Briefing Note – Executive Committee

A motion to receive the Briefing Note from the Executive Committee was moved and seconded. CARRIED.

Dr. Merani invited Mr. Moleschi to address Council. It was noted that for some time now, the College has been struggling with drawing duly constituted panels to consider matters referred to statutory committees for adjudication due to the limited availability of government appointed public members. This has sometimes resulted in cancelled panel meetings. Mr. Moleschi added that legal opinion was sought which confirmed that legislation permits the College to add public members to college committees by way of by-law amendments. The recommendation of the Executive Committee therefore is that amended by-laws be approved by Council that will allow for the appointment of Council Appointed Non-Profession Committee Members (CANPCM) in order to provide immediate relief (between now and September 2016) to the shortage of public participants on panels. Mr. Moleschi added that while immediate appointments will be limited to recent LGC's (public members appointed by the Lieutenant Governor in Council) whose Orders-in-Council have expired, the Executive Committee will draft criteria and establish a process for future appointments for Council's consideration at the June 2016 Council meeting.

President Merani then opened the floor for discussion on this initiative. Several Council members raised concern with such an approach and cautioned that more thought needs to be given to this issue before we proceed.

Following extensive discussion, the President read the recommendation of the Executive Committee **that Council approve the by-law amendments to enable Council Appointed Non-Profession Committee Members to increase the pool of public participants to serve on panels of college adjudicatory committees.**

A motion was moved and seconded that this recommendation be tabled until the next Council meeting in June.

Council discussed the motion to table the recommendation, and subsequent to the discussion, voted on the motion. 15 members voted in favour and 7 members voted against the motion. There were no abstentions. The motion to table **CARRIED.**

9. Matters Arising from Previous Meetings *(continued)*

9.1 Briefing Note - Registrar's Report to Council *(continued)*

Ms. Tina Perlman, Manager, Community Practice, was invited to provide Council with an overview of her program area which deals with oversight of community pharmacies and pharmacy practice issues that support the ability of members to practice to the standards of the profession. Ms. Perlman's presentation commenced at 1:20 p.m. and ended at 1:56 p.m. during which time she provided clarification on matters and responded to questions form the floor.

12. Other Matters *(continued)*

12.2 Presentation by Dr. Kelly Grindrod, University of Waterloo

Dr. Merani invited Dr. Edwards to introduce Dr. Kelly Grindrod to Council, after which, she presented the Pharmacy 5 in 5 Initiative to Council. During her presentation, which commenced at 1:58 p.m. and ended at 2:44 p.m., Council was shown the online, multimodal teaching and assessment tool called "Pharmacy 5 in 5" developed by Dr. Grindrod and her team at the University of Waterloo. The tool is designed to help pharmacists and pharmacy technicians self-audit their knowledge and acquire a deeper understanding of a variety of clinical and professional topics.

Dr. Edwards advised Council that the University was looking to partner with the College on this initiative and would be bringing forward a proposal for Council's consideration at its meeting in June.

10.3 Briefing Note – Executive Committee

A motion to receive the Briefing Note from the Executive Committee was moved and seconded. CARRIED.

Mr. Moleschi was invited to address Council; he advised that in order for the government to enact a broader authority for pharmacists to administer select vaccinations, amendments to the *Pharmacy Act* regulation would be required. The changes being proposed would allow for the administration of vaccinations for 13 diseases that are preventable by vaccines. The amendments would also authorize pharmacy students and interns to administer injections — including those under the Universal Influenza Immunization Program and the selected vaccines — subject to the terms, limits and conditions imposed on their certificate of registration.

In response to a comment from the floor, the Registrar advised that the Ministry had indicated their preference for a specific list, rather than a general one. Several Council members offered suggestions and comments and the Registrar encouraged them to provide these in writing once the proposed changes were posted for public consultation.

Following discussion, **it was moved and seconded that the proposed changes to the *Pharmacy Act* regulations be circulated and posted for public consultation on the College's website.** Council members voted unanimously in favour of the motion. **CARRIED.**

Comments and input will be considered by Council at its meeting in June.

11. For Information

There were no matters for information.

13. Unfinished Business

There was no unfinished business.

Motion respecting Circulation of Minutes

A motion to approve the circulation of the draft minutes of this Council Meeting to Council members was moved and seconded. CARRIED.

14. Motion of Adjournment

It was moved and seconded that the Council meeting be adjourned at 3:00 p.m. and to reconvene on Monday, June 13, 2016, or at the call of the President. CARRIED.

Ushma Rajdev
Council and Executive Liaison

Esmail Merani
President

INDEX

Page

Ontario College of Pharmacists
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COUNCIL BRIEFING NOTE
MEETING DATE: *JUNE 2016*

FOR DECISION	X	FOR INFORMATION

INITIATED BY: Executive Committee

TOPIC: Proposed Amendments to the *Pharmacy Act Regulations (*Administration of Vaccinations by Pharmacists)

ISSUE: Approval of the proposed amendments to the *Pharmacy Act Regulations* to permit expansion of vaccination administration by pharmacists.

BACKGROUND:

- Following Council's consideration and approval for consultation in March, proposed amendments to the *Pharmacy Act Regulations* were posted on the College website for 60 days with a deadline for response of May 29, 2016.

- The proposed changes would allow for the administration of vaccinations for 13 diseases that are preventable by vaccinations. This includes vaccinations for Haemophilus Influenzae Type B, Hepatitis A, Hepatitis B, Herpes Zoster, Human Papillomavirus, Japanese Encephalitis, Meningitis, Pneumococcal Disease, Rabies, Tuberculosis, Typhoid Disease, Varicella Virus and Yellow Fever.

- The proposed regulations would authorize pharmacy students and interns to administer all vaccinations subject to the terms, limitations and conditions imposed on their certificate of registration.

- The Regulation amendments do not authorize pharmacist prescribing of vaccinations. Patients would still be required to obtain a prescription from an authorized prescriber before a pharmacist could administer a Schedule I vaccination.

- Invitations to participate in the consultation were sent via email through OCP e-connect. The consultation was also shared as a news item on the College website and multiple posts were made on social media.

- All written feedback received during the consultation period was posted on the College website in keeping with regular consultation process and posting guidelines.

DISCUSSION:

The consultation received 308 responses (280 from pharmacy professionals, 12 from the public and 16 from organizations).

General themes identified from comments:

Comments from a <u>majority</u> of respondents identified the following points for consideration:

1. **Overall support for expansion of injection privileges**
   - This amendment would greatly enhance the care pharmacists could provide to the public, and would increase patients' access to vaccinations.
   - Pharmacists regularly receive requests to inject these vaccinations; many are already administering proposed vaccinations under a medical directive.
   - Pharmacists already have the training and expertise to administer vaccinations.

2. **Rationale for the proposed list or need to restrict vaccination administration**
   - This is an excellent public health initiative, and pharmacists have the knowledge, skills and ability to administer vaccinations without restrictions.
   - Concerns that the proposed list is incomplete and that there are notable omissions from the list such as tetanus, diptheria and pertussis (Tdap) – especially with recent outbreaks of whooping cough – as well as Measles, Mumps, Rubella (MMR).
   - Some vaccinations are very rarely administered or due to restrictions on administration will not be frequently administered in a pharmacy (e.g. Tuberculosis, rabies and yellow fever vaccination).
   - Non-vaccination injections such as vitamin B12 should be included in the list.

3. **Clarification of reimbursement strategies and workflow implications**
   - Ensure adequate reimbursement for provision of the service to allow sustainable and safe implementation.
   - Ensure operations in pharmacies support safe and effective implementation of expansion of vaccination administration by pharmacists.

4. **Pharmacist prescribing of vaccinations**
   - To significantly improve patient access to vaccinations pharmacists should be authorized to both prescribe and administer vaccinations.
   - Pharmacists are willing to undergo additional training to support prescribing of vaccinations, if required.

Comments from <u>some</u> respondents identified the following points for consideration:

5. **Administration of vaccinations by interns and students**
   - Support for administration of vaccinations by both students and interns; as long as the student or intern has completed training then they have the same technical capability as a pharmacist to administer a vaccination.
   - Hesitancy with respect to intern and/or student administration of vaccinations due to perceived lack of skills and abilities and potential liability where a student or intern makes an error.

6. **Concern regarding administration of specialty travel vaccinations**
   - Travel medicine is a specialty practice requiring additional specialized training and lengthy in-depth review and consultation to ascertain appropriateness for the patient (e.g. frequently changing CDC recommendations), which pharmacists may not have the knowledge, competency and time to adequately undertake.

7. **Desire for expanded scope with a more clinical focus**
   - Administration of injections is a technical function; allowing pharmacy technicians to administer vaccinations would allow pharmacists to focus attention on therapeutic and cognitive services such as prescribing for minor ailments, ordering and monitoring laboratory tests.

8. **Need to share records with physicians and local public health/panorama program**
   - Importance of updating records to prevent duplication of injections, school suspension or inaccurate advice.

9. **Availability of vaccinations in pharmacy**
   - Many pharmacies will not have some of the proposed vaccinations (e.g. specialty travel vaccinations) routinely in stock; therefore patients will still need to make a second trip to the pharmacy to get injection.

Based on the analysis of the feedback and the following considerations, no revisions to the proposed regulations are suggested:

- Currently, pharmacists may administer the influenza vaccination within the context of Ontario's Universal Influenza Immunization Program (UIIP). These proposed amendments to the *Pharmacy Act Regulations* support the Ministry of Health and Long-Term Care's promise to provide Ontario's patients with an improved healthcare experience.

- The authority proposed in the amendments aligns with the current provincial regulatory approach and framework for developing regulations.

- The College will work in collaboration with stakeholders and the Ministry to inform an evaluation of the impact realized by expanding pharmacist vaccination administration. The results of this evaluation will be used to guide further discussions regarding the pharmacist's role in vaccinations.

- The Regulation amendments, if passed, would make these vaccinations more convenient and accessible for patients. Increasing the number of vaccinations pharmacists may administer reduces:
  - the need for patients to make multiple trips between a physician's office or clinic and a pharmacy; and
  - the risks associated with improper medication storage during transport between the pharmacy and physician's office or clinic.

- Where a pharmacy does not have a vaccination in stock and the patient is required to make a return trip to the pharmacy for administration, the patient will still benefit from having access to a location with extended hours of operation and weekend availability.

- The regulations require that pharmacists notify the primary care provider, if any, when a vaccination is administered; therefore concerns about updating patient records are already addressed.

- Pharmacists have the technical skills and training to administer the proposed vaccinations. It is the professional responsibility of the member to ensure they have the appropriate knowledge, skills and abilities to safely and effectively provide the service (e.g. travel vaccinations).

- Pharmacists are already required, as a standard of practice, to review prescriptions for appropriateness and educate patients when dispensing a medication, including vaccinations.

- Students and interns receive training on the administration of injections as part of the pharmacy curriculum, and once training is completed have the same technical skill set and capabilities as a pharmacist.

- A student or intern is professionally liable for any controlled act he or she performs. Students and interns are required to have professional liability insurance in order to registered with the College and perform controlled acts. All controlled acts must be performed under the supervision of a Part A pharmacist whose responsibility would be to confirm the student or intern has the knowledge, skills and abilities to perform a controlled act.

- Decisions regarding funding and workflow strategies to accommodate a potential increase in the volume of vaccine administration are outside of the scope proposed regulations and the mandate of the College. Any complaints brought forward to the College related to a concern about the safety of vaccine administration in a pharmacy would be investigated.

- The Code of Ethics requires that members maintain appropriate human resources to facilitate compliance with Standards of Practice and relevant legislation, policies and guidelines governing the practice of pharmacy. Members also must ensure the operation of pharmacies support professional performance and that the health of others in the work place is not compromised.

NEXT STEPS:

- Council approves the regulation as circulated.

- The amended *Pharmacy Act Regulations* will be submitted to the Ministry of Health and Long-Term Care.

- The College website has a central repository of available continuing education material and courses (e.g. travel medicine). The Ontario Pharmacists Association will also be involved in developing educational materials and resources to support pharmacists in implementing expanded services.

- The College is currently working in collaboration with stakeholders and the Ministry to establish a communication plan to inform the public of key messages as appropriate, including a patient pathway.

- The College is currently working in collaboration with the Ontario Pharmacists Association, the Ministry and other relevant stakeholders to inform an evaluation of the impact realized by expanding pharmacist vaccination administration.

DECISION FOR COUNCIL:

- Recommend that Council approve the proposed amended *Pharmacy Act Regulations*.
- Does Council have any feedback on the comments received regarding the proposed amendments prior to approval and submission to the Ministry of Health?

Appendix A: Proposed Amended *Pharmacy Act Regulations – Amended Subsections*

34. (4) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a Part A pharmacist, an intern or a registered pharmacy student is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to administer influenza vaccination by injection to a patient who is five years of age or older, if the member,

(a) administers the vaccination in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website;

(b) receives an informed consent from the patient or his or her authorized agent; and

(c) meets all the requirements in paragraphs 2 to 6 of subsection (3). O. Reg. 302/12, s. 1.

34. (5) For the purposes of paragraph 2 of subsection 4(1) of the Act, a Part A pharmacist, an intern or a registered pharmacy student is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to administer by injection a vaccination from one of the categories of vaccinations listed in Table 3 to this Regulation, to a patient who is five years of age or older, if the member,

(a) receives an informed consent from the patient or his or her authorized agent;

(b) meets all the requirements in paragraphs 2 to 6 of subsection (3); and

(c) notifies the patient's primary care provider, if any, within a reasonable time, that the member administered a vaccination to the patient, and provides details respecting the administration.

Table 3
Categories of Vaccinations
Bacille Calmette-Guerin (BCG) Vaccinations
Haemophilus Influenzae type b (Hib) Vaccinations
Meningococcal Vaccinations • Monovalent (Men-C-C) • Quadrivalent (Men-C-ACYW) • Quanrivalent (Men-P-ACYW-135) • Multicomponent (4CMenB)
Pneumococcal ~~disease~~ Vaccinations
Typhoid Fever~~disease~~ Vaccinations
Combined typhoid and hepatitis A Vaccinations
Hepatitis A Vaccinations
Hepatitis B Vaccinations
Hepatitis A and B combined Vaccinations
Herpes zoster Vaccinations
Human Papillomavirus Vaccinations
Japanese Encephalitis Vaccinations
Rabies Vaccinations
Varicella Virus Vaccinations
Yellow Fever Vaccinations

Appendix B: Proposed Amendments *Pharmacy Act Regulations* – Tracked Amendments in Regulation

Tracked Proposed Amendments: *Pharmacy Act Regulations,* O. Reg. 202/94 General

Part VIII.3
Controlled Acts

Interpretation

31. In this Part,

"adapt" means to change a patient's prescription respecting,

(a) the dose of the prescribed drug,

(b) the dosage form of the prescribed drug,

(c) the directions for use of the prescribed drug, or

(d) the route of administration for taking the prescribed drug,

but does not include therapeutic substitution;

"Part A pharmacist" means a member who holds a certificate of registration as a pharmacist and who is listed in Part A of the register;

"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 profession;

"prescription" means a direction from a prescriber directing the dispensing of a drug or mixture of drugs for a specific patient;

"renew" means to provide a patient with a prescription that repeats a prescription previously provided to that patient;

"therapeutic substitution" means the substitution of a drug that contains chemically different active ingredients that are considered to be therapeutically equivalent. O. Reg. 302/12, s. 1.

32. (1) Where the provisions of this Part are inconsistent with a law of Canada respecting prescriptions, including those related to a targeted substance, the law of Canada shall prevail and the provisions of this Part to the extent they are inconsistent with that law shall not apply. O. Reg. 302/12, s. 1.

(2) Where the provisions of this Part are inconsistent with the provisions of the Narcotics Safety and Awareness Act, 2010, the provisions of that Act shall prevail and the provisions of this Part, to the extent they are inconsistent with that Act, shall not apply. O. Reg. 302/12, s. 1.

Controlled Acts

33. A member shall not perform a controlled act under paragraph 2, 3, 4 or 5 of subsection 4 (1) of the Act except in accordance with this Part. O. Reg. 302/12, s. 1.

34. (1) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) who meets all the requirements in subsection (3) is authorized to perform the following acts:

1. Administering a substance specified in Table 1 to this Regulation by injection to a patient.

2. Administering a substance specified in Table 2 to this Regulation by inhalation to a patient. O. Reg. 302/12, s. 1.

(2) A Part A pharmacist, an intern or a registered pharmacy student is authorized to perform an act provided for in subsection (1), subject to the terms, conditions and limitations imposed on his or her certificate of registration. O. Reg. 302/12, s. 1.

(3) A member may only perform an act provided for in subsection (1) if he or she complies with the following:

1. The member may only perform the act for the purpose of patient education and demonstration, and before performing the act,

i. must explain that purpose to the patient or his or her authorized agent, and

ii. must receive an informed consent from the patient or his or her authorized agent.

2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient.

3. The member shall ensure that appropriate infection control procedures are in place.

4. The member must possess sufficient knowledge, skill and judgment respecting the substance to be administered, and sufficient understanding of the condition of the patient, to be able to administer the substance safely.

5. The member must consider whether administering a substance by injection or inhalation to the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome after administration and any other relevant circumstances.

6. The member must maintain a patient record that includes,

i. the name and address of the patient,

ii. the name and address of the member,

iii. the date the act was performed,

iv. the name, strength (where applicable) and quantity of the substance that the member administered to the patient,

v. the circumstances relating to the administration of the substance to the patient and any adverse reaction experienced by the patient, and

vi. confirmation that an informed consent was given by the patient or his or her authorized agent. O. Reg. 302/12, s. 1.

(4) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a Part A pharmacist, an intern or a registered pharmacy student is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, ~~is authorized~~ to administer influenza vaccine by injection to a patient who is five years of age or older, if the ~~Part A pharmacist~~member,

(a) administers the vaccination in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website;

(b) receives an informed consent from the patient or his or her authorized agent; and

(c) meets all the requirements in paragraphs 2 to 6 of subsection (3). O. Reg. 302/12, s. 1.

34. (5) For the purposes of paragraph 2 of subsection 4(1) of the Act, a Part A pharmacist, an intern or a registered pharmacy student is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to administer by injection a vaccination from one of the categories of vaccinations listed in Table 3 to this Regulation, to a patient who is five years of age or older, if the member,

(a) receives an informed consent from the patient or his or her authorized agent;

(b) meets all the requirements in paragraphs 2 to 6 of subsection (3); and

(c) notifies the patient's primary care provider, if any, within a reasonable time, that the member administered a vaccination to the patient, and provides details respecting the administration.

35. (1) For the purposes of paragraph 3 of subsection 4 (1) of the Act, a member referred to in subsection (3) who complies with the other requirements of this section is authorized to prescribe the following specified drugs:

1. Varenicline Tartrate.

2. Bupropion Hydrochloride. O. Reg. 302/12, s. 1.

(2) A drug mentioned in subsection (1) may only be prescribed by a member for the sole purpose of smoking cessation. O. Reg. 302/12, s. 1.

(3) A Part A pharmacist, an intern or a registered pharmacy student is authorized to perform the act provided for in subsection (1), subject to the terms, conditions and limitations imposed on his or her certificate of registration. O. Reg. 302/12, s. 1.

(4) A member may only prescribe a drug under this section if he or she,

(a) possesses sufficient knowledge, skill and judgment respecting the drug and the patient's condition to prescribe the drug for the patient;

(b) has considered whether prescribing the drug for the patient is appropriate, given the known risks and benefits of prescribing the drug for the patient and other relevant factors respecting the patient;

(c) gives the prescription to the patient or his or her authorized agent;

(d) advises the patient or his or her authorized agent, at the time of giving the prescription, that he or she may elect to take it to a pharmacy of his or her choosing for dispensing;

(e) notifies the patient's primary care provider (if any) within a reasonable time, that the member prescribed a drug for the patient and provides details respecting the prescription; and

(f) complies with the additional requirements under sections 37 and 38. O. Reg. 302/12, s. 1.

36. (1) For the purposes of paragraph 4 of subsection 4 (1) of the Act, a member referred to in subsection (3) who complies with the other provisions of this section is authorized to perform the following acts:

1. Adapting a patient's prescription.

2. Renewing a patient's prescription for the purpose of continuity of care. O. Reg. 302/12, s. 1.

(2) Subsection (1) does not authorize a member referred to in subsection (3) to adapt or renew a prescription for a controlled substance as defined in the Controlled Drugs and Substances Act (Canada) or a drug designated as a monitored drug by the regulations under the Narcotics Safety and Awareness Act, 2010. O. Reg. 302/12, s. 1.

(3) A Part A pharmacist, an intern or a registered pharmacy student is authorized to perform an act provided for in subsection (1), subject to the terms, conditions and limitations imposed on his or her certificate of registration. O. Reg. 302/12, s. 1.

(4) A member may only perform an act provided for in subsection (1) if he or she complies with the following:

1. The member must either possess the patient's prescription to be adapted or renewed or,

i. receive a copy of the prescription directly from the pharmacy where the prescription was dispensed to the patient,

ii. be satisfied based on verbal confirmation from a pharmacist at the pharmacy where the prescription was dispensed to the patient as to the existence and details of the prescription, or

iii. have access to the medical record that contains information about the prescription.

2. If the member is renewing a prescription, he or she must not prescribe a quantity of the drug that exceeds the lesser of,

i. the quantity that was originally prescribed, including any refills that were authorized by the prescriber, and

ii. a six months' supply.

3. The member must, within a reasonable time, notify the prescriber identified on the prescription adapted or renewed by the member, as well as the patient's primary care provider if the member knows that the patient has such a care provider other than the prescriber, providing details about the patient's prescription, when the member,

i. renews a patient's prescription, or

ii. adapts a patient's prescription, if, in the member's opinion,

A. adapting the prescription is clinically significant in relation to the patient, or

B. the notification is necessary to support the patient's care.

4. At the time that the member adapts or renews the patient's prescription, the member must advise the patient or his or her authorized agent,

i. that he or she is entitled to the prescription, and

ii. that he or she may take the prescription to a pharmacy of his or her choosing for dispensing.

5. The member must comply with the additional requirements under sections 37 and 38. O. Reg. 302/12, s. 1.

37. A member who performs an act provided for in section 35 or 36 must ensure that the following information is recorded on the prescription:

1. The name and address of the patient for whom the drug is prescribed.

2. The name, strength (where applicable) and quantity of the prescribed drug.

3. Directions for the use of the drug, including its dose, frequency, route of administration and any special instructions.

4. The name, address, telephone number and College registration number of the member issuing the prescription.

5. The date the prescription was issued by the member.

6. If applicable, reference to the prescription that the member adapted or renewed, including the name and contact details of the original prescriber.

7. The number of refills that the member authorized, if applicable.

8. Any other information required by law. O. Reg. 302/12, s. 1.

38. A member who performs an act under section 35 or 36 must maintain a patient record that includes details of the member's rationale for his or her decision to act under section 35 or 36 and the following information, if applicable:

1. Reference to, or a copy of, the patient's prescription that the member renewed or adapted, including the name and contact information of the prescriber.

2. A copy of the prescription that the member gave to the patient or his or her authorized agent under clause 35 (4) (c) or that the member gave to the patient or his or her authorized agent to take to a pharmacy of their choosing under paragraph 4 of subsection 36 (4).

3. A record of the results of laboratory or other tests that the member considered in making the decision to act under section 35 or 36.

4. The date on which the member notified the following persons, as applicable, and the method by which the notification occurred:

i. The patient's primary care provider notified under clause 35 (4) (e) or paragraph 3 of subsection 36 (4).

ii. The patient's prescriber notified under paragraph 3 of subsection 36 (4). O. Reg. 302/12, s. 1.

39. (1) For the purposes of paragraph 5 of subsection 4 (1) of the Act, a member referred to in subsection (2) who meets all the requirements in subsection (4) is authorized to perform the act of piercing a patient's dermis with a lancet-type device to obtain blood. O. Reg. 302/12, s. 1.

(2) A member who is a Part A pharmacist, an intern, a registered pharmacy student or a pharmacy technician is authorized to perform the act provided for in subsection (1), subject to the terms, conditions and limitations imposed on his or her certificate of registration. O. Reg. 302/12, s. 1.

(3) A pharmacy technician shall not perform the act provided for in subsection (1) unless,

(a) a Part A pharmacist is physically present on the premises at the time when the pharmacy technician performs the act; and

(b) the pharmacy technician is under the direction of a Part A pharmacist at the time when the pharmacy technician performs the act. O. Reg. 302/12, s. 1.

(4) A member may only perform the act provided for in subsection (1) if he or she complies with the following:

1. The member may only perform the act for the purpose of demonstrating the appropriate use of lancet-type devices for the patient's self care and education or for the patient's self monitoring of his or her chronic disease, and before performing the act,

i. shall explain that purpose to the patient or his or her authorized agent, and

ii. shall receive an informed consent from the patient or his or her authorized agent.

2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient.

3. The member shall ensure that appropriate infection control procedures are in place.

4. The member must possess the knowledge, skill and judgment respecting the performance of the act and understand the condition of the patient, to perform it safely and effectively.

5. The member must consider whether performing the act on the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome and any other relevant circumstances.

6. The member must maintain a patient record that includes,

i. the name and address of the patient and the member,

ii. the date the act was performed, and

iii. confirmation that an informed consent was given by the patient or his or her authorized agent. O. Reg. 302/12, s. 1.

40. Revoked: O. Reg. 451/10, s. 5.

Table 3
Categories of Vaccinations
Bacille Calmette-Guerin (BCG) Vaccinations
Haemophilus Influenzae type b (Hib) Vaccinations
Meningococcal Vaccinations • Monovalent (Men-C-C) • Quadrivalent (Men-C-ACYW) • Quanrivalent (Men-P-ACYW-135) • Multicomponent (4CMenB)
Pneumococcal disease Vaccinations
Typhoid disease Vaccinations
Combined typhoid and hepatitis A Vaccinations
Hepatitis A Vaccinations
Hepatitis B Vaccinations
Hepatitis A and B combined Vaccinations
Herpes zoster Vaccinations
Human Papillomavirus Vaccinations
Japanese Encephalitis Vaccinations
Rabies Vaccinations
Varicella Virus Vaccinations
Yellow Fever Vaccinations

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COUNCIL BRIEFING NOTE
MEETING DATE: JUNE 2016

FOR DECISION	FOR INFORMATION	X

INITIATED BY: Executive Committee

TOPIC: Public Participation on Panels (CANPCM)

ISSUE: Supplemental information to support by-law amendments that will enable Council Appointed Non-Profession Committee Members.

BACKGROUND: The initial Briefing Note seeking Council approval *for 'by-law amendments to enable Council Appointed Non-Profession Committee Members to increase the pool of public participants to serve on panels of college adjudicatory committees'* was considered by Council in March. After a lengthy discussion, Council voted to table the recommendation until the June Council meeting.

While Council saw some merit in using creative means such as by-law amendments to supplement the number of public participants available to serve on Council committees several concerns were raised:

- the need to be careful that any screening/selection process be seen to be fair;
- the screening process would need to be reviewed on a regular basis;
- reimbursement models would be different for the public members appointed by the Lieutenant Governor in Council (LGC) versus Council appointed public members; concerns with conflicts of interest (CANPCMs would be reimbursed by the College);
- CANPCM appointments would be in direct competition with the LGCs and not in keeping with the government's own process of appointing public members;
- there are cost implications to the College.

ANALYSIS: Additional input was sought from the current public members of Council on the issue of CANPCM following the March meeting.

The overriding sentiment was that the government should appoint more LGCs to support the work of the College in addressing the increasing demands in a timely manner; that the College continue to appeal to the Ministry to appoint more LGCs; and that statistics be gathered to measure the impact of having fewer than the maximum number provided for in legislation.

Accordingly, the Executive Committee recommends that the motion put forward in March to enact by-laws that would enable Council Appointed Non-Profession Committee Members (CANPCMs) be deferred until it is apparent that alternative solutions to increased public participation should be pursued.

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COUNCIL BRIEFING NOTE
MEETING DATE: June 2016

FOR DECISION	FOR INFORMATION	X

INITIATED BY: Marshall Moleschi, CEO and Registrar

TOPIC: Report to June 2016 Council

ISSUE: As set out in the Governance Manual, Council holds the Registrar accountable for the operational performance of the organization. As well, the Registrar is responsible for reviewing the effectiveness of the College in achieving its public interest mandate and the implementation of the Council's strategic plan and directional policies. As such, the Registrar is expected to report on these activities at every Council meeting.

BACKGROUND: I respectfully submit a report on the activities since the March 2016 Council Meeting. In addition to various internal meetings with staff and regular meetings and phone calls with the President and the Vice President, summarized below are some of the meetings I attended and matters that I dealt with on behalf of the College during the reporting period.

Ministry/Legislative Initiatives
Once the Ontario Legislature resumed on February 16, 2016, the government's immediate priority was the delivery of the Ontario budget. Of specific interest to OCP are the following budget commitments:

- Authorize pharmacists to administer a wider range of vaccines, increasing immunization efficiency and convenience for Ontarians.
- Expand the scope of practice of registered nurses, allowing them to prescribe some medications directly to patient.
- Making the shingles vaccine free for eligible Ontario seniors between the ages of 65 and 70.
- $5 million of increased revenues from the tobacco tax to support a new investment that will enhance priority populations' access to smoking cessation services.

In recent months, a lot of media attention has been given to the **fentanyl** abuse crisis in Canada. Ontario has been cited as not taking adequate steps to stop doctors from indiscriminately prescribing highly addictive opioids to treat chronic pain. Additionally, a group of physicians and public-health officials in Ontario have called upon the provincial government to implement emergency planning measures to address a spike in overdoses linked to illicit fentanyl and other opioids. Specifically, the province is being called upon to establish a reliable surveillance on the number of people overdosing on opioids, timely toxicology testing on drugs seized at a crime scene and establish a broader distribution of the overdose antidote Naloxone.

In December 2015, the *Safeguarding our Communities Act* (Patch for Patch Return Policy) received Royal Assent. To implement the Act's requirements for used fentanyl patches to be

returned to pharmacies prior to the dispensing of new patches, the Ministry has proposed a regulation http://www.ontariocanada.com/registry/view.do?postingId=21762&language=en.

The College has utilized a working group of early adopters of Patch for Patch to inform discussion with the Ministry concerning the regulation as well as collaboration with the CPSO on complementary guidelines for the respective members. Implementation is expected to be October 2016.

As mentioned earlier in this report, there is growing pressure on provincial governments to address the rise in opioid drug abuse, particularly fentanyl. On March 22, 2016, Health Canada revised the Federal Prescription Drug List to make a non-prescription version of naloxone, which is used to reverse the effects of an opioid overdose.

The Ontario government's **naloxone** program has been limited largely to distributing the drug to public-health units and community organizations that manage needle-exchange programs. On June 7, the Ministry announced that through the authority of the Chief Medical Officer of Health, certain pharmacies would be eligible to provide naloxone emergency kits to eligible persons if certain terms and conditions are met. This first phase of access will conclude on the date the National Association of Pharmacy Regulatory Authorities (NAPRA) schedules are amended to re-classify naloxone as a non-prescription drug.

Bill 21 Safeguarding Health Care Integrity Act, 2014
Attached for Council's information is a letter from Minister Hoskins advising hospital Presidents and Chief Executive Officers that the proposed amendments to the *Drugs and Pharmacy Regulations Act* (DPRA), which were approved by Council in June 2015, will shortly be brought forward for approval by Cabinet. The amendments will expand the College's oversight to hospital pharmacies and the Minister has encouraged hospitals to ensure that necessary steps have been taken to ensure the pharmacies are ready for OCP oversight.

Sexual Abuse Task Force
As mentioned in previous reports, in December of 2014, Minister Hoskins launched a task force to review and modernize laws that deal with sexual abuse of patients by health professionals. Latest information is that the recommendations of the task force will be released by late June.

Bill 119, Health Information Protection Act, 2015
Bill 119 has been proclaimed, making a number of amendments to the *Personal Health Information Protection Act,* 2004, (PHIPA), the *Regulated Health Professions Act, 1991*, *Drug Interchangeability and Dispensing Fee Act* and the *Narcotics Safety and Awareness Act, 2010*. These amendments are intended to strengthen the protection of health information privacy, and increase transparency and accountability in Ontario's health care system. Of specific interest to the College is that the Bill will allow the Ministry to disclose information about a patient's narcotics and monitored drug prescriptions to their health care practitioner.

Bill 119 will therefore impact the Comprehensive Drug Profile Strategy (CDPS). At this Council meeting, Ms. Karen McKibbin, Ontario Public Health Integrated Solutions Branch, and Dr. Robin Williams, Associate Chief Medical Officer of Health, Infrastructure & Systems, Ministry of Health and Long-Term Care will present to Council regarding Ministry plans for integrated access to a patient drug profile for all residents of Ontario.

Physician-Assisted Death
Assisting with death has historically been considered a crime under the Criminal Code. In the context of the *Carter v. Canada* decision, the Supreme Court of Canada (SCC) found that this

absolute prohibition violated an individual's *Charter* right to life, liberty and security of person. Accordingly, the SCC ruled that the criminal law must permit some form of physician-assisted death.

The SCC suspended its decision to allow federal and provincial governments time to develop a framework to support the provision of physician-assisted death. The deadline for the federal government to bring a new law regulating MAiD (medical assistance in dying) was June 6, 2016. However, new legislation is not yet in force. Therefore, as of June 6, 2016 physician-assisted death is lawful where it is in accordance with the parameters set out by the SCC *Carter v. Canada* decision.

Council is being provided with information from the Ministries of Health and Long-Term Care and the Attorney General as well as the Chief Coroner (see Appendix 8 on this meeting's agenda).

Please read the full Guidance Document — Physician-Assisted Death (June 6, 2016) for more information. Members have been advised to continually monitor information from the College about physician-assisted death, as the guidance is based on the information available to the College at the time of publishing. Future development of policies, legislation or regulations may impact this guidance, and will be communicated to the profession as it unfolds.

Stakeholder Relations
I attended meetings with ADM's Cole and McGurn to share concerns and progress on various initiatives. I hope to meet with Minister Hoskins to discuss several issues including travel vaccinations. A meeting is scheduled for June 22nd.

I have met with the OPA, Ontario Pharmacists Association, to discuss issues of joint interest, including the reaffirmation of a statement previously provided to the association regarding its suggested Fee Guide for Uninsured Clinical and Professional Pharmacy Services.

Inter-Professional Relationships
Federation of Health Regulatory Colleges of Ontario (FHRCO) Update
FHRCO continues to provide strategic leadership to health profession regulation in addition to providing ongoing support for regulatory Colleges and mentoring of new Colleges; providing education sessions for College council members, committees and staff, FHRCO also collectively works on many government priorities and regulatory issues. My term as FHRCO's President over the last two years came to an end at the end of April. I look forward to serving as FHRCO's Past President on the Executive Committee.

Attached for Council's information is this College's feedback on the consultation regarding proposed amendments to the *Optometry Act* and relevant regulations with respect to the prescribing of drugs.

Also attached for Council's information is a submission to the Ministry of Health and Long-Term Care from the Clinic Regulation Working Group. The Group was formed in early 2015 and involved several health regulatory colleges who jointly undertook to explore the idea of regulating clinics in Ontario. This college has participated as an observer. The Working Group believes that clinic oversight would be in the public interest and have offered to work together with the Ministry and key stakeholders to better understand the nature and extent of the problem, and to identify the appropriate solution for Ontario.

Presentations/Other Stakeholder Meetings

National Association of Pharmacy Regulatory Authorities (NAPRA) Update

The NAPRA Board of Directors Meeting was held April 23 and 24 in Ottawa. OCP representative, Mr. Mark F. Scanlon, attended the meeting and has provided a memorandum as well as NAPRA's submission to the House of Commons regarding MAiD (both are attached) for Council's information.

District Meetings

Preliminary plans are now in place for the 2016 fall district meeting sessions. I will be heading out on the road with Professor Zubin Austin from the University of Toronto to host seven district meeting presentations in various cities across the province. The sessions will be focused on the new Code of Ethics and ensuring that pharmacy professionals understand their professional and ethical obligations. One of the sessions will be held here in Council Chambers and will be live streamed to anyone who wishes to tune in online. More details about exact dates and locations will be coming in the late summer.

Operational Plan Update

A key part of the Registrar's performance is to regularly provide an update to Council on the College's Operational Plan. The program activities and intended outcomes support the priorities outlined in the Strategic Framework developed by Council in March 2015. Attached for Council's information is an update of progress made on the various strategic directions since the March 2016 Council meeting. Although not yet reported, the College expects to launch a new Public Register in early July, as part of our continued work on transparency. I will provide you with a very brief overview of the new format and invite you to explore the new Register more fully during our breaks on computers set up in Huron A and B. It is appropriate at this time that Council review the priorities, outcomes and planned activities and affirm our ongoing commitment to them as they will be the foundation upon which the 2017 Operations budget will be drafted over the summer for Council consideration in September. I will shortly invite Ms. Sandra Winkelbauer, Manager, Continuing Competency, and Mr. Vince Bowman, Manager, Registration, to present to Council an update on their program areas.

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Ontario

HLTC2968IT-2016-160

JUN 06 2016

Hospital Presidents
Hospital Chief Executive Officers

Dear Sir/Madam:

I would like to provide you with an update on a proposed regulation from the Ontario College of Pharmacists (OCP) that would establish a new provincial regulatory regime for hospital and institutional pharmacies.

As you will recall, our government passed the *Safeguarding Health Care Integrity Act, 2014* as one of the responses to the 2013 chemotherapy underdosing incident. Since the passing of that legislation, the OCP, the Ontario Hospital Association and hospitals have worked with the Ministry of Health and Long-Term Care to improve the safety of pharmacy services, both in hospitals and in drug preparation premises.

The OCP has devoted resources to create standards, expanded its inspections capacity, undertaken base-line assessments and worked to significantly amend O. Reg. 58/11 made under the *Drug and Pharmacies Regulation Act* to expand its oversight to hospital pharmacies.

Your cooperation with the OCP's base-line assessments and with working towards meeting OCP standards is an important part of making hospital pharmacy services safer.

I would like to thank both the OCP and hospitals for laying the foundation on extending the OCP's oversight to hospital pharmacies.

It is my intention that a regulation made under the *Drug and Pharmacies Regulation Act* will shortly be brought forward for approvals to Cabinet along with a proclamation into force of certain sections of the *Safeguarding Health Care Integrity Act, 2014*. Should Cabinet grant its approval, the result would be that hospital pharmacies would be accountable to the OCP for their pharmacy operations.

.../2

In preparation for this event, I encourage hospitals to contact the OCP and take the necessary steps to ensure that your pharmacies are ready for OCP oversight.

Yours sincerely,

Dr. Eric Hoskins
Minister

c: Ontario College of Pharmacists
Ontario Hospital Association

Ontario College of Pharmacists
Putting patients first since 1871

Ontario College of Pharmacists
483 Huron Street
Toronto, ON M5R 2R4

March 23, 2015

College of Optometrists of Ontario
Consultation Feedback
65 St. Clair Ave. E., Suite 900
Toronto ON M4T 2Y3

Sent via email: feedback@collegeoptom.on.ca

Thank you for your invitation to the Ontario College of Pharmacists (OCP) to provide feedback on the consultation regarding proposed amendments to the *Optometry Act* and relevant regulations with respect to the prescribing of drugs.

We concur that listing specific medications in regulations presents a challenge to providing patients with access to optimal care. Lists can have unforeseen consequences and potentially act as a barrier by restricting access to new substances unless regulatory changes are made. When new medications or guidelines are approved for use in Canada, practitioners authorized to prescribe, dispense or administer substances based on specific lists are not able to incorporate advancements in care into their practice without regulatory changes.

We also support optometrist dispensing of medications for the purpose of initiating or determining the quality of a therapy. Permitting optometrists to dispense medications for trial or sampling purposes promotes optimal patient care through the determination and initiation of optimal therapy in a timely manner.

The College may wish to further clarify that the regulations authorize the act of dispensing a drug but are not intended to permit optometrists to sell drugs as defined in the *Drug and Pharmacies Regulations Act*.

The OCP is confident that the College of Optometrists of Ontario will establish the appropriate limits, conditions and processes to ensure that optometrist prescribing and dispensing will be safe and effective. The OCP will work collaboratively with the College of Optometrists to ensure that there will be effective understanding and communication between registrants of our respective colleges.

Sincerely,

Marshall Moleschi, R.Ph., B.Sc.(Pharm), MHA
CEO and Registrar

Increasing Patient Protection through Clinic Oversight

A Submission from the Clinic Regulation Working Group

July 2016

About the Clinic Regulation Working Group

The Clinic Regulation Working Group was formed in early 2015 involving several health regulatory colleges to undertake joint exploration of the idea of regulating clinics in Ontario. As the work progressed, more colleges joined the group. The Working Group now has thirteen formal partners, covering over 60,000 members. The partners are:

- College of Audiologists and Speech-Language Pathologists of Ontario
- College of Chiropodists of Ontario
- College of Chiropractors of Ontario
- College of Dental Hygienists of Ontario
- College of Dental Technologists of Ontario
- College of Dietitians of Ontario
- College of Kinesiologists of Ontario
- College of Massage Therapists of Ontario
- College of Naturopaths of Ontario
- College of Occupational Therapists of Ontario
- College of Opticians of Ontario
- College of Physiotherapists of Ontario
- College of Traditional Chinese Medicine Practitioners and Acupuncturists of Ontario

In addition, several other colleges participated in the group as observers and contributors, including:

- College of Homeopaths of Ontario
- College of Medical Radiation Technologists of Ontario
- College of Midwives of Ontario
- College of Optometrists of Ontario
- Ontario College of Pharmacists

About the Clinic Regulation Project

The purpose of the clinic regulation project was to explore whether clinic regulation would be an appropriate solution to gaps in patient safety, quality care, and efficient use of health care resources in some clinic settings.[1,2] The Working Group explored several potential solutions, but did not aspire to find the best solution.

[1] The Working Group recognizes that not all health care providers work in settings that would be considered "clinics". However, for the purpose of this project, the Working Group used "clinic" to refer to the range of settings where health providers may provide health care services or products.
[2] The Working Group recognizes that some oversight does currently exist in some settings, through FSCO, OHIP, and WSIB programs.

Table of Contents

Executive Summary

Unlike individual regulated health professionals, clinics and their unregulated owners do not have a formal duty of care to patients, and no formal accountability for the quality of the care provided in their clinics. The Working Group sees this as a serious gap in public protection. There are three categories of risk to patients and the health care system that may arise in clinics: risk of physical harm; the cost of ineffective or unnecessary treatment; and inappropriate use of health care resources.

The Working Group undertook research and analysis to explore solutions. The research looked at facility regulation in comparable jurisdictions across the world. In order to evaluate the options, the Working Group developed a list of criteria that any potential regulatory intervention would be measured against. We called these our parameters for regulation. After assessing several alternatives, it appeared that establishing a clinic regulator would offer the greatest protection of the public.

The Working Group developed a hypothetical model for clinic regulation and consulted with a wide range of stakeholders to determine its feasibility. The results of the stakeholder consultation are presented in this report. The feedback we received indicated that while stakeholders agreed that there are issues in clinics, they have reservations about the costs and implications of full clinic regulation.

The Working Group remains certain that improved oversight of the care provided in clinics is essential to improving access, supporting patients and protecting the health care system itself. The Working Group concluded that the public interest could be served by a range of possible interventions, yielding varying elements and degrees of public protection. The Working Group recommends further exploration to identify the option that will best protect patients in Ontario.

The Working Group urges the Minister of Health and Long-Term Care to take action. We believe clinic oversight is entirely consistent with the Ministry of Health and Long-Term Care's goal of improving health care at the systems level to strengthen patient-centred care. The Working Group would welcome the opportunity to work with the Ministry and other key stakeholders to find a solution that is appropriate for Ontario.

A Gap in the Current Regulatory Framework

What is the problem?

Colleges in the Clinic Regulation Working Group have all observed issues and concerns about some of their members' practice in clinic settings. The colleges regulate only their members, and have no jurisdiction over the places where they work.[3]

When clinics and their unregulated owners owe no formal duty of care to patients and have no formal obligation to meet standards, they can sometimes impose practices or care models that directly conflict with the professional obligations of the practitioners they employ. Those practitioners are placed in the position where they have to choose between meeting their professional obligations and meeting the demands of their employer. Many practitioners fear losing their jobs if they refuse to comply with the inappropriate expectations of the employer. As a result, practitioners have limited ability to influence change in the place of practice.

When regulators learn of inappropriate practices, they hold the regulated professional accountable, but the employer can continue with the inappropriate practice, most often hiring another regulated health professional who faces the same struggle as the first. While the colleges take sequential actions to remediate or discipline the member, the questionable care or unethical practices continue unabated. Unless a regulated health professional owns the practice, colleges have no jurisdiction to require changes in the place of practice.

Research in health care shows that the practice environment has an impact on both individual behaviour and health outcomes.[4,5] Yet colleges can only remediate or discipline individual members; they cannot ensure public protection where the issues or concerns are caused by the practice environment.

Examples of the types of problems that the Working Group members have observed are set out below.

Patient safety issues

- Deficient infection control practices
- Lack of appropriate space and equipment to provide care safely
- Unsupervised and inadequately-trained assistants delivering care

[3] The Working Group recognizes that three colleges in Ontario currently do have the ability to oversee the places where their members practice: the College of Physicians and Surgeons of Ontario (CPSO), the Royal College of Dental Surgeons of Ontario (RCDSO), and the Ontario College of Pharmacists (OCP). The gap in oversight identified in this report is relevant for other colleges who do not currently have such authority.
[4] Austin, Wendy. "The ethics of everyday practice: Health care environments as moral communities." Advances in Nursing Science 30.1 (2007): 81-88.
[5] Institute of Medicine, Committee on Quality of Health Care in America. Kohn, Linda, et al. "To Err is Human: Building a Safer Health System."

Quality of care issues

- Use of assistants to deliver care without adequate supervision from a regulated health professional
- Pressure on providers to deliver ineffective or unnecessary treatments
- Patient volume quotas that drive practitioners to sacrifice quality for quantity

Inappropriate business practices

- Use of regulated health professionals' credentials for fraudulent billing
- Inappropriate referrals
- Offering patients gifts or inappropriate incentives
- Inappropriate advertising

As one new professional observed:

"I have recently entered the profession as an independent practitioner and was confronted with ethical issues pertaining to billing, fees and the provision of physiotherapy services. […] I was surprised initially but quickly realized that within a private practice, revenues and profits sometimes trump quality of care and fly in the face of a treatment plan that is based on objective evidence, the patient's beliefs and values and the experience of the practitioner."

The Magnitude of the Problem

Available data from the Working Group colleges from the last three years show that cases where the concern or issue with a member's practice may be due to the practice environment make up between 8% and 50% of their professional misconduct cases (dependant on the College). There are limitations to the data, because college data is intended to track concerns about individual practitioners, and is not suited to explore systems or environmental problems.

Data from the insurance industry also help illustrate the problem. A few examples of the types of issues the insurers have identified include:

- Clinics bill insurance companies for services and supplies that are eligible under the group benefits plan, when the actual services and products obtained were different. For example, billing personal training and gym memberships as insured health care services.
- The clinic either bills directly, or provides the plan member with a receipt to claim for a service that was not actually provided. The proceeds of the claim are often split between the clinic and the plan member.
- In some multidisciplinary clinics, patients are encouraged to utilize all services offered by the clinic even if not medically required.

- Situations identified through site visits such as the clinic being unable to provide documentation on the billed service, the address on receipts is for a fictitious clinic, and the clinic has been closed for some time even though claims continue to be billed.

While it is not possible to say with certainty how many of these issues clinic oversight might effectively address, it is estimated that approximately 3-10% of all health care dollars spent in North America are lost to fraudulent claims. In Ontario, at the end of 2014, the life and health insurance industry reimbursed approximately $10.3 billion in supplementary health care claims which includes those services provided by various paramedical practitioners working in a clinic environment.[6]

The Working Group has observed that the provision of health care services is increasingly moving from public institutions to private clinics. We are concerned that if the current gap in accountability is not addressed, the problems will become more prevalent and serious over time.

[6] Submission from the Canadian Life and Health Insurance Association (CLHIA). December 31, 2015. http://www.ontarioclinicregulation.com/wp-content/uploads/2016/01/CLHIA-Comments-re-Proposal-for-Clinic-regulation-Dec-31-2015.pdf.

Clinic Oversight and the Public Interest

The following section will provide a preliminary analysis of whether stronger oversight of health care clinics would be in the public interest. The Working Group has used the Health Professions Regulatory Advisory Council (HPRAC) framework for the analysis of clinic oversight with some modifications. Broadly following the HPRAC model, the analysis in this section will be based on two criteria: the risk of harm posed by unregulated clinics, and the likely impact of stronger oversight of those clinics.

The Role of Assistants

Assistants are a key element of health care delivery in Ontario. They make an important contribution to stretching health human and financial resources. Evidence demonstrates that they are used increasingly in health care settings.[7] In a system with the appropriate checks and balances, health care assistants can be used effectively for the benefit of the patient and the system.

Effective use of assistants demands appropriate oversight: regulated health professionals who rely on assistants are responsible for evaluating the knowledge, skills and judgment of the assistant, assessing the patient's condition, designing an appropriate treatment plan, and supervising the assistant to ensure that the care is equal in quality to that provided by the regulated health professional.

However, the use of assistants can be subject to abuse. Higher revenues can be generated for the clinic by increasing assistant-to-professional ratios, and by having assistants undertake elements of care that should be reserved to the regulated health professional, while still billing as though they were delivered by the regulated health professional. As a result, the quality of patient care may be compromised in favour of higher revenue.

Throughout the analysis of risk, described below, the role of assistants is a common theme.

Risk of Harm

With respect to health care regulation, discussions of risk often narrowly focus on risk of severe bodily harm. The Working Group submits that such a narrow focus is inappropriate in the modern environment. Instead we believe health care regulation should also consider risks to population health and the health care system. We wish to consider three separate categories of risk: physical harm, opportunity costs of ineffective or unnecessary treatment, and draining of

[7] Canadian Physiotherapy Association. November 2010. "White Paper: Physiotherapist Support Personnel Study."

limited health care resources. In many cases, the risks appear together (for example, the risk of physical harm and the waste of resources arise from the same practice example). They are separated here, somewhat artificially, to illustrate the risks as clearly as possible.

Physical Harm

The Working Group colleges are aware of cases where the physical conditions or inadequate procedures in a clinic could pose a risk of physical harm to patients.

Some clinics have been found to have inadequate infection control practices, potentially exposing patients to diseases and infections.

Some members are employed to provide services at sites that are not primarily health care settings, and do not have the appropriate space and equipment to provide care safely, which could risk causing injury to patients.

Some clinics use assistants to provide care who do not have the adequate training and supervision by a regulated health professional. The Working Group colleges have received reports where care provided by an assistant caused injury, or the assistant failed to identify and respond to adverse outcomes.

Costs of Ineffective or Unnecessary Treatment

Providing inadequate or inappropriate treatment to patients leads to the risk that they will not be able to return to productive, healthy lives. The system is at risk for higher long-term costs as treatable conditions go untreated, eventually becoming worse and requiring more aggressive and expensive intervention.

One example of a business model that often predicts ineffective treatment is utilization of a template treatment plan for most or all patients, regardless of condition. In some cases this happens in conjunction with the over-reliance on assistants to deliver care without adequate supervision. To illustrate, in a complaint received by one of the Working Group colleges, a patient went to a clinic for treatment of her injuries. She reported that all of the patients in the clinic were given the same treatment plan, and her condition did not improve. We have also heard from many members who have observed this practice in places where they or their colleagues have worked.

Regulated health care professionals are required to discontinue treatment once treatment goals have been met, or if the treatment is no longer effective. Providing unnecessary treatment falls below the standard of care expected of professionals. Unnecessary treatments can be seen as another cost: some clinics pressure providers to offer unnecessary treatments or to continue treatment that is no longer effective. Whether the patient, an insurance provider or the Ontario Health Insurance Plan is funding such treatments, limited funds are being applied without beneficial patient outcomes. Ultimately the patient or the system runs out of money and necessary or valuable treatments cannot be provided. Although there are no estimates available

for Canada, it has been estimated that in the United States, $226 billion was spent on unnecessary treatment in 2011.[8]

Inappropriate use of health care resources

The Working Group colleges have observed many issues related to billing irregularities and the inappropriate use of health care resources. These inappropriate practices may not immediately harm patients, however over the long-run they will have the effect of increasing overall cost for care and limiting access to care when it is actually needed.

As data from insurers show, a commonly reported type of inappropriate billing is where clinics bill for insured health care services when the services provided were in fact different. The Working Group colleges are aware of cases where clinics billed gym memberships, personal training, and spa services such as manicures as insured health care services.

Some clinics also use a provider's credentials as the basis for fraudulent billing. For example, in a pilot project where health professionals tracked the use of their credentials for automobile insurance claims, 11% of the participants found that their credentials were used by at least one facility that they had never been affiliated with.[9] The Working Group colleges are also aware of cases where members' credentials were used for insurance claims by previous employers after they had stopped working there.

The cost of fraud can be significant. In a report on fraud in the motor vehicle accident sector in Ontario, it was estimated that in 2010, the amount of fraud ranged from $768 million to $1.56 billion.[10] As analysis from the life and health insurance industry points out, fraudulent billing results in higher costs for extended health care plans. To manage costs, plan sponsors (mostly employers) may respond by reducing the level of benefit or increasing copay amounts. These changes may negatively impact the ability for plan members to access care.

Potential Impact of Clinic Regulation

How would clinic regulation affect the current model of accountability? How would the public interest be served by this change?

Stronger oversight of clinics and unregulated owners requires that accountability occur both at the individual provider level and the systems level. Recent research from the Professional

[8] The King's Fund. July 2015. "Better value in the NHS: The role of changes in clinical practice." http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/better-value-nhs-Kings-Fund-July%202015.pdf.
[9] Health Claims for Auto Insurance (HCAI) Anti-Fraud Working Group. Professional Credential Tracker (PCT) Pilot Final Report. http://hcaiinfo.ca/Related_Initiatives/documents/PCT_FinalReport.pdf.
[10] Ontario Ministry of Finance. November 2012. Final Report from the Ontario Automobile Insurance Anti-fraud Task Force. http://www.fin.gov.on.ca/en/autoinsurance/final-report.html.

Standards Authority in the United Kingdom suggests that both professional and systems regulation are needed to ensure quality in health care:

> *"The evidence of the link between the behaviour and competence of people providing care and the contextual environment in which they do so is now compelling… It seems strange to us therefore that people are regulated separately from the systems and places in which they work."*[11]

Based on the collective experience of the Working Group colleges, we also concluded that to ensure the highest level of public protection, a clinic oversight model must be able to hold clinics and their unregulated owners directly accountable. (More details about the Working Group's analysis are available in Appendix 1, starting on page 19.)

Clinic oversight could establish standards designed to ensure quality of care and appropriate business practices that would apply to the business organization and all individuals who worked there. A proactive approach, which would include periodic inspections and ongoing reporting, would offer the benefit of identifying deficits before they cause negative outcomes.[12]

Clinic oversight could also support regulation of individual health professionals. One of the results of the current gap in accountability for clinics is that health care professionals may be put in a position that makes it difficult for them to meet their professional obligations. Under the present regime, regulators are unable to directly address the environment that undermines professional behaviour. If the clinic itself was subject to professional obligations similar to the individuals who work there, the regulated and unregulated staff would be supported in their endeavours to place patient interests first and to provide competent and ethical care.

The Working Group also believes that clinic oversight could promote greater interprofessional collaboration. The Working Group colleges recognize that increasingly their members work in multidisciplinary settings and collaborate with other health professionals. One of the parameters we established was that any clinic oversight model must be able to work in multidisciplinary settings, including where unregulated providers may work. A multidisciplinary approach to clinic oversight would mean that one regulator can look at the whole journey of care, rather than different regulators looking at specific parts of the care. We recognize that changes have been made to the RHPA model in recent years to decrease barriers to interprofessional collaboration, and we believe a multidisciplinary clinic oversight model could further contribute to that goal.

The benefits of oversight of the clinic itself could extend to the unregulated providers it employed. In this context it is important to note that in the model developed by the Working

[11] Professional Standards Authority. August 2015. *Rethinking regulation*. http://www.professionalstandards.org.uk/docs/default-source/psa-library/rethinking-regulation.pdf?sfvrsn=2.
[12] Using an example from the legal profession, data from the Legal Ombudsman of England and Wales showed that there is a correlation in England between the implementation of proactive entity regulation and the reduction of complaints against law firms. From the Law Society of Upper Canada's consultation paper "Promoting better legal practices." https://www.lsuc.on.ca/uploadedFiles/compliance-based-entity-regulation-consultation-paper.pdf.

Group, "clinic" could potentially be defined broadly to include a wide variety of practice settings, including virtual practices, employment entities that operate to offer care in homes or other locations remote from the point of service planning and management, and practices where care is delivered exclusively by unregulated providers. Currently, unregulated providers are subject to little or no formal oversight and are not formally required to comply with standards or owe a duty of care to patients. Formal clinic regulation could be a means to introduce a measure of formal oversight for this group without adding other new regulatory bodies.

Economic impact of clinic regulation

For the purpose of this discussion, the analysis is based on the clinic regulation model developed by the Working Group. A description of the model can be found in Appendix 3.

Parameters established by the Working Group required that the regulatory model be cost-neutral (i.e. cost recovery only), and not impose undue burden on clinics. Stronger clinic oversight would introduce costs to clinic owners, but strategies could be used to keep these costs to a reasonable level.[13] Two separate costs might be introduced by regulation.

First, the model developed by the Working Group is one of self-regulation. It anticipates that the cost of regulation would be shared between the clinics subject to the oversight, through registration fees and fees for clinic inspections.

Second, regulated clinics would have to spend time and resources on compliance activities. Based on the model the Working Group envisioned, these would be limited to an initial application for registration, annual renewal, and, possibly, preparation of an annual report. Activities associated with compliance, while raised as a concern by some stakeholders in the consultation, are actually the costs of maintaining appropriate standards and should be considered to be an aspect of providing patient care, rather than a by-product of regulation.

Precise costs are difficult to estimate accurately because there is no existing model upon which to draw for reference.

In order to establish a very rough estimate of costs for regulation in the model the Working Group used as a basis for its consultation, cost data from some of the Working Group member colleges was used as a baseline for estimating the administrative cost.[14] Within the group, per registrant costs for the administrative elements of regulation ranged between $387 and $1,455.[15]

Due to the absence of any kind of registry and the potential to include clinics where no regulated health professionals work, it is difficult to accurately estimate how many clinics the model under discussion would include; however it is reasonable to expect the number to be

[13] For example, the approach used by the College of Physicians and Surgeons of Ontario to set fees for the Out-of-Hospital Premises and Independent Health Facilities inspection programs is a useful model.
[14] Based on cost data from the most recent complete fiscal year. Includes costs to provide space and equipment, staff for a registration department, and cost to support Council and the Quality Assurance Committee.
[15] The larger the registrant base, the lower the per registrant cost tended to be. The registrant base of the colleges whose data was used to derive this estimate ranged from 564 to 12,132.

in the tens of thousands. Therefore it may be reasonable to estimate that the per clinic share of the administrative cost, which would be paid through annual registration fees, would be close to, or below, the lower end of the range.

The other element of expense that the regulatory model we are discussing would introduce is the cost of doing on-site inspections. Three health regulatory colleges currently have facilities inspection programs: the College of Physicians and Surgeons of Ontario (CPSO), the Royal College of Dental Surgeons of Ontario (RCDSO), and the Ontario College of Pharmacists (OCP). The Working Group collected cost data from their facilities inspection programs, and found that the cost for conducting inspections varied widely due to differences in the types of facilities that are inspected and the complexity of the inspections. The cost to conduct an inspection ranges from $100 to several thousand dollars.

The cost of clinic inspection depends on several factors, such as the number and types of standards that the clinic would be inspected against, the geographic location and size of the clinic, and the types of services provided. As the cost data from the existing facilities inspection programs illustrate, the possible range of costs is quite large. Both the CPSO and RCDSO classify the facilities they inspect into categories and charge a fee based on actual administrative and inspection costs associated with that category of facility. The model considered by the Working Group anticipated a similar fiscal structure where clinic inspection expenses would be borne by the individual clinic at the time of the inspection and would vary according to the factors described above. In this model, a small clinic offering a single type of service would likely pay an inspection fee at the lower end of the range (costs would include inspector's time and travel costs) whereas a complex, multidisciplinary clinic would likely require a longer time and more than one inspector – leading to higher costs.

Alternative oversight mechanisms

Having identified the gap, the Working Group sought a solution that would address it.

The clinic regulation model used for discussion above envisions self-regulation for clinics by the professionals that work in them. It is an extension of the existing RHPA model and could be adapted as the RHPA is adapted. While the Working Group recognizes there are many possible ways to design a clinic regulation framework, the choice to mirror the RHPA was a deliberate one. It gave us a familiar framework to draw from in order to be able to more realistically evaluate impact on the Ontario health care system. It is noteworthy that the model we used excluded many components of professional self-regulation thought to be extraneous in entity regulation, so that it only includes regulatory tools that are appropriate for the problem that we are trying to solve. We used this model for discussion because it was the only way to achieve all of the objectives we set for patient and system protection (see discussion of parameters for clinic regulation on pages 20 and 42 below).

Short of full regulation, some of the health system and patient protection features of regulation may be achieved with less assertive interventions. The full range of potential interventions could include (in rough order of patient and system benefit from least to highest):

- Establishing a clinic registry
- Accreditation of clinics
- Measures under existing legislative powers
- Changes to the *Regulated Health Professions Act* and/or profession-specific regulations to increase college authority over clinics
- Formal regulation of clinics

The following is a preliminary analysis of these alternatives.

A clinic registry

Establishing a clinic registry would achieve the goal of making more information about clinics available to patients and helping them make informed choices about where to seek care. The registry could also provide other helpful information to patients about clinics, the services they provide, how to judge the quality of the service they receive, and how to get recourse if they have concerns. These tools would greatly empower patients to protect their own interests. The benefit to public protection would be even greater if there are minimum requirements for getting onto the registry, and verification mechanisms.

However, this approach would not impose any additional accountability on the part of clinics and unregulated owners to meet standards, and would not create additional authority to act to address problems or issues. There would be no mechanism for ongoing quality assurance and dealing with complaints. Any issues or concerns that do arise would have to be dealt with by the same regulatory bodies that exist today. This approach would not address the accountability gap that currently exists.

Accreditation of clinics

Introducing a requirement that clinics must be accredited, either by existing third-party accreditation bodies[16], or some other accreditation authority, would ensure that clinics are meeting minimum standards when it comes to safety, quality, and business practices. Accreditation also provides helpful information to patients when they are deciding where to go for care.

Even though accreditation can help clinics meet and maintain standards over time, it would not create authority to investigate complaints and take action against clinics and unregulated owners if they fall below standards or commit misconduct. Any issues or concerns that do arise would have to be dealt with by the same regulatory bodies that exist today. This approach would not address the accountability gap that currently exists.

Options under existing legislation

Some measures can be taken under the existing legislative powers with regard to clinics. For example, colleges can further develop resources and tools to support and empower their

[16] For example, Accreditation Canada and the Commission on the Accreditation of Rehabilitation Facilities (CARF) both have quality-focused standards for accreditation.

members who encounter challenges in their workplace. Colleges could develop joint standards for clinics. Colleges could also increase coordination and information sharing with each other, and with other bodies such as Public Health and law enforcement, so that the existing oversight mechanisms are deployed when appropriate.

The challenge with this approach is that without jurisdiction over the clinics and their unregulated owners, the colleges have limited ability to influence change in the practice setting. The current legislative framework also makes it difficult for colleges to conduct joint adjudication of complaints involving multidisciplinary practices. This approach would also have limited impact on practice settings that do not employ any regulated health professionals. The Working Group colleges are also concerned about any clinic oversight model that might place strains on college resources.[17] Such an approach may result in the establishment of standards, and stronger enforcement of specific infractions (for example, infection control, criminal fraud), but would not address the underlying gap in accountability, so there may be limited gains in public protection.

Changes to the Regulated Health Professions Act and/or profession-specific regulations

Changes could be made to the *Regulated Health Professions Act* and/or profession-specific regulations that would allow colleges to set standards for and assess clinics where their members work. Measures could also be put in place to further enable colleges to collaborate to set standards, and to investigate and adjudicate complaints. This collaboration would ensure consistent outcomes and more efficient use of resources.

However, this approach still would not give colleges the authority to act against clinics and clinic owners who are not members of a college. It would also have limited impact on practice settings that do not employ any regulated health professionals. If such an approach were to include mechanisms for issuing licences or certificates of authorization to clinics, and for holding joint investigations and panels to deal with conduct matters, then challenges would arise when there are multiple, and in some cases overlapping jurisdictions. Furthermore, this approach would likely add to the workload of the existing colleges, and the Working Group is concerned about any model that would place strains on college resources. This approach could go some ways in addressing the issues in some of the practice settings that currently have no oversight, but it would be a partial solution to the problem. (More details of this analysis are contained in this report, starting on page 24.)

Formal regulation of clinics

Formal regulation of clinics, using the preliminary model that the Working Group developed, or one similar to it, would achieve the highest level of public protection. A formal regulation model would contain crucial features that ensure public protection, such as minimum requirements for registration/licensure, authority to set standards, authority to conduct inspections, ability to investigate and adjudicate complaints, and authority to sanction clinics for breaching standards or committing misconduct. The benefit to public protection

[17] One of the parameters for regulation established by the Working Group is that any clinic oversight model must not create undue burden on the existing health regulatory colleges.

would be even greater if the regulation model is designed broadly to cover practices that provide health care services and products, but do not employ any regulated health care professionals.

Establishing a clinic regulation model would be a complicated and costly undertaking, so careful consideration should be given to whether the intervention is proportionate to the risk to the public.

The extent to which the regulation of clinics would produce positive health system impacts in the following areas:

Health outcomes: A clinic oversight model could have positive impacts on health outcomes. As stated earlier in the report, the Working Group believes that the current accountability gap for clinics and unregulated owners may lead to issues affecting patient safety and quality of care. By having stronger oversight of clinics, those issues could be identified and corrected. Clinic oversight could reduce risks to patient safety, improve quality of care, and ensure that limited health care resources are spent efficiently, which would contribute to better health outcomes.

Access to care: Stronger clinic oversight could, on balance, improve access to care. Better oversight of clinics could prevent "leakage" from the system resulting from the inappropriate use of health care resources, which could result in more resources being available to provide care to patients who need and can benefit from it. At the same time, some of the alternative interventions discussed above could result in additional costs for clinics, which could potentially be passed onto patients through higher fees for services. It is also possible that some health care providers would have to spend time on compliance activities, which could take time away from seeing patients. The net impact on access to care can be better assessed after a specific intervention has been identified.

Health human resource productivity: On balance, stronger clinic oversight could have a positive impact on health human resource productivity. As the Working Group has identified, the lack of accountability for clinics has resulted in health care resources being spent on ineffective and unnecessary care. Such inappropriate use of health care resources would be reduced with stronger oversight, which would ensure that resources are spent on care that actually offers benefits to patients.

Labour mobility: The alternative interventions discussed above are unlikely to have impact on entry to a regulated profession, therefore they should not have any effect on labour mobility.

Likely support for clinic oversight

While stakeholder consultation conducted by the Working Group focused on the specific model that we developed, rather than the full range of possible interventions, the feedback does offers some indications as to the likely level of support for different clinic oversight models.

Many of the stakeholders, particularly the professional associations, who submitted comments acknowledged that there is a gap in public protection in the current system, and that some intervention may be needed. The consultation feedback revealed that stakeholders are varied in what they believe is the appropriate solution.

Consultation responses suggest that some respondents have a preference for using existing regulatory mechanisms to address the issues that may come up in clinics.

Some stakeholder comments suggest that they may support a formal clinic regulation model that is focused on specific subsets of clinics (for example, clinics owned by unregulated individuals, or multidisciplinary clinics).

In terms of reaction to the model that the Working Group put forward, which involves formally regulating clinics, the feedback was mixed. Consultation responses showed that regulated health professionals are more likely than not to support such a model. On the other hand, clinic owners and other stakeholder groups tended not to support a clinic regulation model.

As explained Appendix 1 (starting on page 32), there are limitations to the reliability of the consultation data.

The level of support for a clinic oversight model may change depending on how a particular model would address the concerns identified by stakeholders (the most common ones being financial cost and administrative burden). Stakeholder opinions may also change with more and better information about the kinds of problems clinic oversight is trying to address, and how a clinic oversight model would work. For example, some individuals who attended the town hall consultation events expressed concerns about the potential clinic regulation model based on misunderstandings about the model, but their concerns were often alleviated once they were provided with a better explanation of how the potential model would work.

Conclusion and Recommendations

The Working Group believes that despite the effective regulation of health care professionals, there still exists an accountability gap in clinics which puts patients and the health care system at risk, and is a barrier to providing patient-centred care. We urge the Minister of Health and Long-Term Care to take action to address this gap. As the Ministry takes on a systems view to improving health care services and aims to reduce fragmentation, we believe implementing clinic oversight is entirely consistent with the Ministry's goals.

The goal of the clinic regulation project was to explore whether clinic regulation is an appropriate response to the current gaps in safety, quality of care, and efficient use of health care resources in some clinic settings. The Working Group did not aspire to find the best solution. The Working Group concluded that the public interest could be served by a range of possible interventions, yielding varying elements and degrees of public protection. They might include a clinic registry; accreditation of clinics; measures implemented under existing legislative powers; amendments to the *Regulated Health Professions Act* (RHPA) and/or profession-specific regulations; and formal regulation of clinics. While some model of clinic regulation seems to offer the broadest public protection, the Working Group recommends further exploration to identify the option that will best protect patients in Ontario.

The Working Group believes that clinic oversight would be in the public interest. We would welcome the opportunity to work together with the Ministry and key stakeholders to better understand the nature and extent of the problem, and to identify the appropriate solution for Ontario.

Appendix 1 – Outcomes of the Clinic Regulation Working Group Activities

This section will provide details on the research and analysis conducted by the Working Group that led to their conclusion that formal clinic regulation is the solution that offers the strongest public protection. The Working Group also conducted stakeholder consultation based on the clinic regulation model that we developed. The results of the consultation are presented below.

Background

The purpose of the clinic regulation project is to explore whether clinic regulation is an appropriate solution to gaps in patient safety, quality care, and efficient use of health care resources in some clinic settings.

Arising from experiences in regulating their respective professions, the Working Group members share concerns about issues in unregulated clinics; it is difficult for regulators to assure quality of care in environments where regulated health professionals are sometimes put in a position where they may be forced either to compromise integrity and quality of care or to leave their practices. Consequently, even in environments where regulated professionals practice, there may be issues with safety, quality of care, and business practices. These put patients and health care resources at risk.

Working Group members considered the potential to make regulations or by-laws under existing legislation to empower each College to take different or additional action to address the problem. However, the Working Group found that no change within existing legislation would enable Colleges to have authority over unregulated clinic owners (whether individuals or corporations) and without such authority, attempts to address the problems at the member-specific level may not, ultimately, be sufficient.[18]

Accordingly, the group went on to explore whether there might be an appropriate specific model of clinic regulation that would fit into the existing Ontario health regulatory landscape.

[18] The need to have the authority to regulate clinic owners independently of the health professionals who work in these settings is more significant in professions where the practitioners are less likely to be the decision-makers or clinic owners. For example, the colleges for pharmacists, physicians and dentists exert authority over workplaces within the existing legislative context because these professionals may be required to be owners or decision-makers in these settings. This is not the reality for other professionals, such as massage therapists or physiotherapists where the business owners are frequently not regulated health professionals and, as such, are not subject to duty of care to patients.

Parameters for Clinic Regulation

Prior to the consideration of which model would be suitable for regulating clinics in Ontario, the Working Group agreed to a set of minimum requirements for any potential model. These parameters served both as a means to ensure that all parties were in agreement about the nature of the solution the Working Group was seeking, and as criteria for assessing the different options available.

To strengthen protection of the public interest, clinic regulation must:

1. Address quality of care.
2. Facilitate accountability and adherence to professional standards.
3. Mandate participation, with ability to suspend or limit clinic operations.
4. Have a quality assurance component.
5. Not contradict the *Regulated Health Professions Act* (RHPA).
6. Not create undue burden on the clinics and professionals.
7. Be able to work in a multidisciplinary setting, including where unregulated providers may work.
8. Be non-duplicative and cost-neutral.
9. Not create undue burden on Colleges.

In addition, the Working Group also identified a number of secondary parameters. To read the full list of parameters, see Appendix 2.

Exploring Potential Solutions

In the process of exploring alternative solutions that could achieve the stated goal of the project, the Working Group reviewed the findings of an environmental scan, literature research, and commissioned legal research of potential legislative frameworks. Below is a summary of the findings from that research.

Existing Oversight Mechanisms in Ontario

The Working Group recognized that some forms of oversight do exist for some clinics. In order to meet the parameter that aims to minimize duplication with existing clinic oversight mechanisms in Ontario, research was done to better understand the audit and oversight mechanisms in the current Ontario Health Insurance Plan (OHIP), Financial Services Commission of Ontario (FSCO), and Workplace Safety and Insurance Board (WSIB) models. Some members of the participating Colleges whose services are funded by any of these programs

would already be subject to some oversight mechanisms. The features in these three models are summarized in Table 1 below.

Table 1 – Summary of Features in Existing Clinic Oversight Mechanisms in Ontario

Model / Feature	Billing Compliance	Fraud Investigation	Business Practices	Clinical Care Standards
OHIP	Y	Y		
FSCO	Y		Y	
WSIB	Y	Y		

It is clear that the three existing models that currently provide oversight of clinics in Ontario are mainly focused on ensuring accurate billing and deterring fraud. To minimize duplication, any potential clinic oversight model would likely not need to focus on addressing billing practices and fraud, and instead defer to the three existing mechanisms to provide oversight in those areas.

Existing Models of Facility Regulation

An environmental scan was conducted in order to identify existing facility regulation models in other professions and jurisdictions. A total of 24 distinct regulatory models were identified, information from those models was used to build a list of possible regulatory features that could be included in the proposed model for regulating clinics in Ontario. Summary information on the 24 models identified is in Table 2 below.

Table 2: Common Features in Existing Facility Regulation Models (in Health care)

Jurisdiction - Type of Facility / Elements and Features	**Mandatory Participation**	**Standards for Record Keeping /Privacy**	**Premise Inspections**	**Standards for Physical Facility**	**Standards for Staff Qualifications/Duties**	**Standards for Equipment & Materials**	**Public Register**	**Standards for Clinical Care**	**Requirement for Quality Assurance**	**Designated Person in Charge**	**Display of Licence and/or Inspections**	**Standards for Business and Admin. Practices**	**Complaints/ Discipline Process**
Ontario – Out-of-hospital and Independent health facilities	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y			Y
Ontario – Pharmacies	Y	Y	Y	Y		Y	Y			Y	Y	Y	Y
Ontario – Dental practices using anesthesia	Y	Y	Y	Y	Y	Y	Y	Y					
Ontario – Dental practices using CT scanners	Y	Y	Y		Y	Y	Y	Y	Y				
BC – Diagnostic facilities	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	
BC – Pharmacies	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
BC – Dental practices using anesthesia	Y	Y	Y	Y	Y	Y		Y					
Alberta – Medical facilities	Y	Y	Y	Y	Y	Y		Y	Y	Y			
Alberta – Pharmacies	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	
Alberta – Dental surgical facilities	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	
PEI – Physiotherapy clinics	Y	Y	Y	Y	Y	Y	Y			Y	Y		Y
Newfoundland – Physiotherapy clinics	Y				Y		Y					Y	
U.S. (federal) – Medicare providers (rehab)	Y	Y	Y	Y	Y	Y	Y	Y	Y			Y	
Arizona – Physiotherapy businesses	Y	Y									Y		Y
Connecticut – Outpatient clinics	Y	Y	Y	Y	Y	Y	Y						
Connecticut – Medical spas					Y			Y			Y		
Massachusetts – Physiotherapy facilities	Y	Y	Y	Y			Y			Y	Y		Y
North Dakota – Rehabilitation agencies		Y	Y	Y	Y	Y	Y	Y	Y				
Texas – PT and OT facilities	Y		Y				Y			Y	Y		Y
Australian Capital Territory – Health facilities	Y	Y		Y				Y					
New South Wales – Private health facilities	Y	Y	Y	Y	Y	Y		Y	Y				

Unique Features in Existing Facility Regulation Models (in Health care)

- General requirement to comply with relevant laws
- Clinic liability insurance
- Good moral character of individuals involved with the clinic
- Separate obligations on non-regulated clinic owners
- Reporting of misconduct to regulator
- Requirement for regulated health professionals to work only in regulated facilities
- Periodic reporting to the regulator
- Case load limits

Approaches to Defining "Clinic"

In order to implement any regulatory model, there must be a workable definition for "clinic" that is appropriately inclusive to achieve the stated goals for regulating clinics, is enforceable, and does not conflict with other existing legislation. The Working Group recognized that there would be challenges if the definition that is overly broad, and that any definition would need a clear list of exceptions.

Broadly speaking, there are two possible approaches for defining "clinic" in a potential regulatory model: by the people who work there, and by the type of service provided.

Table 3 – Types of Definition for "Clinic"

Type of Definition	Description	Advantages	Disadvantages
By type of practitioner who works in the practice	Any practice where a member of a college works	- Ensures that employers of members of a college are held to the same professional standards as the members themselves	- Would not allow the regulation of practices where unregulated providers provide similar services as members of a college - May cause employers to hire unregulated providers instead to avoid regulation and further reducing quality

Type of Definition	Description	Advantages	Disadvantages
By the type of services provided in the practice	Any practice which provides defined health care services	- Enables oversight of practices where only unregulated practitioners work - Consistent with the way most other regulators define 'facility' (20 out of 24 models we looked at)	- Need to consider any legal obstacles and enforceability (e.g. what if practice terms are not legally protected)

Potential Legislative Frameworks

The Working Group commissioned a lawyer with expertise in professional regulation and health law to research, compile, and assess different legislative frameworks that might be used to implement clinic regulation given the stated goals and parameters established by the Working Group.

Five alternative legislative frameworks were identified as a result of this work. The options were also ranked based on three considerations: i) ease of drafting or revising legislation, ii) creating the regulatory model, and iii) what would ultimately work best, from the legal perspective. A summary of the analysis of the five options is in Table 4 below, in the order they were ranked (best to worse).

The analysis borrowed heavily from the facility inspection programs at the College of Physicians and Surgeons of Ontario (CPSO), for two reasons. First, out of the three colleges that currently have facility inspection programs in Ontario, the CPSO's model is the closest to meeting the Working Group's parameters for a clinic regulation model. Second, at the time the analysis was conducted, there was also a review of the CPSO's facility inspection programs underway, and we wanted to capitalize on the analysis and recommendations that was produced for that review.

Table 4: Alternative Legislative Frameworks for Implementing Clinic Regulation

Option	Potential Advantages	Potential Disadvantages
#1 – Join and expand CPSO's proposal to create one amalgamated regulatory scheme for all clinics in Ontario[19]; two variations: i) One regulator for all clinics ii) One regulator for clinics where physicians perform procedures, and a different regulator for the other clinics	- One comprehensive regulatory scheme to regulate all clinics - Incorporating proposal into an already-significant overhaul would require relatively less additional work - Capitalize on the appetite for the proposed regulatory framework	- CPSO may not be amenable to including non-doctor clinics in their proposed framework; and/or - Members of partner colleges may not be amendable to having CPSO regulate clinics where they work - CPSO's proposed regulatory model is based on risk – would the services provided by non-physicians be considered sufficiently risky to warrant regulation?
#2 – New statute granting jurisdiction to regulate "clinics" by a new regulatory body	- Allow colleges to collaborate to establish registration requirements, clinic standards, joint panels/committees for handling complaints, and quality assurance mechanisms - One regulator means less duplication/overlap of activities, more consistent interpretation and application of rules, and more consistent investigation/discipline outcomes - Easier to draft a new legislative framework as opposed to incorporating into existing legislation drafted for a different purpose (though work is still significant) - Could use CPSO's *Out-of-Hospital Premises Inspection Program* or the *Independent Health Facilities Act* as guides for developing legislation	- In light of CPSO's proposal, this approach may be seen as creating a piecemeal system for regulating "clinics" in Ontario - New legislation may be less politically palatable than revisions to existing legislation, or seen as a more significant endeavor

[19] College of Physicians and Surgeons of Ontario. Submission to Health Quality Ontario. *The Regulation of Facilities: Looking Forward*. http://www.cpso.on.ca/CPSO/media/documents/CPSO%20Members/OHPIP/HQO-Submission.pdf.

Option	Potential Advantages	Potential Disadvantages
#3 – Amendments to regulations under the profession-specific acts following the CPSO's Out-of-Hospital Premises Inspection Program (OHPIP)	- Easier to amend an existing legislative model than to create a new one - The OHPIP is a proven model from the legislative, regulatory, operational, and financial perspectives - Can capitalize on CPSO's experience in terms of mistakes/successes in the program which will save time and resources - Can modify elements of the OHPIP to fit the objectives of this project	- CPSO has recently proposed a significant overhaul to the program based on lessons-learned and perceived inefficiencies - OHPIP was designed to apply to facilities where physicians perform procedures, may need significant revisions to apply to other types of clinics and treatments - It is likely that enforcement activities would fall to the individual colleges, which may lead to inconsistent outcomes, and may undermine the concept of interdisciplinary clinic regulation
#4 – Jurisdiction to regulate clinics incorporated into the RHPA and profession-specific acts	- Allow colleges to collaborate to establish registration requirements, clinic standards, joint panels/committees for handling complaints, and quality assurance mechanisms - Joint investigations/adjudications allow for pooling of resources, and more consistent outcomes/decisions	- Will not create jurisdiction over the clinic itself and/or over clinic owners who are not members of a college - If every college has jurisdiction to issue licenses for clinics owned/operated by its members, could impact efficacy of clinic oversight (e.g. more difficult to detect fraudulent licenses, maintain a public register of licensed clinics) - Likely need statutory prohibition against members working in unlicensed clinics, which could potentially be challenged under the *Competition Act* or the *Charter* - If using joint panels to deal with conduct matters, may run into jurisdictional challenges (e.g. is the issue related to a member's work in the clinic, or the member's practice more generally?) - There are a number of practical difficulties with setting up joint panels

Option	Potential Advantages	Potential Disadvantages
#5 – Jurisdiction to regulate clinics incorporated into existing legislation – e.g. the *Independent Health Facilities Act* (IHFA)	- Adding to existing legislation may seem like less work and more politically palatable than creating new legislation	- Would be challenging to incorporate a fairly sophisticated new regulatory scheme into existing legislation that was originally drafted to address different issues and serve a different purpose - It would likely be difficult to separate the regulatory powers and functions that related to "independent health facilities" and those that relate to "clinics" - IHFA represents a Ministry of Health/public accountability model, which has a different purpose and focus than a public protection/public interest model - Will need to work out details of a funding agreement with the Ministry of Health to pay for the additional regulatory activities resulting from the changes

Alternative Models for Clinic Regulation

After assessing potential regulatory features against the parameters, considering different ways to define "clinic", and options for legislative frameworks, it was then possible to build alternative models for clinic regulation by putting together different combinations of those three components. The table below illustrates five possible models, as examples for the Working Group to consider.

Table 5: Alternative Models for Clinic Regulation – Examples for Consideration

	Alternative Model 1 – *Join CPSO proposal*	Alternative Model 2 – *New statute and regulatory body*	Alternative Model 3 – *Changes to RHPA following OHPIP model*	Alternative Model 4 – *Incorporate into RHPA and practice acts*	Alternative Model 5 – *Incorporate into existing legislation e.g. IHFA*
Regulatory Features					
Mandatory participation	✓	✓	✓	✓	✓
Standards for record keeping/privacy	✓	✓	✓	✓	✓
Premise inspections	✓	✓	✓	✓	✓

	Alternative Model 1 – *Join CPSO proposal*	Alternative Model 2 – *New statute and regulatory body*	Alternative Model 3 – *Changes to RHPA following OHPIP model*	Alternative Model 4 – *Incorporate into RHPA and practice acts*	Alternative Model 5 – *Incorporate into existing legislation e.g. IHFA*
Standards for physical facility	✓	✓	✓		✓
Standards for staff qualifications/duties	✓	✓	✓	✓	✓
Standards for equipment & materials	✓	✓	✓		✓
Public Register	✓	✓	✓	✓	✓
Standards for clinical care	✓	✓	✓	✓	✓
Requirement for quality assurance	✓	✓	✓	✓	✓
Designated manager/ person in charge	✓	✓	✓		✓
Display of license information		✓			
Standards for business and admin. practices		✓		✓	✓
Complaints and discipline process	✓	✓		✓	
General requirement to comply with laws					
Clinic liability insurance		✓		✓	
Good moral character		✓			
Obligations for non-regulated clinic owners *or* Clinic ownership restrictions		✓			
Reporting of non-compliance/misconduct		✓			
Require RHPs to only work in regulated clinics				✓	
Periodic reporting to regulator			✓		

	Alternative Model 1 – *Join CPSO proposal*	Alternative Model 2 – *New statute and regulatory body*	Alternative Model 3 – *Changes to RHPA following OHPIP model*	Alternative Model 4 – *Incorporate into RHPA and practice acts*	Alternative Model 5 – *Incorporate into existing legislation e.g. IHFA*
Definition of "clinic"	By the type of services provided in the clinic	By the type of services provided in the clinic *or* By the people who work in the clinics	By the type of procedures or services provided in the clinic	By the people who work in the clinics	By the type of services provided in the clinic
Legislative framework	Join and expand CPSO's proposal to create one amalgamated regulatory scheme for all clinics	New statute granting jurisdiction to regulate "clinics" by a new regulatory body	Amendments to profession-specific acts and regulations following the CPSO's Out-of-Hospital Premises Inspection Program	Jurisdiction to regulate clinics incorporated into the RHPA , profession-specific acts, and associated regulations	Jurisdiction to regulate clinics incorporated into existing legislation (e.g. *Independent Health Facilities Act*)

Several other policy alternatives were also considered but discarded, including:

1. Implement clinic regulation through the *Health Protection and Promotion Act* (HPPA)
2. Implement clinic regulation through the *Occupational Health and Safety Act*, Regulations for Health Care and Residential Facilities
3. Implement clinic regulation through the *Consumer Protection Act*

Developing a Unique Model for Regulating Clinics in Ontario

The Working Group assessed the alternative models for providing clinic oversight, and found that none of the alternatives based on existing approaches or legislation satisfied the parameters that the group established. The group reached the consensus that the best alternative was to establish a separate clinic regulator, which would require new legislation.

The Working Group further agreed that a preliminary model for this new legislation should be drafted for the purpose of stakeholder consultation, in order to obtain specific and meaningful feedback. A preliminary model was developed with legal consultation, and approved by the Councils of the partner colleges to be used for stakeholder consultation.

The Working Group conducted informal consultations with certain stakeholders during the summer and fall of 2015, which resulted in further refinement of some aspects of the model. Highlights of the model that was used in the consultation materials are below, for a more detailed description, see Appendix 3.

Highlights of the Preliminary Model Used for Stakeholder Consultation

Note: The model described below was created only for the purpose of exploring how to approach the problem. The Working Group did not aspire to identify the best solution.

The proposed model for clinic regulation is similar to health professional regulation under the Regulated Health Professions Act (RHPA).

"Clinic" could include any office or location where at least one regulated health professional provides health care services, or is responsible for the care provided by another person under his or her supervision.

An alternative definition would include all locations where health care services are delivered or performed (regardless of whether a regulated health professional works there).

Both definitions are broad and would include settings in which appropriate oversight may already exist (hospitals, for example). In order to avoid overlap with existing regulations or oversight mechanisms, a list of exceptions to the definition of "clinic" would need to be developed.

In the proposed model, regulation would:

- Make it illegal for unregulated clinics to provide some or all health care services to the public. (Health care services might be those services provided by regulated health professionals; or they could, under the alternative definition, be so broad as to include all health care services, in which case that term would also require definition.)
- Create an oversight body with a mandate to ensure that Ontarians receive health care services in safe and ethical clinics.
- Set registration requirements and standards for service delivery, including, but not limited to, standards for safety, delivery of care, and business practices.
- Create an on-line Register that lists all regulated clinics, the people who work there, clinic inspection results and much more information to help patients make informed decisions about where to seek health care services.

Regulated clinics would be inspected on a regular basis to ensure that they meet the standards established by the regulator. The regulator could also carry out inspections in response to complaints or concerns where there were reasonable and probable grounds to believe that the standards were being breached.

If the inspection uncovered problems or concerns with a clinic, then an oversight body would have the power to impose restrictions on the clinic's operations, to suspend its licence until the issues were addressed or even to revoke its license.

In addition to inspections, regulated clinics could be required to submit annual reports.

The clinic regulator and the individual professions regulators would share information to ensure comprehensive oversight of the premises and the professionals who work there. For example, if the clinic regulator discovered issues or concerns with the practice of a particular regulated health professional, this would be reported to that professional's regulatory college. Similarly, if a regulator of health professionals became aware of issues or concerns with a clinic, this would be reported to the clinic regulator.

Whistleblower protection would be included for those who wished to make anonymous reports.

There would also be appeal or review processes for clinics with objections to decisions made by the regulator.

Stakeholder Consultation

The Working Group partner colleges began to have informal consultations with certain stakeholders during summer and fall of 2015, leading up to the launch of the formal consultation on November 18, 2015. The Working Group reached out to a variety of stakeholder groups, using different communications tools.

The goal of the consultation was not to test the popularity of the idea of clinic regulation. The consultation was not appropriately designed to objectively collect such information. The intention was to identify strengths and weaknesses of the proposed model, to inform decisions about overall viability or to make changes to improve the model.

A summary of the consultation timeline and activities is below.

Time	Consultation Activities
Informal Consultations July-Sept 2015	Liaise with Ministry of Health Discussions with health professional associations Outreach to other regulatory colleges - Shared updates on the project at the Federation of Health Regulatory Colleges of Ontario (FHRCO) meeting - Outreach to each college through meetings or correspondence Discussions with Health Quality Ontario (HQO) Discussions with insurance industry through the Canadian Life and Health Insurance Association (CLHIA) Focus group discussion with members of the public (Citizen's Advisory Panel at the College of Physiotherapists of Ontario)
Preparation for Launch Oct-Nov 2015	Continue to liaise with Ministry of Health Member outreach (email, newsletter, social media) Discussions with the Health Professions Regulatory Advisory Council (HPRAC)
Formal Consultation Nov-Dec 2015	Nov. 18: Webinar and Website Launch Nov 23-Dec 9: Town Hall meetings (Kitchener-Waterloo, Sudbury, Windsor, Ottawa, Toronto, Brampton) Dec. 15: Meeting with health professional associations Dec. 31: Deadline for comments and submissions *(Extended to January 31, 2016 for health professional associations)*

Level of Engagement

Below are summary statistics that show the level of engagement with stakeholders during the formal consultation period:

Communications Vehicle	# of Visitors/ Attendees
Website	7,850
Webinar	350 live + 730 re-watch

Communications Vehicle	# of Visitors/ Attendees
On-Line Consultation Survey	1,357
Town Hall 1 (Kitchener-Waterloo) Nov 23	40
Town Hall 2 (Sudbury) Nov 25	5
Town Hall 3 (Windsor) Nov 26	20
Town Hall 4 (Ottawa) Dec 1	70
Town Hall 5 (Toronto) Dec 2	60
Town Hall 6 (Brampton) Dec 9	30
Written submissions (Emails + Comment Cards)	150
College-specific consultation activities	265

Below is a breakdown of the types of stakeholders who participated in the consultation:

Stakeholder Group	Online Consultation	Town Halls
Regulated health professionals	1,221	164
Unregulated health providers	67	5
Patients, Family Members of Patients, and Members of the Public	35	29
Clinic Owners – *RHPs*	199	41
Clinic Owners – *Non-RHPs*	28	6

For more information about participants in the online consultation, see Appendix 4.

Analysis of Consultation Feedback

The analysis of the consultation feedback has two components: first, an overview of statistical results from the online survey responses, and second, an analysis of the themes in the stakeholder comments.

Statistical Analysis of Online Survey Responses

An analysis of the statistics from the survey responses revealed the following information:

- More than half of respondents (58%) did not have accurate knowledge about the current state of clinic oversight prior to learning about the project. One in five respondents (20%) erroneously believed that there is more oversight of clinics in the current system than there is.

- Respondents expressed high levels of concern about all issues that could arise in clinics. The area with the highest concern is quality of care (at 89%) and the area with the lowest concern is billing fraud (at 74%).
- When asked whether clinic oversight would provide reassurance about these issues, more people said yes than no, but there were many who were unsure. This was true whether respondents were answering as patients or as health care providers.
- The majority of respondents felt that more oversight was required in settings where none of the providers are regulated or where unregulated assistants are used to provide care. Most respondents felt that sole regulated practitioners did not require additional oversight.
- Overall, regulated health professional respondents tended to support clinic regulation. Other groups of respondents tended not to support clinic regulation. As stated above, the survey was not designed in a way that would collect a representative sample of the Ontario population, so these results cannot be considered to demonstrate how the Ontario public might react to the idea of clinic regulation.

For more details about the statistical survey results, please see Appendix 4.

Themes in Stakeholder Comments

Stakeholder comments were categorized into various themes as they emerged (as opposed to pre-determined themes), and then the instances where a theme came up were tallied. The themes summarized below are those with the highest rate of occurrence in stakeholder comments.

Theme: The existing oversight mechanisms are adequate

Among stakeholders who wrote comments, many expressed the sentiment that the existing level of oversight in clinic settings is adequate for protecting the public. The most common reason cited for this belief is that the regulation of individual health care professionals ensures accountability. Others also point to the existence of other oversight mechanisms, such as the FSCO regulations, and OHIP and WSIB audits, as other ways clinics are already subject to oversight.

Some respondents also identified a concern that clinic regulation may duplicate what the colleges and other oversight bodies already do and would not offer any added benefit.

Similarly, among those respondents who acknowledge that there are problems in the current system, some suggest that the existing regulatory tools and bodies should be used to address those problems, rather than creating a new regulator. For example, some suggested that the existing colleges could regulate clinics.

Respondents who are not regulated health professionals were slightly more likely to express this sentiment compared to those who are regulated health professionals. The respondents who made these kinds of comments were much more likely to be those who say they do not support a clinic regulation model (84.7%, compared to the overall share of 43.5%), so these comments are not representative of all respondents.

Theme: Regulated vs. Unregulated

Many stakeholder comments reflect the belief that the need for additional oversight differs depending on whether the individuals involved are regulated or not. This is consistent with the statistical results that demonstrated that respondents believed that settings where unregulated providers work are the most in need of additional oversight.

Many commenters wrote that for sole practitioners, settings where care is delivered by regulated health professionals, or where the clinic is owned by a regulated health professional, further regulation would be redundant. Some commenters believed that clinics where health care services are delivered exclusively by unregulated practitioners should be regulated. A suggested alternative to clinic regulation was regulation of currently unregulated practitioners.

Concern was also expressed about ownership of clinics by unregulated individuals who are presently under no obligations to meet standards of any kind. Some respondents suggested that as an alternative to clinic regulation, the objective could be achieved by requiring that all clinics be owned by regulated health professionals, so that the colleges would have oversight of the clinic.

Respondents who wrote these types of comments were slightly more likely to be regulated health professionals, and slightly more likely to say they do not support a clinic regulation model, compared to the overall proportions. These results could be interpreted to mean that while these respondents may not support a model that would oversee all clinics, they may support a model where the oversight is focused on settings where unregulated individuals provide the care or own the clinic.

Theme: Concerned about added burden of clinic regulation

The most common concerns expressed about a potential clinic regulation model are the added cost and compliance burden.

Many respondents were concerned about the cost of fees that might be levied by the clinic regulator. Many also pointed out that the cost may be passed on to patients through increased fees for the services, and therefore may reduce access to care.

Another expressed concern was the additional administrative burden and time spent on compliance activities. Many argue that this additional work would take time away from providing patient care, and would add stress to those who are responsible for this work.

Some respondents worry that the added cost and administrative burden would be particularly detrimental for small practices and sole practitioners. Some even go as far to say that certain practices may have to close because they will no longer be financially viable. Some respondents also believe that the added regulation may discourage health professionals from continuing their practice, or from entering practice in the first place.

Perhaps not surprisingly, respondents who are clinic owners were more likely to express these concerns compared to other stakeholder groups. Also not surprisingly, respondents who made these comments were more likely to be those who do not support a clinic regulation model (74%, compared to the overall share of 43.5%).

Theme: Acknowledgement that problems exist, and clinic regulation could offer benefits

Many respondents acknowledged that there are problems in the current system, and were supportive of having more clinic oversight, although to different degrees. Some agree that all clinics should be regulated and suggested that it would better protect both patients and the professionals who work there. Some respondents believe that having clinic regulation could benefit clinics by helping them improve their practice, enhance public confidence, and would make it harder for the "bad clinics" to continue operating.

Others suggested that some oversight short of formal regulation could be beneficial, such as establishing clinic guidelines, and having some mechanism to assess clinics. Some believe that greater oversight is needed for certain settings, for example, where high risk procedures are performed, private practice clinics, and multidisciplinary clinics.

All stakeholder groups were equally likely to express this sentiment, and not surprisingly, respondents who made these comments were much more likely to support a clinic regulation model (76%, compared to the overall share of 44.5%).

Theme: More regulation is not a guarantee of better outcomes

Many respondents suggested clinic regulation would not be a guarantee that all clinics would provide good quality care and conduct themselves ethically. A commonly cited reason for this sentiment was that clinics would find loopholes in the new regulation, or would only appear to be compliant during the inspection, when they were not meeting standards the rest of the time.

Some respondents were also concerned about the ability of a new regulator to regulate effectively: respondents argued that it would be difficult to develop meaningful standards for so many different types of clinics, and wondered whether a regulator could effectively monitor compliance and enforce those standards.

Respondents who are not regulated health professionals were more likely to express this sentiment compared to those who are regulated health professionals, which may be a reflection of a general skepticism towards regulation among those who have not experienced regulation themselves. These respondents were much more likely to say that they would not support a clinic regulation model (88.7%, compared to the overall share of 43.5%), so these comments are not representative of all respondents.

Theme: Patients can and should have a greater role

Some respondents stated that patients are capable of looking after themselves, and rather than adding more regulation, the government/regulators should provide tools to empower them. Many respondents said that patients can seek out information to help them choose which clinic to go to, and judge the quality of the care and service they receive from the clinic. A few respondents also suggested that patients could be empowered with more information and education to help them choose between providers and to judge the quality of care for themselves.

A corollary of that is some respondents' belief that market forces will reward good clinics and punish bad clinics, so regulatory intervention is not necessary.

Respondents who are not regulated health professionals were more likely to express this sentiment compared to those who are regulated health professionals. These respondents were overwhelmingly not in support of a clinic regulation model (90.6%, compared to the overall share of 43.5%), so these comments are not representative of all respondents.

Theme: Disadvantaging alternative or complementary health care professions

Some respondents are concerned that clinic regulation would create a barrier for providers and/or clinics that offer alternative or complementary treatments. That would result in reduced access to those types of services for patients. Some respondents also felt that the clinic regulation proposal implies a bias against unregulated health care providers.

Not surprisingly, almost all of the respondents who made these comments are unregulated health care providers, so these comments likely reflect a concern that is specific to that stakeholder group.

Theme: Need more information

Some respondents felt that they needed more or clearer information in order to provide feedback about the proposal. The types of information they wanted to see include data to demonstrate the size of the problem, clearer definitions for "clinic" and "health care services", and more details about the proposed model.

All stakeholder groups were equally likely to express this sentiment. These respondents were much more likely to say they would not support a clinic regulation model (68.2%, compared to the overall share of 43.5%), which could be due to the belief that there is insufficient data to demonstrate the need for it.

Limitations of the Online Consultation Data

Two limitations to interpreting the online consultation responses are highlighted below.

First, the themes in the survey comments are not representative of the views of all respondents. Respondents who indicated they are not supportive of the clinic regulation concept were more likely to write comments, so their views are over-represented in the results.

Second, the general themes and statistics collected in the consultation cannot be assumed to demonstrate an informed response to the proposal. It would appear that some respondents may not have reviewed or understand the information in the consultation materials: some respondents made suggestions about things that are addressed in the materials, or asked questions to which the answers are contained in the materials.

Usage statistics for the website and videos reinforce this. Visits to the consultation website lasted for only 4.5 minutes on average. The two substantive videos on the website have fewer than 700 views.

Accordingly, it may be best to interpret some of the responses as reaction to the *idea* of clinic regulation, rather than the specific model that was put forward. In many cases the specific concerns identified were addressed (or attempted to be addressed) in the proposal itself.

Comments from Town Halls and Patient Focus Group

The Working Group also conducted six town hall meetings and one patient focus group discussion about the concept of clinic oversight. The themes that arose in those discussions are the same as those found in the online consultation comments, therefore they will not be summarized separately.

Comments from Associations

The feedback from professional associations and other health care organizations contain many of the same themes as feedback from individual stakeholders. Themes in the association comments include:

- Recognition and support for the public interest reasons for undertaking this initiative. Some associations applauded the Working Group for raising the issues and starting the discussion.
- Acknowledgement that problems exist in some clinics, particularly clinics that are owned by unregulated individuals or where the care is delivered exclusively by unregulated providers.
- Concern about the lack of data to demonstrate that the problems are of sufficient magnitude to warrant the level of intervention proposed.
- Concern about increased cost and administrative burden (especially for small practices) and the potential result of fewer resources available to provide patient care.
- Concern that clinic regulation would duplicate existing regulation, which could lead to inconsistent or conflicting standards, confusion for the public, and added burden on regulated health professionals who are already subject to similar rules.
- Related to that point, many proposed exemptions for settings that they believe already have effective oversight, for example, clinics owned by regulated health professionals, sole practitioners, home care settings, and clinics regulated under the *Independent Health Facilities Act* (IHFA).
- Feedback on the definition of "clinic" was mixed; some felt the proposed definition (particularly the second one based on health care services) was too broad, while others preferred the broader definition.
- Concern that the narrower definition in the proposed model (based on where regulated health professionals work) could reduce employment opportunities for regulated health professionals by providing an incentive for clinic owners to hire unregulated providers instead of regulated health professionals in order to avoid regulation.
- Concern that creating a separate regulator may reduce the confidence in and perceived need for professional self-regulation.
- Some suggested that additional oversight could be achieved through the existing colleges and regulatory bodies, by strengthening the existing colleges' mandate and authority, and by increasing coordination between existing oversight bodies.
- Others suggested that as an alternative to regulating clinics, oversight could be achieved by regulating clinic owners.
- Concern that a single regulator may not have the credibility or expertise to regulate the wide variety of practice settings that could be captured by the model.
- Concern that clinic regulation would put unregulated providers at a disadvantage, and limit the ability for patients to choose services provided by unregulated providers. Some felt that the clinic regulation proposal is implicitly biased against unregulated providers.

Most of the associations indicated that while they support the initiative, they do not support the specific model that was put forward for consultation. Some indicated an interest in further exploring the issues and alternative solutions.

Stated Position	Organization	Summary of Comments
Overall Supportive (1)	Canadian Life and Health Insurance Association (CLHIA)	Supportive of the concept, with recommendations for fine-tuning the model.

Stated Position	Organization	Summary of Comments
Supportive of the initiative, but not the model (10)	Ontario Athletic Therapist Association (OATA)	Acknowledge there is gap in public protection, would prefer that it is addressed by existing colleges.
	Ontario Physiotherapy Association (OPA)	Does not support the proposed model, but interested in exploring alternatives.
	Ontario Physiotherapy Clinics Association (OPCA)	Acknowledge there is gap in public protection, but believe that additional regulation should be focused on non-RHP clinic owners.
	Ontario Podiatric Medical Association (OPMA)	Acknowledge there is gap in public protection, would prefer that the existing colleges regulate clinics.
	Ontario Chiropractic Association (OCA)	Acknowledge there is gap in public protection, but believe the data available does not support implementation of the proposed model.
	Ontario Association of Speech-Language Pathologists and Audiologists (OSLA)	There is insufficient evidence to support implementation of the proposed model, but believe there is need to explore how to address the issues.
	Ontario Association of Naturopathic Doctors (OAND)	Concerned that proposed model would add burden on RHPs, instead should regulate non-RHP clinic owners.
	Ontario Opticians Association (OOA)	Acknowledges that there are problems in some clinics, but prefer that they be addressed by existing colleges.
	Registered Massage Therapists' Association of Ontario (RMTAO)	Acknowledges there is gap in regulatory oversight, supports the concept of clinic regulation, but not the proposed model.
	Ontario Society of Occupational Therapists (OSOT)	Does not support the proposed model, but supports further exploration of the issues and alternative solutions.
Overall not supportive (7)	Association of Ontario Midwives (AOM)	More regulation will not be in the public interest; concerned about unintended consequences.
	Orthotics Prosthetics Canada (OPC)	Clinic regulation may unfairly bias the public against unregulated health providers, which would not be in patients' best interest.
	Ontario Rehab Alliance (ORA)	Lack compelling data on the risk of harm to justify imposing more regulation.

Stated Position	Organization	Summary of Comments
	Pedorthic Association of Canada (PAC)	Clinic regulation would bias the public against unregulated health providers, instead recommends regulating those providers under the RHPA.
	Ontario Kinesiology Association (OKA)	Does not support any model that would add cost to the system, and create barriers to access of services.
	Ontario Dental Hygienists' Association (ODHA)	Acknowledge there may be problems, but believe there is insufficient evidence to support implementation of a new regulatory scheme.
	Advanced Scope for Naturopathic Doctors (ASND)	Not convinced that a new oversight body is required, but open to exploring other regulatory responses relating to clinics.
No stated position (2)	Ontario Herbalist Association (OHA) and Canadian Council of Herbalists Associations (CCHA)	Concerned that clinic regulation would have negative consequences for unregulated health care providers.
	Dietitians of Canada (Ontario)	Need more data on the scope and severity of the problem; concerned about potential negative consequences of the proposed model.

Submissions Available Online

The Working Group has posted all stakeholder submissions on the clinic regulation consultation website, at www.ontarioclinicregulation.com.

Appendix 2 – Parameters for Clinic Regulation

The Clinic Regulation Working Group identified a number of relevant parameters and criteria with which to assess potential regulatory options. They identified nine key parameters, and seven secondary.

Key Parameters

To strengthen protection of the public interest, a clinic regulation model must:

1. Address quality of care.
2. Facilitate accountability and adherence to professional standards.
3. Mandate participation, with ability to suspend or limit clinic operations.
4. Have a quality assurance component.
5. Not contradict with the *Regulated Health Professions Act* (RHPA).
6. Not create undue burden on the clinics and professionals.
7. Be able to work in a multidisciplinary setting, including where unregulated providers may work.
8. Be non-duplicative and cost-neutral.
9. Not create undue burden on Colleges.

Secondary Parameters

A clinic regulation model:

10. Should be 'value-added' to the process of regulation.
11. Any enforcement mechanism in the proposed solution should be responsive to information received.
12. Should clearly identify responsibilities of all participating Colleges for enforcement.
13. Should be the minimum required to address the problem.
14. Should be agreed to and supported by payers.
15. Must be as transparent as possible to support the public interest.
16. Must not deprive the public of having a choice to seek out unregulated providers.

Appendix 3 – Detailed Description of the Preliminary Clinic Regulation Model Used for Stakeholder Consultation

Note: The model described below was created only for the purpose of exploring how to approach the problem. The Working Group did not aspire to identify the best solution.

The potential model for clinic regulation mirrors the *Regulated Health Professions Act* (RHPA). New legislation, the *Regulated Health Clinics Act* (RHCA), would establish the authority to regulate clinics, and set out the overall framework. The details for how to go about regulating would be set out in the *Regulated Clinics Procedural Code* (RCPC).

About the *Regulated Health Clinics Act* (RHCA)

The definition for "clinic" could be:

> *Any office or location in Ontario where a member of a health regulatory college provides or supervises health care treatment or services or where health care treatment or services are provided under delegation and/or authorization from a member of a health regulatory college.*
>
> Or
>
> *Any location where health care services are delivered or performed.*

The legislation would make it illegal for an unregulated clinic to deliver health care services to the public.

The Working Group does not want to create a system that is overly burdensome for practitioners or that creates unnecessary and expensive administrative overlap. So, recognizing that some practice settings are already regulated, a list of exceptions for certain types of practice settings would be created. These exceptions could include hospitals and regulated health professionals working alone, among others.

The proposed legislation would also establish the relationship between the Minister of Health and Long-Term Care and the clinic regulator. It would set out the duty and powers of the Minister, give the Minister the power to appoint a supervisor for the clinic regulator, and require the regulator to submit annual reports to the Minister.

About the Regulated Clinics Procedural Code (RCPC)

1. About the regulator

A new body would be established to regulate clinics – the Health Clinic Authority (HCA).

The HCA would have a mandate to work with the Minister of Health and Long-Term Care to ensure that the people of Ontario receive health care in safe and ethical clinics. Its primary duty would be to serve and protect the public interest.

The HCA would have a number of objects, such as:

- To regulate clinics where health care services are delivered
- To establish standards for qualification for clinics
- To establish standards for the delivery of health care services in clinics
- To foster relationships with key stakeholders, such as regulated health professionals, health regulatory colleges, and the public
- To promote interprofessional collaboration
- To develop standards and programs that would help clinics respond to changes in practice environments

The HCA Council (or Board) would be composed of representatives of health regulatory colleges, and public members appointed by government.

2. How clinics would be regulated in the potential model

In order to be registered with the HCA:

- A clinic must designate a principal representative,
- The principal representative may be a regulated health professional, and
- The principal representative must be able to demonstrate good moral character

The Registrar of the HCA would make decisions about applications for registration, with a mechanism in place to appeal those decisions.

The HCA would publish a Public Register that lists all registered clinics, with relevant information about the clinics that would be useful to patients, caregivers, and others who deal with the clinics, such as:

- The clinic's name, location, and contact information
- The names of any regulated health professionals who work in the clinic, with links to registration information from their respective colleges
- The names of any unregulated practitioners who deliver health care services at the clinic
- The dates of clinic inspections and their outcomes
- Any restrictions on the clinic's license
- Details about past clinic inspection results

- Information about a decision that is being appealed
- Any other information the regulator believes should be included

The primary tool for ensuring patient safety would be regularly-scheduled clinic inspections. The inspections would ensure that clinics continue to meet HCA standards.

If the HCA receives a complaint or report about a clinic that provides reasonable and probable grounds to believe that the clinic is not meeting standards, an inspection could be triggered.

Clinic inspections would be conducted by an inspector or a team of inspectors. The inspection team would have one or more regulated health professionals, and, as much as possible, the composition would match the types of professions that work in the clinic.

Reports of clinic inspections would go to a Premises Inspections Committee for review. If the Committee has concerns about the clinic, it could require the clinic to make changes, place restrictions on or suspend its license. Apart from whether the clinic met standards, if the inspection revealed concerns about an individual regulated health professional, that information would be reported to that professional's regulatory college.

If the Committee required the clinic to make changes to meet standards, it would have the power to order a re-inspection to ensure that the requirements were met.

To further strengthen protection of patients and the public, the Committee would have the power to impose emergency suspensions of clinic licenses if it found that the conditions in a clinic pose immediate harm to patients. In the worst cases, where the inspection revealed significant risk to patients, the Committee could revoke the clinic's license.

There would be a corresponding process for clinics to appeal decisions made by the Premises Inspections Committee.

As with health professional regulation, the new law would include zero tolerance of sexual abuse of patients. If the abuse was committed by a regulated health professional, the case would be referred to the professional's regulatory college, but a process to handle sexual abuse by unregulated staff would need to be developed.

Clinics would be required to display the clinic license and inspection reports on-site, and to submit annual reports to the HCA.

There would also be measures in place to help ensure that if providers who work in a clinic have concerns about the clinic, they can report those concerns to the regulator without fear of reprisal from their employer.

3. Regulators working together

The clinic regulator and individual health regulators would work together to ensure seamless oversight of the patient's health care experience at the clinic. Just as the HCA would report any concerns about a regulated health professional to his or her college, similarly, if a college becomes aware of concerns or issues in a clinic, it would report these to the clinic regulator.

Individual colleges might need to add "providing services in an unregulated clinic" to their list of specific types of professional misconduct. And the *Regulated Health Professions Procedural Code* might need to add a requirement that the Colleges report concerns about clinics to the HCA.

Appendix 4 – Statistical Analysis of Clinic Regulation Online Consultation Survey Responses

Stakeholder Category

Survey question: Please indicate whether you are a (you can check more than one).

Category	Responses	Percent
Regulated health professional	1221	90.8%
Unregulated health care provider	78	5.8%
Patient	90	6.7%
Family member or caregiver of a patient	43	3.2%
Member of the public	104	7.7%
Clinic owner	228	17.0%
Representative of an organization	45	3.3%
Other (please specify)	36	2.7%

Regulated Health Professionals – Breakdown by Profession

Survey question: If you are a regulated health professional, please indicate which one.

Profession	Responses	Percent
Audiologist	6	0.5%
Chiropodist	4	0.3%
Chiropractor	79	6.5%
Dental hygienist	5	0.4%
Dental technologist	55	4.5%
Dentist	2	0.2%
Denturist	1	0.1%
Dietitian	374	30.6%
Homeopath	2	0.2%
Kinesiologist	34	2.8%
Massage therapist	105	8.6%
Medical laboratory technologist	0	0.0%
Medical radiation technologist	0	0.0%
Midwife	0	0.0%
Naturopath	3	0.2%
Nurse	3	0.2%
Occupational therapist	11	0.9%
Optician	2	0.2%
Optometrist	0	0.0%
Pharmacist	0	0.0%
Physician	0	0.0%
Physiotherapist	497	40.7%

Profession	Responses	Percent
Podiatrist	0	0.0%
Psychologist	1	0.1%
Psychotherapist	6	0.5%
Respiratory therapist	0	0.0%
Speech-language pathologist	12	1.0%
Traditional Chinese medicine practitioner / Acupuncturist	20	1.6%

Regulated Health Professional Respondents Who Are Solo Practitioners

Survey question: If you are a regulated health professional, are you also a solo practitioner?

Solo Practitioner?	Responses	Percent
Yes	442	36.0%
No	786	64.0%

Prior perception of clinic regulation

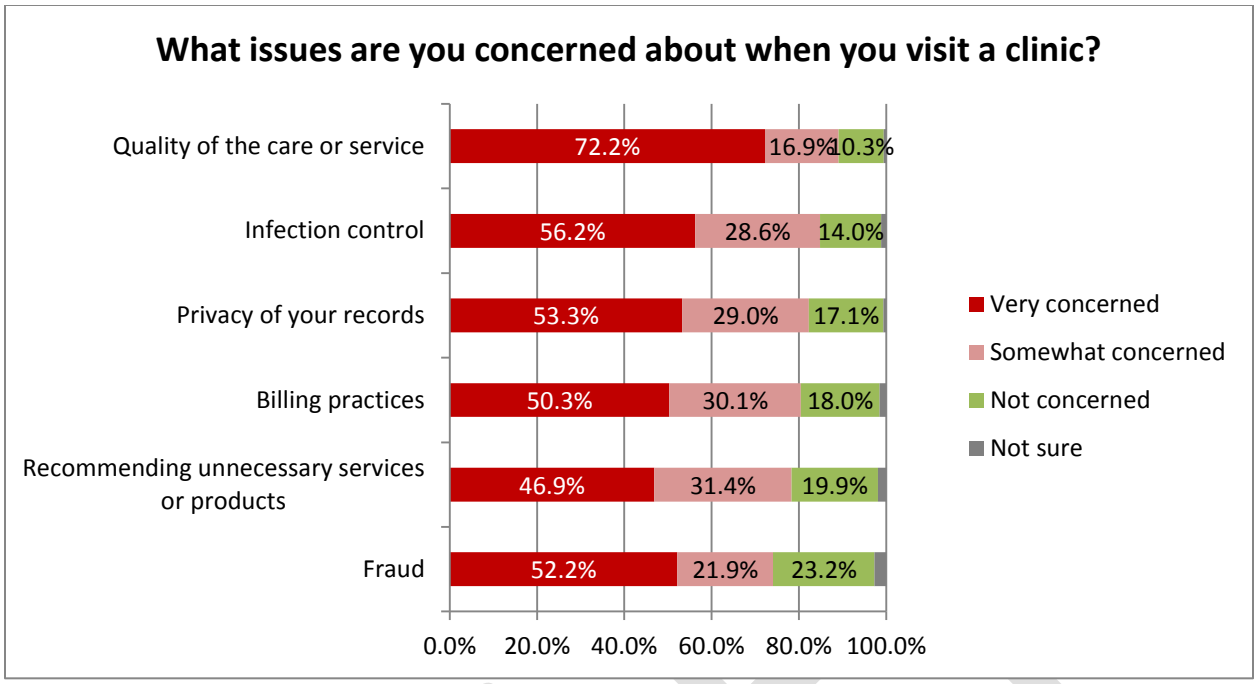
Survey question: Prior to learning about clinic regulation or visiting the consultation website, did you believe that Ontario's health care clinics were regulated?

We asked survey respondents about their perception of clinic regulation in Ontario prior to learning about the project and reading the website. 42% of respondents believed that some clinics are currently regulated while some are not; 38% of respondents believed that no clinics were regulated; and 20% believed that all clinics were regulated. The responses to this question suggest that more than half of respondents (58%) did not have accurate knowledge about the current state of clinic oversight prior to learning about the project.

Concerns when visiting a clinic

Survey question: What issues are you concerned about when you visit a clinic?

We asked respondents about their level of concern regarding various issues that could arise when they visit a clinic. The majority of respondents are somewhat or very concerned about all of the issues we asked about, suggesting that they are all important to people who go to clinics. The area that most respondents expressed concern about is quality of care (89% somewhat or very concerned). The area that the fewest respondents expressed concern about was fraud (74% somewhat or very concerned).



Would patients feel reassured if there was oversight of clinics?

Survey question: As a patient or a family member of a patient, if there was oversight of clinics in the areas of patient safety, quality care, and business practices, would you feel reassured when you visit a clinic?

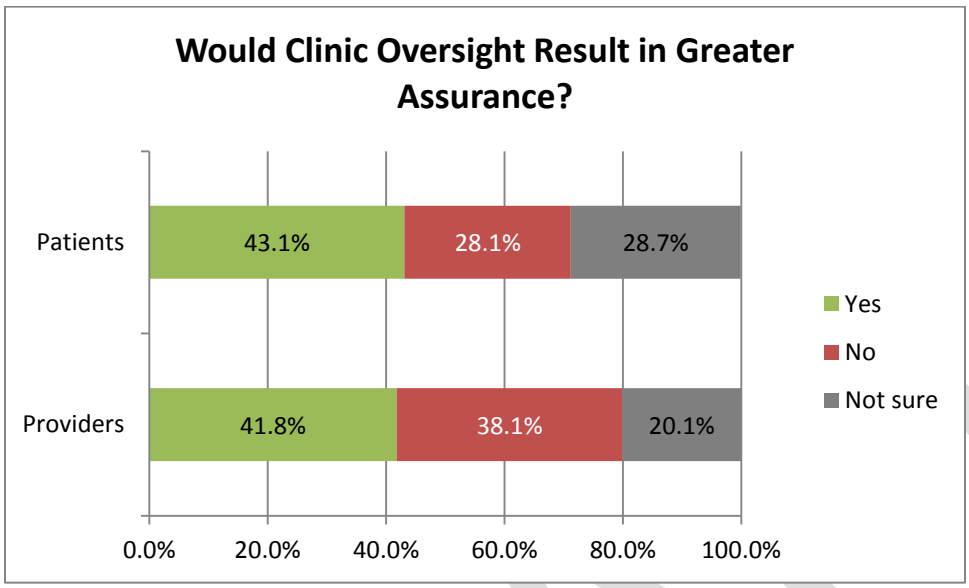
We asked respondents, from the perspective as patients, if they would feel reassured when they visit a clinic if there was oversight in the areas of safety, quality care, and business practices. More respondents said they would feel reassured compared to those who said they would not (43% compared to 28%), and the rest said they are not sure (29%).

Would providers feel reassured if there was oversight of clinics?

Survey question: As a health care provider, if there was oversight of clinics in the areas of patient safety, quality care, and business practices, would you feel more comfortable working for a clinic?

For those respondents who are health care providers, we asked them if they would feel more comfortable working for a clinic if there was oversight in the areas of safety, quality care, and business practices. Slightly more respondents said they would feel more comfortable compared to those who said they would not (42% compared to 38%), and the rest said they are not sure (20%).

Looking at responses to those two questions together, it would suggest that respondents believe that clinic oversight is more likely to result in greater assurance for patients who visit clinics than it would for health care providers who work in clinics.



Access to information and patient decision-making

Survey question: Do you believe that having access to inspection reports of health care clinics would help patients make decisions about where to go for their care?

We asked respondents whether they believe having access to inspection reports of health care clinics would help patients make decisions about where to go for their care. Slightly more respondents believe that it would help compared to those who believe it would not (39% compared to 35%), and the rest said they are not sure (26%).

Which settings need oversight?

Survey question: An important part about deciding whether clinic oversight is a good idea is determining which health care settings should be subject to oversight. Do you think patients would be better protected if the following health care settings were subject to oversight and inspections?

In a question related to the definition of "clinic" in a potential clinic regulation model, we listed several types of settings that could be captured in a potential model, and asked respondents

whether they believe those settings should be subject to oversight and inspections by a clinic regulator. The responses reveal that respondents see the highest need for oversight in settings where no regulated health care professional is involved in the delivery of care. The majority of respondents feel that regulated health professionals working alone would not need additional oversight.

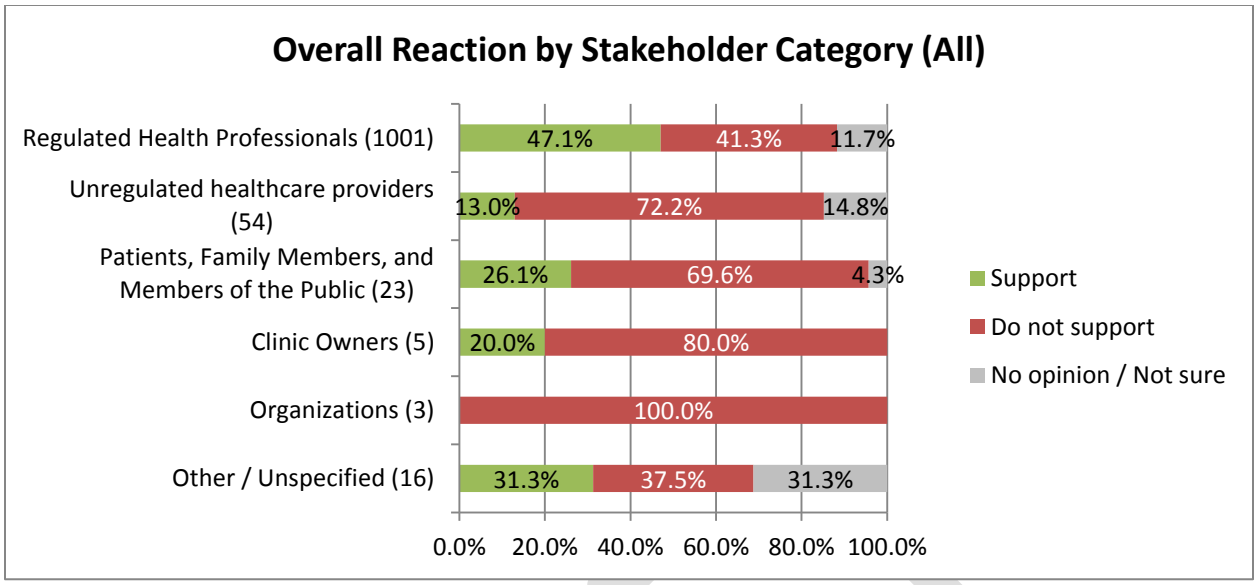
	Yes, it needs oversight	**No, it doesn't need oversight**	**Not sure**
A health care professional working alone, who is regulated by a health regulator.	27.65%	61.15%	11.20%
Multiple health care professionals, from the same or different professions, working in the same clinic.	38.23%	49.69%	12.07%
Places where unregulated assistants provide care under the supervision of one or more regulated health professionals.	55.36%	34.44%	10.20%
Where health care professionals make medical or health devices or products.	54.27%	30.87%	14.86%
Where no regulated health care professionals work, but health care services are delivered.	76.25%	14.34%	9.41%

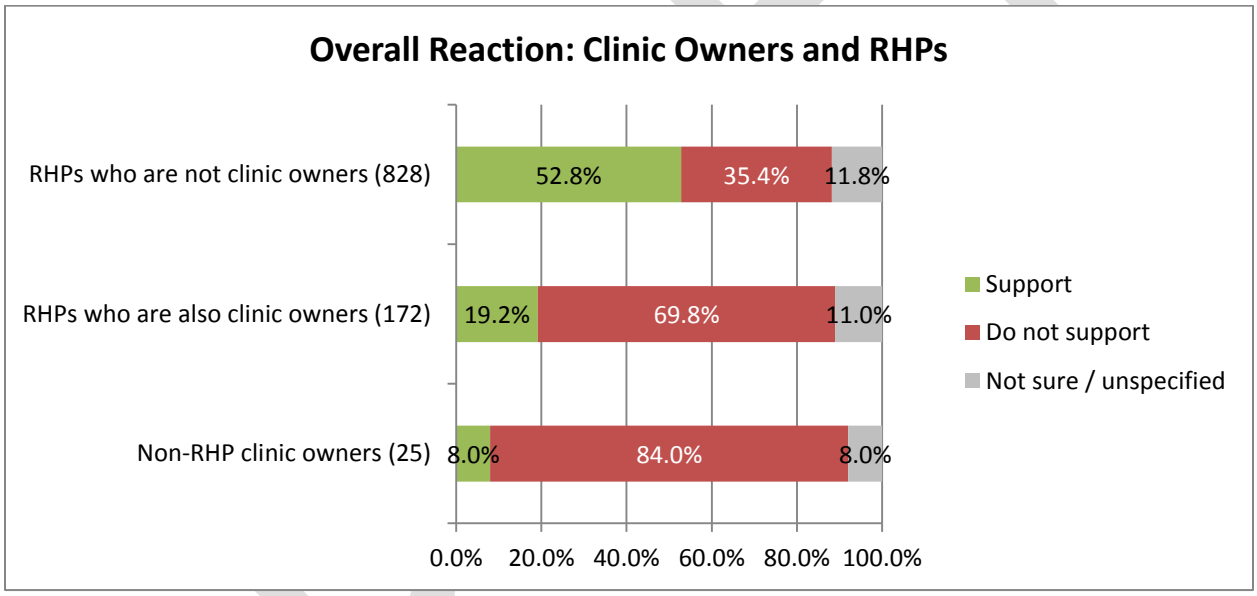
Overall reaction to the clinic regulation concept

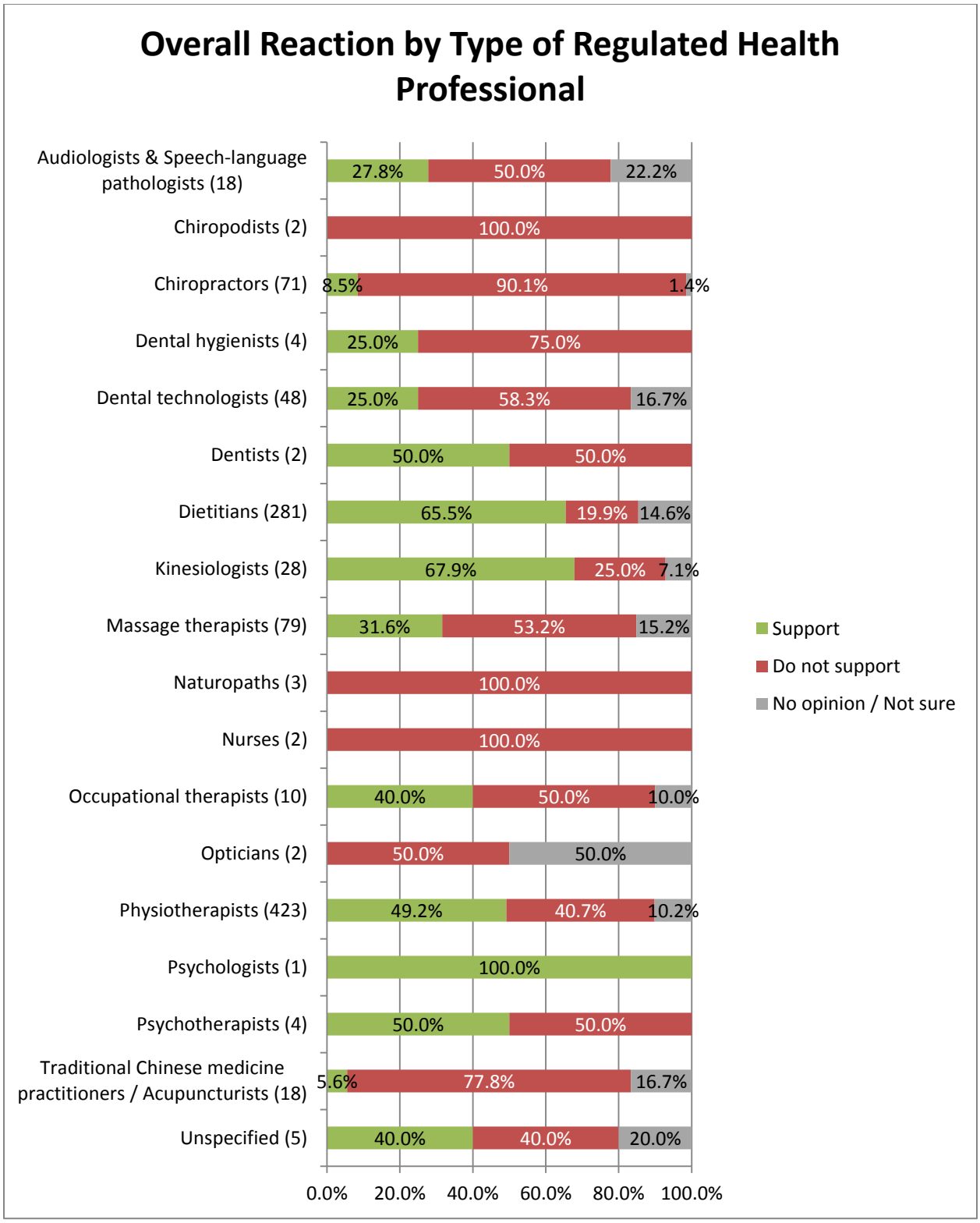
Survey question: Overall, do you support the oversight of health care clinics in Ontario under the proposed model, or a model similar to it?

The final question in the survey asked respondents whether overall, they would support some kind of clinic oversight model. The responses are fairly evenly split, with around 44.5% of respondents who said they support clinic oversight, and around 43.5% of respondents who said they do not support it. The rest are not sure or have no opinion (12%).

When comparing responses among different stakeholder groups, regulated health professionals expressed the highest level of support for the concept of clinic oversight, while clinic owners who are not regulated health professionals expressed the lowest level of support for the concept.


Overall Reaction by Stakeholder Category (All)
Regulated Health Professionals (1001)
47.1%
41.3%
11.7%
Unregulated healthcare providers (54)
13.0%
72.2%
14.8%
Patients, Family Members, and Members of the Public (23)
26.1%
69.6%
4.3%
Clinic Owners (5)
20.0%
80.0%
Organizations (3)
100.0%
Other / Unspecified (16)
31.3%
37.5%
31.3%
0.0% 20.0% 40.0% 60.0% 80.0% 100.0%
Support
Do not support
No opinion / Not sure


Overall Reaction: Clinic Owners and RHPs
RHPs who are not clinic owners (828)
52.8%
35.4%
11.8%
RHPs who are also clinic owners (172)
19.2%
69.8%
11.0%
Non-RHP clinic owners (25)
8.0%
84.0%
8.0%
0.0% 20.0% 40.0% 60.0% 80.0% 100.0%
Support
Do not support
Not sure / unspecified


Overall Reaction by Type of Regulated Health Professional
Audiologists & Speech-language pathologists (18)
27.8%
50.0%
22.2%
Chiropodists (2)
100.0%
Chiropractors (71)
8.5%
90.1%
1.4%
Dental hygienists (4)
25.0%
75.0%
Dental technologists (48)
25.0%
58.3%
16.7%
Dentists (2)
50.0%
50.0%
Dietitians (281)
65.5%
19.9%
14.6%
Kinesiologists (28)
67.9%
25.0%
7.1%
Massage therapists (79)
31.6%
53.2%
15.2%
Naturopaths (3)
100.0%
Nurses (2)
100.0%
Occupational therapists (10)
40.0%
50.0%
10.0%
Opticians (2)
50.0%
50.0%
Physiotherapists (423)
49.2%
40.7%
10.2%
Psychologists (1)
100.0%
Psychotherapists (4)
50.0%
50.0%
Traditional Chinese medicine practitioners / Acupuncturists (18)
5.6%
77.8%
16.7%
Unspecified (5)
40.0%
40.0%
20.0%
0.0%
20.0%
40.0%
60.0%
80.0%
100.0%
Support
Do not support
No opinion / Not sure

Ontario College of Pharmacists
Putting patients first since 1871

Memo

Date: **May 11, 2016**

To: **Executive Committee**

From: **Mark Scanlon, OCP Representative on NAPRA**

Re: **NAPRA Meeting Update – April 2016**

NAPRA Board of Directors meeting was held Saturday, April 23 and Sunday, April 24, 2016 in Ottawa, Ontario.

Model Standards for Pharmacy Compounding of Non-Sterile Preparations

The NAPRA Board approved the Model Standards for Pharmacy Compounding of Non-Sterile Preparations for 120 days consultation.

Medical Assistance in Dying

The NAPRA Board approved the following recommendations:

- consider supporting NAPRA's work with national groups such as FMRAC and CCRNR for the development of high level statements for an inter-disciplinary approach to medical assistance in dying

- examine the content of the Bill C-14 with a view to develop an opinion on its implications and elements of considerations to share with the federal government Minister of Justice and Minister of Health (attached)

- support the preparation of changes that may be required to a few documents currently in place at NAPRA (complete list to be identified)

- NAPRA to undertake the development of a position on medical assistance in dying

Agreement with NABP re: Pharmacy Domain

NABP has requested that NAPRA provide application review services when they receive applications for a .pharmacy TLD from a Canadian pharmacy applicant. To this end, NABP and NAPRA have developed an Agreement, for services, which outlines the responsibilities of each party and remuneration for NAPRA to undertake this new service.

Governance Ad-Hoc Committee

Ad-hoc committee has been appointed to oversee the development of a proposal to address organizational changes.

Executive Director Search

Carole Bouchard is retiring from her position as Executive Director of NAPRA, a position she has held since 2008. A search for a new Executive Director has begun.

Marihuana for Medical Purposes

No doubt this is a complicated issue. NAPRA recognizes that there has been a recent CPhA statement which may be receiving publicity that may run counter to some of the concerns that NAPRA has around the issue.

The following previous NAPRA statements are being retained as relevant on the issue of marihuana for medical purposes, while other points are no longer being retained and supported.

- NAPRA recognizes the situation faced by the Government of Canada regarding the Courts' decision to grant patients the right to have access to marihuana for medical purposes; however, it cannot endorse its use without the substance having undergone the same review process as for any other approved drugs on the Canadian market

- NAPRA is of the view that only products that have gone through the drug approval process in Canada for safety, efficacy, and quality – should be sold by pharmacists. Those approved products have received a number such as a Drug Identification Number (DIN), a Natural Product Number (NPN),a Drug Identification Number – Homeopathic Medicine (DIN-HM) or Exemption Number)EN). Marihuana has not received any of these numbers from Health Canada.

Respectfully submitted,

Mark F. Scanlon
OCP Representative on NAPRA

NAPRA ANORP

National Association of Pharmacy Regulatory Authorities ®
Association nationale des organismes de réglementation de la pharmacie

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May 5, 2016

Mr. Anthony Housefather, M.P.
Chair, Standing Committee on Justice and Human Rights
Sixth Floor, 131 Queen Street
House of Commons
Ottawa, Ontario K1A 0A6

Via: Mr. Michael MacPherson, Clerk of the Committee
Email: JUST@parl.gc.ca

Re: Submission regarding Bill C-14, *An Act to amend the Criminal Code and to make related amendments to other Acts (medical assistance in dying)*

Dear Mr. Housefather,

The National Association of Pharmacy Regulatory Authorities (NAPRA) wishes to provide the Standing Committee on Justice and Human Rights with comments on the content of the Bill currently being studied. Although we realize that our submission arrives after the deadline specified we respectfully ask that our input on this important Bill be considered by the Committee members.

NAPRA is a not-for-profit organization representing all provincial and territorial pharmacy licensing authorities whose mandate is the protection of the public. Our membership also extends beyond traditional geographic borders to include the Canadian Forces Pharmacy Services. Our members play a key role in ensuring that optimal regulatory practices are in place for a safe practice environment for the benefit of all Canadians. Over 40,000 pharmacists are licensed by our members to practice pharmacy across the country and operate within specific regulatory practices and requirements. Furthermore, most of our members have started to regulate pharmacy technicians as a new profession.

NAPRA believes that it is essential that legislation on medical assistance in dying be in place for June 6, 2016 in order to avoid a gap when the Carter v. Canada decision takes effect. With the public interest in mind, it is important that a federal framework be in place to ensure that healthcare professionals such as pharmacists and pharmacy technicians are enabled to participate in the process, while not being prevented from exercising a "conscientious objection" to participate in line with their professional code of ethics. Overall, NAPRA supports the majority of elements of the Bill but sees a need to either further clarify or amend the following sections to eliminate confusion or inapplicability.

- It is noted that the term "substance" was used in the Bill instead of "drug" as defined in the *Food and Drugs Act*. NAPRA respectfully suggests that the word "substance" be defined in the Bill or changed to reflect the terminologies used in federal legislation to describe "drug".

.../2

- Section 241 (4) Exemption for Pharmacist - NAPRA is pleased to see a specific exemption for pharmacists, however this exemption does not seem to address all of the situations covered in the rest of the Bill. The Bill refers to the ability of a medical practitioner or nurse practitioner to "obtain" drugs and then administer or "provide" them to the patient, in addition to their ability to prescribe drugs for the patient [e.g. 241.1 (b), 241.2 (8)]. The Bill appears to allow medical or nurse practitioners to obtain the necessary drugs from the pharmacist without having to issue a prescription for a particular patient, for example via an "office use" prescription. However, the exemption for pharmacists as written does not appear to allow pharmacists to dispense drugs for the purpose of medical assistance in dying directly to a medical or nurse practitioner. As such, NAPRA suggests that the exemption for pharmacist be broadened to include this possible situation, if that is the true intent of the Bill. If the intent is to require that medical practitioners and nurse practitioners issue a patient-specific prescription, as we believe that it should, other sections of the Bill will need to be amended to clarify.

  Pharmacy technicians are now regulated in many jurisdictions of Canada and are independently responsible for certain aspects of the dispensing process. It is not clear if pharmacy technicians will be exempt from criminal liability for their role in dispensing drugs for medical assistance in dying under section 241 (3) - Exemption for person aiding practitioner. If not covered under section 241 (3), it is suggested that pharmacy technicians be added to the Exemption for pharmacist in section 241 (4).

- Section 241.1 Definitions – the definitions of pharmacist in English and French do not have the same meaning. Therefore, we suggest that the definition in English be amended to add after the word practice "as a pharmacist" and to delete the word "pharmacy".

- Section 241.2 Safeguards - (3)(h) requires that the medical practitioner or nurse practitioner immediately before providing the medical assistance in dying, give the person an opportunity to withdraw their request and ensure that the person gives express consent to receive medical assistance in dying. NAPRA believes that this requirement must be rethought to ensure that it could be operationalized in the context of self-administration by the person (definitions 241.1 medical assistance in dying (b)). In our view, this and other provisions of the Bill do not align well with the context of medical assistance in dying as expressed in part (b) of the definition.

- Section 241.2 Informing pharmacist (8)- NAPRA is glad to see that there is a provision for the medical practitioner and nurse practitioner to inform the pharmacist that the substance prescribed is intended for the purpose of medical assistance in dying. A multi-disciplinary health team approach to medical assistance in dying is important and therefore, NAPRA respectfully suggests that the pharmacist be informed not only verbally, but in writing. The Bill can be amended to add "in writing " after the word inform.

> Furthermore, NAPRA believes that inter-professional collaboration would be enhanced if the medical practitioner or nurse practitioner were required to provide the pharmacist with a copy of the patient consent form and the written opinion of the second independent practitioner. This would provide another level of safeguard to ensure that the required steps under section 241.2 have been carried out.

On a more general level, we wish to reinforce the need for the federal government to ensure that drugs that would be required for providing medical assistance in dying be available and authorized for this purpose in Canada. Furthermore, we encourage the federal government to continue to study a few other subjects such as mature minors, people who suffer only from mental illness and advance requests in the context of medical assistance in dying.

We trust that the above-mentioned comments will be helpful to the Committee work. We remain available for any questions the Committee members may have regarding our submission or any assistance that may be deemed necessary.

In closing, we wish to assure you that NAPRA members have already developed interim guidance documents for pharmacists on the topic of medical assistance in dying (previously called physician assisted death) and are continuing to work with other health care practitioner groups and governments in their respective jurisdictions in order to be ready for the implementation of medical assistance in dying.

Sincerely yours,

Carole Bouchard, B. Pharm., M.A.P.
Executive Director, NAPRA
613-569-9658 ext. 224
cbouchard@napra.ca

cc: Provincial/territorial pharmacy regulatory authorities
NAPRA President

Ontario College of Pharmacists
Putting patients first since 1871

Strategic Priorities 2015 - 2018

Progress Update – June 2016

Mission

The Ontario College of Pharmacists regulates pharmacy to ensure that the public receives quality services and care.

Vision

Lead the advancement of pharmacy to optimize health and wellness through patient-centred care.

Values

Transparency – Accountability - Excellence

Key to Impact of Strategic Initiatives: PF = Patients First, EC = Effective Communication, CQI = Continuous Quality Improvement

Strategic Priority #1: CORE PROGRAMS – FULFILLMENT OF MANDATE - Processes meet or exceed societal expectations. *(Members, Premises)*

Values – Transparency, Accountability, Excellence

Outcomes/KPI	Activity	Strategic Initiatives Focus			Last Quarter Noteworthy Accomplishments	This Quarter Accomplishments
		PF	EC	CQI		
Fair and objective assessment framework.	Refine assessment tools and activities. Premises: Current authority and others i.e. long-term care, family health teams. Members: Pharmacists - at entry, in practice, (site based and standardized). Pharm techs – as above.	High	Med	High	• Completed over 1700 member assessments since pilot began in Jan. 2015. • CQI activity in the quarter on practice site assessments - started pilot for appointment scheduling with 3 PAs, "ideal assessment" framework further refined, feedback from DMs regarding Prior Notice Letter (PNL) being gathered and PNL enhancements considered. • Development of assessment framework for RPhT's continuing competence in final stages; reviewed by focus group. • Initiated project to develop and validate assessment tool for RPhTs at entry to practice with consideration to CC framework. • Finalized policies and processes to support large-scale pilot of Practice Assessment of Competence at Entry (PACE). • Communicated PACE pilot to College stakeholders as a "Key Initiative". • Completed initial recruitment and screening of College-appointed PACE Assessors. • Project plan and timelines for QA re-design determined; Re-design Advisory Group established; Logic model developed for quality assurance activities. • Revised and updated hospital assessment tool and process. • Developed draft assessment schedule based on risk matrix.	• Practice assessment tool for both members and premises in community refined and standardized to increase reliability. • Provincial and national stakeholders Working Groups established and oriented to facilitate validation of Pharmacy Technician Standardized Assessment Tool for entry-to-practice. • Model for peer/practice QA assessment developed for piloting. • Pilot of revised hospital assessment tool completed.

Key to Impact of Strategic Initiatives: PF = Patients First, EC = Effective Communication, CQI = Continuous Quality Improvement

Strategic Priority #1: CORE PROGRAMS – FULFILLMENT OF MANDATE - Processes meet or exceed societal expectations. *(Members, Premises)*						
Values – Transparency, Accountability, Excellence						
Outcomes/KPI	**Activity**	**Strategic Initiatives Focus**			**Last Quarter Noteworthy Accomplishments**	**This Quarter Accomplishments**
		PF	**EC**	**CQI**		
A decision-making framework that is consistently applied across the organization.	Utilize risk tools for use at adjudicative committees. Develop informed and objective decision-makers – training/legal support. Define and mine data to support decisions. Develop or acquire analytic and technical expertise.	Low	Low	High	• In the hearings area, performance benchmarks developed to assess individual prosecutor performance against benchmarks. • Conducted final phase of 'usability testing' (friends & family) prior to launch of new Public Register. • Updated records management system from Meridio to HPRM to improve access and management of information. • IT Security Threat Risk Assessment completed – awaiting final report. • Draft change management framework developed; concepts being put through PDSA tests of change process. • Relevance to Suitability to Practice process implemented within Registration to assist with decisions about applicants with a history of character or conduct issues. • Developed framework for addressing shortage of public participants on panels. • Project plan developed for e-learning modules to support member understanding and implementation of Code of Ethics into everyday practice; 6 modules and 3 video case scenarios in development. • Registration Advisors trained in communication styles and coaching to support their evolving role in engaging and coaching applicants and members.	• Quarterly statistical reports on statutory timeline targets for complaint processing finalized. • Consultation with ICRC panels to obtain feedback and recommendations for changes to the Risk Assessment Tool (RAT) conducted and reported for consideration by the WG. • Analyzed and refined 2016 HPDB data submission to better reflect pharmacists' profiles prior to submission • 2015 Annual Report published to the College website and distributed to the Ministry of Health and Long-Term Care. • IT Security Threat Risk Assessment (STRA) report analyzed. Recommendations rated High Priority addressed and action documented. Successfully contained and recovered from a "Ransom" attack.
A defined Professional Development Framework that incorporates coaching, remediation and monitoring.	Raise awareness of Standards of Practice and Code of Ethics. Develop and refine tools and resources that apply to all members. Develop specific tools and resources that apply to identified applicants/ members/premises. Develop model for coaching and remediation/monitoring.	Med	High	Med		• PACE remediation resources and Learning Action Plan templates completed. • Logic model created to guide development of new remediation approach.

Key to Impact of Strategic Initiatives: PF = Patients First, EC = Effective Communication, CQI = Continuous Quality Improvement

Strategic Priority #2: OPTIMIZE PRACTICE WITHIN SCOPE – Patients receive quality health care services from pharmacy professionals.

Values – Transparency, Accountability, Excellence

Outcomes/KPI	Activity	Strategic Initiatives Focus			Last Quarter Noteworthy Accomplishments	This Quarter Accomplishments
		PF	EC	CQI		
Pharmacists consistently practicing to established expectations including Standards of Practice and Code of Ethics.	Develop and communicate Code of Ethics. Provide guidance and education on expectations of Standards of Practice and Code of Ethics. Provide guidance and education on specialty standards e.g. sterile compounding. Use OCP assessments and professional development to remediate/coach.	Med	High	Med	• Completed a series of articles for *Pharmacy Connection* relating to key concepts in the new Code of Ethics *(see "Resources" column).* • Held additional Decision Making and Introduction to Practice Assessment workshops. • Launched additional practice resources including "Practice Tips" on Twitter and "Close-Up on Complaints" in *Pharmacy Connection* to share learnings and best practices with members. • Published "Moving the Mountain" video on College website and YouTube channel, with focused excerpts designed to support member understanding of College's current strategic direction. • Completed Practice Assessment guidance documents and posted on website and link included in Assessment notice letter to encourage DMs and members to prepare for assessment *(see "Resources" column).* • Working Group established to consider College implementation of NAPRA sterile compounding standards. NAPRA model standards for sterile compounding reviewed and mapped to USP 800. • Received positive feedback from DMs and members regarding learnings from practice assessments reinforcing value of approach and investment. • Developed a framework which will increase access to safe and effective vaccinations.	• 700 pharmacist assessments conducted identifying coaching opportunities to be used in QA assessor coaching pilot. • Recruited QA coaches/assessors for pilot peer and practice assessment. • Consultation on implementation of NAPRA sterile compounding standards commenced. Prompting questions posted on OCP website. • Seven additional Decisions, Decisions workshops, reaching approximately 350 pharmacists, undertaken in the quarter. • Interim Guidance Document relating to Medical Assistance in Dying developed and posted to OCP website. • Guidance document for hospital assessments developed and posted to the website. • Clinical Working Group on Compounding developed framework for consultation on sterile compounding standards. • Expectations for research outcomes clarified for the U of T partnership to enhance the scope of practice.
Pharmacy Technicians consistently practising to established expectations including Standards of Practice and Code of Ethics.	Develop and communicate Code of Ethics. Provide guidance and education on expectations of Standards of Practice and Code of Ethics. Provide guidance and education on specialty standards e.g. sterile compounding. Use OCP assessments and professional development to remediate/coach.	Med	High	Med	• None.	

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Strategic Priority #2: OPTIMIZE PRACTICE WITHIN SCOPE – Patients receive quality health care services from pharmacy professionals.

Values – Transparency, Accountability, Excellence

Outcomes/KPI	Activity	Strategic Initiatives Focus			Last Quarter Noteworthy Accomplishments	This Quarter Accomplishments
		PF	EC	CQI		
Pharmacies meeting Standards of Operation and consistently providing an environment to support pharmacy professionals practising to established expectations including the Standards of Practice and Code of Ethics.	Educate and reinforce to the "controllers of the pharmacies" their obligations. Develop and communicate Standards of Operation.	Med	Med	Med	• Principle-based draft framework created for the development of Standards of Operations resource document which will pull together all current expectations of pharmacy operations into a central resource. • Approximately 500 pharmacy operational assessments completed Dec-Feb. • Hospital baseline assessments completed. Reports prepared for Ministry to support cabinet submission of regulations. Language of proposed regulations confirmed.	• Established a revised schedule of facility inspections which results in increased frequency - once every 1.5 -2 years for high risk pharmacies; and once every 2.5 - 3 years for low risk pharmacies.
The pharmacy profession integrates technology and innovative approaches to improve the quality and safety of patient care.	Raise awareness of PPMS (pharmacy practice management systems) with members, stakeholders, government. Participate and influence e-Health initiatives. OCP assessments and adjudications encourage and support innovation in practice.	Low	High	Med		• eHealth - Participation on Executive Steering Committee for the Comprehensive Drug Profile Strategy whose focus is to design and build capacity to accommodate a Patient Drug Profile for Ontarians aligned with a goal of providing all health care providers with timely and integrated access to patient medication information.

Key to Impact of Strategic Initiatives: PF = Patients First, EC = Effective Communication, CQI = Continuous Quality Improvement

Strategic Priority #3: INTER & INTRA PROFESSIONAL COLLABORATION - High performing health professional teams in place to achieve coordinated patient-centered care.						
Values – Transparency, Accountability, Excellence						
Outcomes/KPI	**Activity**	**Strategic Initiatives Focus**			**Last Quarter Noteworthy Accomplishments**	**This Quarter Accomplishments**
		PF	**EC**	**CQI**		
Pharmacy Team: Pharmacy services are organized to empower pharmacists and pharmacy technicians to practice to their full scope. Pharmacists and pharmacy technicians maximize their respective roles.	Gather data to determine the degree to which pharmacies are meeting expectations and understand the barriers. Educate members through videos, sharing best practices. OCP to encourage and support experimental models that integrate technicians in practice.	Med	High	High	• Provided data to OPEN on Mapping Health Geography and Pharmacy Access project as a means of contributing to meaningful data collection.	
Health Care Team: Pharmacists and pharmacy technicians exercise their responsibility within the patient's professional team.	Develop and provide guidance to members on how they can educate and collaborate with other health care professions. Develop guidance on expectations at transitions of care. Gather information from patients on their understanding of the pharmacy services role in health care team.	High	High	Med	• In cooperation with the College of Physicians and Surgeons of Ontario, preliminary Guidance to Pharmacists and Pharmacy Technicians relating to Physician-Assisted Death were developed and communicated to members to complement Guidelines provided to physicians. • Staff participation on a Ministry Working Group was valuable in influencing the regulation drafting to take into account practical considerations for managing the Patch-4-Patch program with prescribers in the community and hospital.	• Published 2nd Transition to Care article in Spring *Pharmacy Connection*. • MAiD - Clinical tools and updated guidelines developed in alignment with colleges of physicians and nurses in order for pharmacists and pharmacy technicians to be prepared for their role in the provision of Medical Assistance in Dying.

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COUNCIL BRIEFING NOTE
MEETING DATE: JUNE 2016

FOR DECISION	X	FOR INFORMATION

INITIATED BY: Finance and Audit Committee

TOPIC: OCP Remuneration and Expenses for professional members of Council and committees (non government appointees)

ISSUE: A discussion on the benefits and drawbacks of the current remuneration model for members of Council and College committees (other than those appointed by the Lieutenant Governor in Council).

BACKGROUND: During the course of the financial audit which led to the approval of the audited financial statements for the year ended December 31, 2015, members of the Finance and Audit Committee asked the auditors to provide an opinion on the appropriateness of the current reimbursement model for non-public members from a Revenue Canada perspective. The current model assumes that time is volunteered and Council/committee members are paid an allowance toward expenses that would reasonably be incurred to attend College meetings. The dollar value of the allowance is fixed, based on whether the Council/committee participant resides within or outside the community where the meeting takes place. The remuneration model is outlined in the College by-law and is further described in a policy (see attachments). The Auditor opined that "in order to keep paperwork to a reasonable level, it is commonly accepted practice to provide a flat rate payment in cases where it is clear that some level of the reimbursable expenses would clearly have been incurred". "…it can be expected to be acceptable to the Canada Revenue Agency as a non-taxable reimbursement of expenses. "

While the auditor has confirmed that the current remuneration model is acceptable from a CRA perspective, the Committee discussed the suitability of the model given that it does not recognize or compensate members for the time they dedicate to serving as a Council and/or committee member. Accordingly, the Committee recommended that the matter be put to Council for discussion to consider if the College should

a) retain the current 'allowance towards expenses with volunteered time' model or;
b) move to an 'honorarium that compensates for time in addition to reimbursing actual expenses'

Once discussed and decided upon, the Committee recommends that the model be reviewed regularly to coincide with the strategic planning sessions.

ANALYSIS:

Benefits/Drawbacks of the existing 'allowance toward expenses that would reasonably be incurred' model:

Benefits	Drawbacks
• Simple, less paperwork/approvals; • Participants free to choose their accommodations; • No T4/T4As issued • Full expense allowance received regardless of duration of the meeting • Less expensive for the College • Volunteered time consistent with principle of public service	• Participants not compensated for: ▪ attendance by teleconference ▪ prep time/pre-reading ▪ travel time ▪ decision writing if undertaken outside OCP offices • Out of line with other regulators/LGCs • Less equitable for members - $165 vs. $300 depending on where you live

Benefits/Drawbacks of an 'honorarium that compensates for time in addition to reimbursing actual expenses' model:

Benefits	Drawbacks
• Participants can be compensated for: ▪ attendance by teleconference ▪ prep time/pre-reading ▪ travel time ▪ decision writing conducted at home • In line with all other regulators • More equitable in that all participants regardless of where you live receive same amount	• Can be rule heavy/need to justify time and expenses/provide receipts – see Public Member guideline • T4/T4As issued • More expensive for the College due to: ▪ higher administrative effort ▪ EHT and CPP costs ▪ actual meeting costs dependent on rate

OPTIONS:

Discuss and decide if the College should consider

a) retaining the current 'allowance towards expenses with volunteered time model' or;
b) moving to a 'taxable honorarium which compensates for time plus expenses '.

Once a position is established or confirmed by Council, the Finance and Audit Committee would then consider the appropriate values for compensation and/or remuneration under the respective model and bring the issue back to Council with an estimate of the financial impact.

ARTICLE 6
REMUNERATION AND EXPENSES

6.1 Remuneration and Expenses.

6.1.1 When they are on official College business, members of Council and Committees, working groups and task forces, other than persons appointed by the Lieutenant Governor in Council, shall be paid the following:

(a) a travel allowance, which shall consist of a rate for distance traveled of 45 cents per kilometre; or air fare, bus or rail fare, plus transportation to and from air, bus or train terminals;

(b) an expense allowance of $300.00 for each day when out of the community in which the Council member resides;

(c) an expense allowance of $210.00 in lieu of the daily allowance described in subparagraph 6.1.1(b), whenever arrival is necessary the night prior to a scheduled meeting;

(d) a daily expense allowance of $165.00 when on College business in the community in which the Council member resides, which amounts include travel allowance.

6.1.2 If the Council appoints a Member, other than a Council or Committee member, to represent the College at a meeting or conference, the Member shall be reimbursed for expenses incurred at the rate set out in subparagraph 6.1.1, plus registration fees, if applicable. The Member shall not accept reimbursement for expenses from any other body.

6.1.3 An amount in excess of the amounts authorized under subparagraph 6.1.1 may be paid to a Council member or Committee member provided the amount was specifically included in the College budget for the year in which the expenses are incurred, or with the express, prior authorization of the Executive Committee.

Expense Reimbursement for Out of Community Council Members

June 2014

This policy describes the principles and framework for Out of Community Council Member's reimbursement. It is an integral part of "Remuneration and Expense" under Article 6 of the by-law and provides additional information regarding travel procedures, expenses, rates, etc. The current model for reimbursement provides for an allowance towards expenses that would reasonably be incurred i.e. accommodation, meals, and other incidental expenses. The allowance is not an income replacement and no T4A will be issued.

Policy Overview

The rules and limitations of Council/Committee expense eligibilities are established and amended by Council from time to time and incorporated into Council's Governance Manual. This policy is aimed at providing accounting staff with the guidelines for processing expense claims submitted by Council and Committee Members.

The College recognizes that although member's time is volunteered and is therefore unpaid, members choosing to serve on Council or committees should not be out of pocket for costs incurred.

Out of the community is defined as a member residing more than 40 kilometres from the meeting site (the assumption is this distance will generally require overnight accommodation).

This applies to all members of the Council and Council committees who are considered as Out of Community Council Members when they are on official College business.

Responsibilities

If traveling on OCP business Council/Committee members (CCM) are responsible for following the expense guidelines and for keeping all original receipts and submitting expense claims within two weeks of the date they were incurred.

The Executive Team and Program Managers are responsible for making sure CCMs comply with this policy and confirming member participation and expenses.

Where an expense is not clearly denoted in this policy and uncertainty exists about the ability to reimburse for the item, consultation in advance with the Accounting Services Coordinator is recommended.

Accounting ensures that travel expenses are properly authorized in accordance with this policy and any other related College policies.

Guidelines for Expense Reimbursement

Eligible expenses for attending College business outside of the community where the CCM resides:

Expense allowance

- Daily expense allowance as provided for under Article VI of the College by-law.
- If attending multiple committee meetings in a day the CCM may only claim one expense allowance.
- Proof of stay or travel is required when a CCM claims an expense allowance in lieu of the daily allowance whenever arrival is necessary the night prior to the scheduled meeting.

Travel Expenses

- Economy class airfares, train, or bus tickets to the destination:
  - Seat selection fees, if a CCM needs a particular seat to accommodate physical constraints
  - Baggage fees (except for excess baggage)
  - Change fees, if the change is authorized/requested by OCP
  - Rental car or mileage reimbursement for use of personal vehicle, if the estimated costs are estimated to be lower than airfare, train, or bus
  - Original invoiced or receipts must be submitted for transportation by train, bus, or plane or car rental if allowed. Travel receipts must include departure and arrival dates/times and must indicate traveller's name.

Public Transportation to and from airport, bus or rail stations

- CCMs will be reimbursed for the cost of taxi or airport buses, other transit fares provided receipts are included with the reimbursement form. Car rental expenses may be reimbursed if the cost is less than the above.

Unchangeable travel arrangements

- CCMs will be reimbursed for your cost of non-refundable tickets when a meeting or activity is cancelled and they have made reasonable effort to get a refund or future credit.

Parking Expenses

- CCM may claim for parking expenses when using a personal vehicle/rental car to a maximum of $30 per day. Receipts must be provided.

Use of personal car

- Use of personal cars will be reimbursed at the current
- kilometer rate referenced in the by-law (currently $.45/kilometer. The Mapquest website is the reference to be used in calculating distance travelled.
- (http://www.mapquest.com/directions). OCP assumes no responsibility for any personal cars used for travelling on College business. When travelling by personal vehicle with other Council or Committee members, only one mileage reimbursement
- is permitted. (Kilometerage rates are calculated to include gas, repairs and insurance, as well as wear and tear on the vehicle.)

Ministry of Health and Long-Term Care

Remuneration Framework

for Public Appointees to the Health Professions Regulatory Bodies (Colleges) established under the Regulated Health Professions Act, 1991

Table of Contents

Introduction

Application and Scope

This Remuneration Framework ("Framework") is intended to apply to individuals who are appointed by Order-In-Council (OIC) to the Councils of the health professions regulatory bodies (Colleges) established under the *Regulated Health Professions Act, 1991* (RHPA) and its 26 associated profession-specific Acts. See **Appendix 1** for a list of the Regulatory Bodies Covered by this Framework.

This Framework is consistent with the Management Board of Cabinet's *Agencies & Appointments Directive* (the Directive). In the event of a conflict or inconsistency between this document and the Directive, the Directive prevails.

Purpose

This Framework is intended for use by individual appointees, the Colleges and the Ministry to clarify the parameters for payment of per diem honoraria for appointees performing the business of the Council of the College.

Effective Date

This Framework is effective for work conducted as of **April 1, 2016** and replaces all previous Guidelines issued to appointees or Colleges, and is subject to change pursuant to Ministry of Health and Long-Term Care and/or Management Board of Cabinet policies and directives. As necessary, supplementary policy statements, guidelines or amendments may be issued.

Conditions of Appointment

Acceptance of the appointment indicates acceptance of the conditions of appointment. Conditions of appointment, including those relating to financial compensation, if any, are subject to change pursuant to Government and/or Ministry of Health and Long-Term Care policies.

All appointees to the Councils of the RHPA Colleges are part-time. Remuneration paid to part-time appointees are made on a per diem basis. The Minister of Health and Long-Term Care is responsible for paying honoraria and expenses for public appointees, pursuant to the applicable statutory provisions, the policies established by the Government and the Ministry, including those policies set out in this Framework.

Ethical Framework

Government appointees are required to fulfill the duties of their appointment in a professional, ethical and competent manner and avoid any real or perceived conflict of interest. In particular, and without limiting the generality of the foregoing obligations, a government appointee shall:

1. not use or attempt to use his or her appointment to benefit himself or herself or any person or entity;
2. not participate in or attempt to influence decision making as an appointee if he or she could benefit from the decision;
3. not accept a gift that could influence, or that could be seen to influence, the appointee in carrying out the duties of the appointment;
4. not use or disclose any confidential information, either during or after the appointment, obtained as a result of his or her appointment for any purpose unrelated to the duties of the appointment, except if required to do so by law or authorized to do so by the responsible Minister;
5. not use government premises, equipment or supplies for purposes unrelated to his or her appointment; and
6. comply with such additional requirements, if any, established by the entity to which the person is appointed, and/or the responsible Minister.

For the purposes of the above, "confidential information" means information that is not available to the public.

Conflict of Interest

Appointees are expected and required to avoid activities which may place them in conflict of interest with their appointment. Although the Minister attempts to ensure that appointees are free of potential conflicts, conflict of interest is primarily a matter of personal responsibility and integrity.

Principles[1]

1. A member of an agency, board or commission should not use information obtained as a result of his or her appointment for personal benefit.
2. A conflict-of-interest situation should be declared at the earliest opportunity.
3. No member should divulge confidential information obtained as a result of his or her appointment or election, unless legally required to do so.

Personal, Material or Financial Benefit

"Conflict of interest normally relates to a direct pecuniary interest of the appointee or elected member either personally or through the member's family.

Direct pecuniary interest should be interpreted as an individual interest rather than one that is common to a class of persons. However, there is conflict of interest if the member or his or her

[1] Management Board of Cabinet. Establishment and Administration of Agencies: A Manager's Guide (pages 6-1-23).

immediate family could benefit personally from a decision while a larger group of people could not.

Immediate family should be interpreted to include the spouse, parents or children of the appointed or elected member."[2]

More specifically, an appointee shall not seek nor accept a fee, gift or personal benefit, except compensation authorized by Order-In-Council that is connected, directly or indirectly, with the performance of his or her usual duties.

Declaring Conflict

Where there is a potential conflict of interest with the business of Council or a committee, appointees are **required** to inform the Chair or President of the Council and/or the Registrar/Executive Director at the earliest opportunity and, where a real or perceived conflict exists, to take all reasonable steps to avoid the conflict.

Appointees should also review and comply with any conflict of interest policies established by the College for Council members. The Ministry recommends that, upon declaration of a conflict, the appointee refrain from further participation in discussions relating to the matter.

Where declaration of conflict by an appointee affects the quorum required for the conduct of business, the matter should be deferred to a subsequent meeting when a sufficient number of members will be present. If, because of the specific composition of the committee, delay will not alleviate the lack of quorum and there is no option to reassign the duty to another public appointee, the President/Chairperson or Registrar/Executive Director should immediately contact the Ministry (Manager, Public Appointments Unit) for assistance.

Where there is a potential conflict of interest with the ongoing daily business of Council, the appointee is **required** to inform the Ministry of Health and Long-Term Care through the Manager, Public Appointments Unit and/or the Minister's Office. Members may be asked by the Minister to resign.

Consequences of Non-Compliance

If an appointee fails to declare a conflict of interest, or continues to participate while in conflict of interest, the Minister, with the approval of the Lieutenant-Governor, may revoke his or her appointment and appoint a new member to the agency in question, unless the failure to declare and/or avert the conflict of interest is a result of a *bona fide* error in judgement.

If the contravention has resulted in a personal gain, or in a financial loss to the agency, the government may disqualify the person from further government appointments and require restitution of the funds in question.

[2] Ibid.

Ministry Contacts

Appointees to regulatory bodies are reimbursed directly by the Ministry of Health and Long-Term Care. Completed and signed per diem and expenses claims, along with any required receipts, should be forwarded to the designated staff person within the College to secure verification of attendance and for submission to the **Health Boards Secretariat**.

Appointees are required to use the most current version of the electronic claim form, and, where payments are to be made, receive payment by electronic funds transfer.

Any questions regarding remuneration payment should be directed to the Health Boards Secretariat.

Contact:

Manager, Health Boards Secretariat
151 Bloor Street West, 9th floor
Toronto, Ontario M5S 1S4

hbs@ontario.ca
Tel: (416) 327-8512
Fax: (416) 327-8524

Remuneration Framework

General

The basis of all appointments to Government of Ontario agencies, boards and commissions (ABCs) is public service. Therefore, any remuneration that may be paid is not expected to be competitive with the marketplace or the appointee's usual occupational compensation. There is no requirement that appointees be paid. In fact, in many cases appointees do not receive any payment for their services beyond reimbursement of out-of-pocket expenses. The level of remuneration payable, if any, is dependent upon the ABC to which the individual is appointed; the personal qualifications of the individual appointee are not usually a factor[3].

The honorarium is a nominal fee paid to partially off-set the cost of a public service contribution rather than to pay the appointee for services rendered or compensate her/him for lost income or the opportunity to earn income.

The Ministry of Health and Long-Term Care acknowledges that there is usually a disparity in the amount of remuneration available to occupational members of Council compared to that available to public appointees. This disparity in no way implies that the participation and contribution of public appointees are any less valuable than that of the occupational members or that public members have less authority on Council.

Basis of Remuneration

Where applicable, payment may be made to individuals for carrying out the business of the ABC to which they are appointed, that is, performing functions and tasks inherent in, or assigned to her/him as a result of, the appointment and are appropriate to his or her position as a Council member (i.e., a governor or director of the College) or an adjudicator.

In general, such functions or tasks are those which are performed within the context of formal meetings of the Council or committees of Council, or a statutory hearing or review conducted by an adjudicative committee. The proceedings or outcome(s) of such meetings or hearings are usually recorded (e.g., in minutes) and/or published (e.g., a Discipline Committee decision). Where applicable, preparation time and the writing of decisions are included. However, depending on the mandate of the ABC, such "business" may also include attending or presenting to conferences or public forums which are directly related to the business of the ABC and the individual's assigned functions or tasks.

Appointees also have a responsibility to become familiar with and maintain their knowledge regarding the business of their ABC. The Ministry of Health and Long-Term Care encourages and supports continuing education for public appointees.

[3] The exceptions are medical and legal personnel where the enabling statutes require that they be used in their professional capacity.

Exceptional Circumstances

Appointees to Ontario's regulated Health Colleges must be recompensed in a consistent manner. As such, exceptional circumstances requiring diversion from the parameters of this Framework are expected to be infrequent. Deviation from the parameters of this Framework cannot be approved on a sustained/long-term basis.

Any request for remuneration which exceeds the parameters of this Framework must be accompanied with a written explanation of the exceptional circumstances involved from the Chair of the Committee to the Ministry (Manager, Health Boards Secretariat).

Unauthorized Payments

Public appointees to the Councils of the health professions regulatory bodies may not accept unauthorized remuneration from the College or from any health profession body in respect of her or his appointment.

Colleges may not supplement payments to public appointees to the Council of the College by making unauthorized payments or "topping-up" payments for honoraria or out-of-pocket expenses.

Eligible Payments

Eligible payments to OIC appointees to RHPA regulatory bodies are established by OIC # *451/94,* dated March 9, 1994 (see **Appendix 2**) and this Framework. They include a per diem honorarium and reimbursement of necessary and reasonable expenses actually incurred in conducting the *business* of the College to which the individual is appointed, such as travel, accommodation and meals.

Government Taxes

Honoraria paid to appointees is taxable under the *Income Tax Act*. Thus, in order to receive remuneration (honoraria and/or expenses); appointees are required to provide their Social Insurance Number to the Ministry by completing a TD1/TD1ON form. Reimbursement for expenses incurred is not generally subject to taxation.

The CRA has determined that, for *tax purposes*, remuneration received by College appointees is considered income from employment. This means that:

- At the end of the calendar year, you will receive a T4 slip issued by the Province of Ontario.
- Remuneration is provided to the appointee only and not to an incorporated company or charity.
- You will be required to provide the Province of Ontario with your social insurance number.
- Effective May 2015, deductions at source on account of income tax are made on per diem remuneration. **All members are required to complete a TD1/TD1ON form for the purposes of withholding tax.**
- Your services are not considered to be taxable supplies and you should not charge Harmonized Sales Tax (HST) on your services.
- Effective December 2013, your remuneration is exempted from pensionable income for Canada Pension Plan (CPP) purposes. Therefore, the CRA will not permit contributions to the CPP by the payer or the part-time appointee.

Assignment of Honoraria

Honoraria is payable **only** to the individual appointee; it may not be directly "assigned" to a third party, that is, to another individual or a business or corporate entity. However, should an appointee wish to do so, they are at liberty to donate any honoraria payable or received to a charitable organization of their choice and receive a tax receipt, as applicable.

Appointees are also at liberty to waive receipt of honoraria associated with the appointment. A decision to waive payment of honoraria should be made in writing to the Health Boards Secretariat.

Special Assignments

In exceptional circumstances, because of her or his special knowledge or skills, it may be desirable and necessary for a public appointee to undertake an additional, special task, which:

i. arises from and is directly related to his or her participation in or assignment to Council or a statutory or standing committee of Council, and
ii. requires a significant additional time commitment which warrants specific remuneration.

Special assignments arise under exceptional circumstances and are interpreted by the Ministry of Health and Long-Term Care to mean activities:

i. which are in addition to and over and above the usual activities or responsibilities of a general member of Council or the associated statutory or standing committee of Council;
ii. which are appropriate to and do not conflict with the appointee's position as a governor of the College or an adjudicator[4];
iii. that, in other circumstances, might reasonably be assigned to a staff member or outside consultant;
iv. which are delegated to the appointee because of his/her particular knowledge, skill or interest; and
v. which require significant time and effort for which the appointee would require or, where the assignment involves the appointees professional qualifications, would usually expect to receive, specific remuneration.

Where, because of exceptional circumstances, a special assignment involving remuneration is proposed, the appointee and College must receive **prior approval** for payment of such remuneration from the Ministry of Health and Long-Term Care. Such approval is sought through written application to the Manager, Health Boards Secretariat, in advance of the assignment and the payment of any remuneration or expenses.

The application should outline:

- the specific purpose and scope of the assignment;
- the exceptional circumstances which give rise to the assignment;
- the proposed duration (begin and end dates) for the assignment;
- the proposed total cost (honoraria and expenses, if any) of the assignment, including the proportion of such costs to be paid by the Ministry and the College.

[4] Members of Council are "governors" of the College, similar to members of a board of directors. Without limiting the generality of the terms, governors or directors perform primarily policy making and overall supervisory functions rather than day-to-day operational functions. Adjudicators arbitrate or determine issues which fall within the statutory jurisdiction of an administrative tribunal.

The appointee and the College should note that appointees may not enter into any relationship with the College which directly or indirectly imply or result in an employer-employee or client/contractor relationship. In addition, in considering acceptance of a special assignment, the appointee may wish to take into consideration the potential for "apprehension of bias" or conflict of interest with respect to his or her participation in statutory decision-making pertaining to or arising from any findings, conclusions or recommendations arising directly from the special assignment.

Finally, it is a conflict of interest for public appointees to College Councils to accept any remuneration or benefit from any person or body, except as authorized by her or his role, Management Board or the Ministry of Health and Long-Term Care, for engaging in activities directly related to, or arising from, her or his appointment.

Honoraria

Remuneration for part-time appointees must be on a per diem basis. Per diems are generally based on 7.25 hours of work. A per diem is the amount that is payable for conducting the formal business of the College (e.g., attending a meeting or hearing).

A per diem is to be interpreted as the amount payable for work periods in excess of three hours; when less than three hours of work is involved, one-half of the established per diem rate will be paid. **Only one per diem payment can be made to an appointee for a calendar day.**

Where a single-day proceeding concludes earlier than its scheduled duration, appointees may be remunerated equal to the scheduled duration.

The applicable per diem rate and the activities for which honoraria may be claimed are determined by the following general factors:

- whether the appointee is attending a statutory or non-statutory meeting; and
- the appointee's assigned role in the meeting.

Honoraria may be claimed for attendance, preparation, decision-writing and/or deliberation time for meetings of the College Council and Statutory Committees. Specific conditions apply to remuneration for preparation[5], decision-writing and deliberation time, which are outlined in subsequent sections. In general, honoraria may be claimed for the activities listed in **Chart 1**.

Chart 1: Claims for Honoraria

Committee	Attendance	Preparation	Decision-Writing	Deliberation
Council	X	X		
Inquiries, Complaints and Reports Committee (ICRC)	X	X	X	
Executive Committee	X	X		
Fitness to Practice Committee	X	X	X	
Patients Relations Committee	X	X		
Quality Assurance Committee	X	X		
Registration Committee	X	X	X	
Discipline Committee *Meetings*	X	X		
Discipline Committee *Hearings*	X	X	X	X
Standing Committees of Council	X			
Ad-Hoc Committees and all other meetings	X			

[5] Note that specific provisions apply to preparation claims for the Inquiries, Complaints and Reports Committee (ICRC) and Discipline Committee Hearings.

Attendance Honoraria Payable for Council, Statutory and Standing Committee Meetings

The Ministry believes that public appointees should not be discouraged or prevented from assuming enhanced responsibilities within the Council for purely financial reasons. Thus, in establishing rates of remuneration, it has allowed for higher per diems to be paid to appointees who assume the responsibilities of the Chair or Vice-Chair of the College's Council, and the Chair or Vice-Chair of a statutory committee or a standing committee of Council, providing that the criteria outlined in **Chart 2** are met.

Because the rate of remuneration of an appointee will vary with her or his election as the Chair/President or Vice-Chair/Vice-President of Council, or designation as a Chair or Vice-Chair of a statutory or standing committee of Council, the College must inform the Ministry of such designation, in writing, to the Manager, Health Boards Secretariat, and copied to the Manager, Public Appointments Unit.

Remuneration for Council Chair/President

The term "Chair" and "Vice-Chair" are used in a generic manner and include the terms "President" and "Vice-President".

With her or his election to the position of Chair/President of a College Council, the appointee assumes a significant amount of additional responsibility and, of necessity, an enhanced work load.

Funding the administrative and operational activities of the Council President is the responsibility of the College and not the Ministry. However, the RHPA provides that the Minister shall reimburse public appointees. Moreover, it is a conflict of interest for a public appointee to accept remuneration or compensation not paid or authorized by the appointee's OIC or the Ministry.

Thus, of necessity, the Ministry is required to remunerate a public appointee for performing duties related to the administration and/or operation of the College, which are not the Ministry or the government's responsibility and, therefore, would not be compensable by the Ministry or government.

Where a public member has been elected Council Chair/President, the Ministry requires that:

(1) the College inform the Health Boards Secretariat of the election results, specifying the public member's name and elected term;
(2) the College prepare and negotiate an annual budget for the Council Chair/President with the Manager, Health Boards Secretariat. This annual budget should be based on an established job description for the Chair/President and estimate required honoraria and expenses. The agreed annual budget and accompanying financial arrangements will be documented in a letter of agreement between the College and the Ministry of Health and Long-Term Care.

Chart 2: Attendance Honoraria – Council, Statutory and Standing Committees			
Position	**Criteria**	**Per Diem Rate**	
Chair/President of Council	• Presiding at Council, Executive Committee or other committee meeting which the statutes or College by-laws specify be chaired by the Council Chair/President or representing Council at external meetings, and when carrying out College administration duties designated by statute or College by-laws as duties of the Chair. • The College is to notify the Health Boards Secretariat where a public member has been appointed as Council President, and an annual budget/Ministry authorization is required for compensation. • Not applicable unless performing specified duties of the position. If the Chair/President of the College Council is not acting as Chair of a Committee meeting, but as a general member, only the general member per diem rate is applicable.	**1 Day:** 50% Day:	**$250** $125
Vice-Chair/ Vice-President of Council	• The position has defined operational and/or policy duties enshrined in either the statute or the College's by-laws. • Not applicable when not performing specified duties of position.	**1 Day:** 50% Day:	**$175** $87.50
	• Where the Vice-Chair is acting in the absence of the Council Chair as delegated or pursuant to the applicable rules of College's by-laws respecting succession.	**1 Day:** 50% Day:	**$250** $125
Chair of Statutory or Standing Committee of Council	• Presiding at meeting/hearing of applicable committee. • Not applicable when participating in other committee meetings or general Council meetings.	**1 Day:** 50% Day:	**$250** $125
Vice-Chair of Statutory or Standing Committee of Council	• Where the Vice-Chair has defined operational or policy duties separate from the committee Chair AND the committee has a minimum of seven (7) members. • Not applicable when participating in other committee meetings or general Council meetings.	**1 Day:** 50% Day:	**$175** $87.50
	• Where the Vice-Chair is acting in the absence of the Chair as delegated or pursuant to the applicable rules of College's by-laws respecting succession, to manage the entire proceeding of the meeting or hearing.	**1 Day:** 50% Day:	**$250** $125
General members of Council or Committees	• Applicable when conducting the business of Council or Committees.	**1 Day:** 50% Day:	**$150** $75

Attendance Honoraria Rates Payable – Other Meetings and Activities

Participation in meetings of all other (established or ad hoc) committees or task-groups of Council, educational seminars, workshops and conferences is remunerated on the basis of the standard rate of **$150.00 per diem**, regardless of the role of the member.

Electronic Meetings

From time to time, for reasons of economy and/or timeliness, Colleges may hold meetings via interactive electronic communication media (e.g., by telephone or videoconference). As long as such electronic meetings represent a duly constituted meeting of Council or a committee (i.e., booked and minuted by the College), the attending or participating appointee may request payment of attendance honorarium.

The amount payable for "attendance" at electronic meetings is based on the applicable per diem rate for the member and Committee. **No payment, other than the applicable honorarium may be claimed in respect of electronic meetings.** Where any expenses are incurred in respect of electronic meetings (such as personal long-distance telephone, facsimile or internet charges), such expenses are the responsibility of and reimbursable by the College upon presentation of the required documentation.

Preparation, Decision-Writing, Deliberation, Travel and Cancellation Honoraria

Preparation Time

Being fully prepared to conduct College business is a normal requirement and expectation of one's appointment and, thus, compensation for preparation time is not an entitlement of one's appointment. However, the Ministry recognizes that, in some instances (such as, multi-day meetings or when dealing with highly specialized, technical information), an appointee may be required to dedicate more time than usual to prepare properly to discharge her or his duty. To accommodate such instances, the Ministry, at its discretion, compensates appointees for preparation time.

In all cases, **preparation time is remunerated on the basis of the standard per diem rate ($150.00 per diem)** regardless of the rate at which the member is compensated for attendance at the meeting.

Appointees may request honoraria for preparation time for meetings of the College's Council, and as assigned, to the meetings of a statutory committee. Such statutory committees that may claim preparation time are:

- Council
- Inquiries, Complaints, and Reports Committee
- Executive Committee
- Fitness to Practice Committee
- Patient Relations Committee
- Quality Assurance Committee
- Registration Committee
- Discipline Committee Meetings
- Discipline Committee *Hearings*, where applicable.

For budgetary reasons, honoraria is not available for preparation time for other committees or activities at this time. With the exception of preparation time for the Inquiries, Complaints and Reports Committee meetings and Discipline Committee *Hearings*, appointees may request honoraria for the amount of preparation time actually undertaken, as set out in **Chart 3**.

Chart 3: Preparation Honoraria		
Meeting of:	**Meeting Duration**	**Remuneration Rate**
Council and all statutory Committees **EXCEPT** the Inquiries, Complaints and Reports Committee and Discipline Committee *Hearings*	For each scheduled half-meeting day (up to 3 hours)	Up to one-half (50%) per diem
	For each scheduled full meeting day (greater than 3 hours)	Up to one (100%) per-diem

Inquiries, Complaints, and Reports Committee (ICRC)

Determination of the amount of preparation time claimable by ICRC members is based on Committee workload data, specifically, the number of matters considered. The College is required to confirm the number of inquiries, complaints and reports considered at each meeting with the Ministry. The remuneration rate is outlined in **Chart 4**.

Chart 4: Inquiries, Complaints and Reports Committee – Preparation Honoraria	
Inquiries, Complaints and Reports considered per meeting	**Remuneration rate**
25 or less	Up to 1 per diem
26 to 35	Up to 2 per diems
36 to 50	Up to 3 per diems
Greater than 50	Up to 4 per diems

Discipline Committee Hearings

Preparation is not generally required for Discipline Committee Hearings. The Ministry recognizes, however, that there are specific circumstances when members of a Discipline Committee panel are required to prepare for a hearing (i.e. in advance of motions, review of transcripts prior to a continuation, etc.). Where applicable, preparation for Discipline Committee Hearings may be payable up to a maximum of one per diem, per matter. In such cases, preparation is only payable where the College provides information to the Health Boards Secretariat to specify that such preparatory work was required.

Decision Writing

To facilitate effective decision-writing, the Ministry, at its discretion, compensates an appointee assigned to adjudicative committees or panels dealing with matters of professional misconduct, incompetence or incapacity, for decision-writing, and typically include the:

- Inquiries, Complaints, and Reports Committee
- Fitness to Practice Committee
- Registration Committee
- Discipline Committee *Hearings*

Remuneration for the time required to prepare, review and draft decisions is available only to appointees who are:

- assigned to committees which are statutorily mandated to adjudicate matters (complaints, allegations or charges) relating to the professional misconduct, incompetence or incapacity of College registrants/members; and
- assigned the responsibility of preparing and drafting the Committee's decision by the Committee chair. Remuneration is not available for time required to draft or type Committee reports or minutes, regardless of the nature of the committee, or for drafting or editing College newsletters, communiques or other publications.

Appointees may request honoraria for decision writing time actually undertaken, as applicable, **up to a maximum of one per diem per matter**[6]. Decision writing is compensated at the standard rate **($150.00 per diem)** regardless of the honoraria rate payable for attendance.

Deliberation

Compensation for time required to deliberate following completion of a statutory hearing of the Discipline Committee may be claimed only if the panel of the Committee conducting a statutory hearing is required (by the length of the hearing day or need to review complex and lengthy submissions) to schedule additional meeting time on a different day to complete the statutory hearing process. In claiming honoraria for deliberation time, the appointee must specify the hearing or hearings involved (such information is public information).

Deliberation time is compensated at the standard rate ($150.00 per diem) regardless of the honoraria rate payable for attendance. Appointees may request honoraria for deliberation time actually undertaken, up to a maximum of one per diem per matter.

Travel Time

Travel time beyond that undertaken as part of a normal day's work may be remunerated, at an **average hourly rate not to exceed a total payment of 60 percent of the approved[7] per diem rate**. A normal day's work is defined as 7.25 hours. The average hourly rate is to be calculated on the basis of a 7.25 hour work day.

Where travel to and from[8] in-person College activities require a member to work in excess of 7.25 hours in a calendar day, members may claim necessary travel time to and from the College activity at a rate of $20.69 per hour, up to a maximum of $90 per day. Given that a member's claim for travel time is based on *time*, rather than distance, it is important that members keep a careful log of their time so as to ensure that accuracy is maintained where claims for travel time are submitted.

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[6] "Per matter" is interpreted as per *file* and <u>not</u> based on duration. i.e. a member participating on a three-day matter may only be eligible for up to one per diem for decision writing.
[7] Standard member rate ($150 per diem)
[8] "To and from" is interpreted as the travel between the member's primary place of residence and the meeting location.

No remuneration for travel time is payable on the day prior, or after, the meeting day.

Example 1: Where an appointee is scheduled for a full-day's proceeding which takes 7.25 hours, and spends 2 hours travelling to and from the proceeding location, the appointee may be remunerated up to a total of one per diem for attendance plus two additional hours of travel time.

Example 2: Where an appointee is scheduled for a full-day's proceeding which concludes after five hours, and spends two hours travelling to and from the proceeding location, the appointee may be remunerated for one per diem, but will not be eligible for remuneration for travel time.

Example 3: Where travel to and from the College meeting necessitates travel on the day before or after the meeting, the member may claim related travel *expenses*, however the member is not eligible for remuneration for travel time.

Cancellation of Scheduled Hearings and Meetings

In general, payment of honoraria is contingent upon attendance for the purposes of College business. The Ministry recognises, however, that from time to time, appointees may suffer a loss of income or the opportunity to earn income, as well as an off-setting per diem, as a result of having made a commitment and arranged one's activities to attend a meeting or hearing which is subsequently cancelled at short notice or adjourned/terminated in process.

While attempting to mitigate such situations, the Ministry reminds appointees that they should not expect to be fully compensated for all loss of income and inconvenience arising from the cancellation of a scheduled meeting. It is expected that upon notification of a cancellation, all reasonable attempts will be made to mitigate against the loss of income and expenses for that period. Appointees are also encouraged to consider waiving the cancellation honoraria where there has been no actual loss of either income or opportunity to earn income.

Where the appointee is requested and makes arrangements to attend a meeting of the College Council or a meeting, review or hearing of a statutory committee for which an honorarium is normally payable, and such meeting, review or hearing is cancelled by the College, the appointee may request payment of honoraria on the basis outlined in **Chart 5**.

In all cases, cancellation payments will be made at the standard member rate **($150 per diem)**.

If an appointee has received remuneration from some other source (e.g., salaried employment) during the period for which the cancellation honorarium would have been claimed, she/he shall neither request nor receive any payment for cancellation.

Appointees who have made unchangeable travel arrangements and, thereby, have incurred non-refundable travel costs, will be reimbursed for out-of-pocket expenses.

Preparation Time for Cancelled Meetings

In general, if an appointee has undertaken and would normally claim for preparation time with respect to a statutory meeting that is cancelled, she or he may request payment for such preparation time with respect to the original scheduled meeting date or with respect to the date of the rescheduled review/hearing, **but not both**, if the meeting is rescheduled for a date within 30 days of the original cancellation date. In cases where a hearing or review is adjourned to be continued at a later date for the purposes of securing more information and/or reviewing new information or submissions, it may be appropriate to request additional preparation time. However, such requests must be accompanied by a written explanation.

The College is required to confirm the reason for the cancellation and attach the accompanying cancellation notice.

Chart 5: Cancellation Honoraria		
Meeting	**Condition of Cancellation**	**Allowable Claim**
Council Meetings	• Notice of meeting published to public; and • Meeting **cancelled three (3) or less** business days prior to published start date.	• Max of one (1) per diem.
Statutory adjudicative committees except Discipline Committee Hearings	• Formal notice of meeting issued by College; and • Meeting **cancelled three (3) or less** business days prior to scheduled start time.	• Max of one (1) per diem.
Discipline Committee Hearings	• Formal notice of Hearing was issued to parties; and • Hearing cancelled/ adjourned **three (3) or less** business days prior to scheduled start time.	• Max of one (1) per diem. Hearing must be identified on the claim (party names are public).
	• Hearing adjourned **in-process** and no other business can be substituted.	• The per diem that would have been payable for the adjourned day. If multi-day hearing was scheduled, up to one (1) additional per diem.
Other Statutory and Standing Committees, excluding electronic meetings	• Formal notice of meeting was issued by the College; and • Meeting is **cancelled three (3) or less** business days prior to scheduled start time.	• Max of one (1) per diem.
Electronic (such as teleconference) meetings or ad-hoc	• Not applicable.	• No claim allowed.

Federation of Health Regulatory Colleges, Conferences and Educational Sessions

Appointees are expected to develop a working knowledge regarding the *business* of the College, the Council and any committees to which they are appointed, and to maintain the currency of such knowledge. Periodic attendance of such educational events, as a participant or a presenter, is generally encouraged.

The Ministry is supportive of both the Federation of Health Regulatory Colleges (Federation) and public member participation in conferences/ongoing member education. However, the Ministry is not in a position to reimburse open-ended expenditures relating to Federation work/conference sessions that have the potential to consume funding intended by the Legislature to support the statutory functions of the College. Obviously, the College's statutory activities must remain the Ministry's priority when making funding decisions.

Colleges may support public member attendance at Federation activities/sessions, conferences or educational sessions in the same manner as other members of Council (e.g., by the payment of registration fees and/or expenses). **It is expected that provision to cover the expenses of conference attendance for all members will be included in the overall College budget and that public appointees will have equal access to such educational opportunities.**

Payment for conference/educational session participation by the Ministry of Health and Long-Term Care is contingent upon prior approval of the Manager, Health Boards Secretariat, and the availability of necessary funds within the Ministry's budget. Where approved, honoraria payment for attendance at such conferences or educational sessions will be paid by the Ministry at the standard member **($150 per diem)** rate, regardless of the role of the member or rate at which a member may be regularly be compensated for meeting attendance.

Claiming Honoraria and Expenses

Claims for payment of honoraria and reimbursement of eligible expenses are administered by the Ministry of Health and Long-Term Care's Health Boards Secretariat.

Timing of Claims

Appointees may submit claims for honoraria and expenses following the meeting/event, once per month or quarterly, depending on their financial situation and the usual practice of the College regarding reimbursement. However, all claims relating to the period immediately before the end of the Province's fiscal year (**March 31st**) must be submitted within two weeks of that date so that they are eligible for payment out of that fiscal year's allocation.

In any case, the claim must be submitted for payment **no later than four (4) months after the meeting/hearing, etc. to be eligible for reimbursement**. This is especially important for appointees who are nearing the end of their term or whose term has expired. The Ministry will not consider claims received after this period for retroactive payment.

Claim Forms

Claims for honoraria and expenses must be submitted on the appropriate form (see **Appendix 3**) to the College directly. **Claim forms must be completed electronically**, printed, and signed by the appointee and must attach all required original receipts. Failure to use the required form, print it correctly, sign it, or attach required original receipts will delay processing.

Please note that the claim form is periodically updated. Please contact the Health Boards Secretariat for a copy of the latest claim form.

Receipts

Reimbursement will be made only for expenses actually incurred. Therefore, it is essential that original receipts are submitted along with your claim forms. Please note that the Ministry of Health and Long-Term Care requires that original receipts (rather than photocopies, facsimiles or credit card slips) be provided.

Claim Processing

Where Health Boards Secretariat staff have all necessary attendance registers and receipts, staff will process completed claims within 5 business days from the date they are received by the Secretariat. After verification by the Health Boards Secretariat, claims are then forwarded to the appropriate departments at Ontario Shared Services (OSS). OSS provides remuneration payments in accordance with the bi-weekly OPS pay schedule. Reimbursement is made via electronic funds transfer by OSS directly to the appointee.

Appointees are encouraged to claim regularly to ensure more frequent payments to them.

Electronic Funds Transfer (EFT)

Payment is made only by Electronic Funds Transfer (Direct Deposit). See **Appendix 4** for a copy of the required form. Please note that the application form is periodically updated. Please contact the Health Boards Secretariat for a copy of the latest version.

Appendix 1: Regulatory Bodies Covered by this Framework

1. College of Audiologists and Speech-Language Pathologists of Ontario
2. College of Chiropodists of Ontario
3. College of Chiropractors of Ontario
4. College of Dental Hygienists of Ontario
5. College of Dental Technologists of Ontario
6. Royal College of Dental Surgeons of Ontario
7. College of Denturists of Ontario
8. College of Dietitians of Ontario
9. College of Homeopaths of Ontario
10. College of Kinesiologists of Ontario
11. College of Massage Therapists of Ontario
12. College of Medical Laboratory Technologists of Ontario
13. College of Medical Radiation Technologists of Ontario
14. College of Midwives of Ontario
15. College of Naturopaths of Ontario
16. College of Nurses of Ontario
17. College of Occupational Therapists of Ontario
18. College of Opticians of Ontario
19. College of Optometrists of Ontario
20. Ontario College of Pharmacists
21. College of Physicians and Surgeons of Ontario
22. College of Physiotherapists of Ontario
23. College of Psychologists of Ontario
24. College of Registered Psychotherapists of Ontario
25. College of Respiratory Therapists of Ontario
26. College of Traditional Chinese Medicine Practitioners and Acupuncturists of Ontario

Appendix 2: Order-In-Council Prescribing Remuneration for Appointees

Ontario
Executive Council
Conseil des ministres

Order in Council
Décret

On the recommendation of the undersigned, the Lieutenant Governor, by and with the advice and concurrence of the Executive Council, orders that:

Sur la recommandation du soussigné, le lieutenant-gouverneur, sur l'avis et avec le consentement du Conseil des ministres, décrète ce qui suit :

pursuant to section 8 of the Regulated Health Professions Act (Code), 1991, S.O. 1991, Chapter 18:

(a) Council members appointed by the Lieutenant Governor in Council be paid $150.00 per day together with their travelling and other expenses actually incurred while engaged upon the work of the Council, effective March 1, 1994;

(b) Council members designated, from time to time, as Vice Chair or Chair of a statutory or standing committee of Council, be paid $175.00 or $250.00, respectively, together with travelling and other expenses actually incurred while engaged upon the work of the committee, effective March 1, 1994.

Recommended _____ Minister of Health

Concurred _____ Chair of Cabinet

Approved and Ordered MAR 9 - 1994 Date

_____ Lieutenant Governor

Appendix 3: Sample Claim Form

Note: Claim forms must be completed electronically. The form contains drop-down fields and auto-populates/auto-calculates fields to assist you in completion. Below is an example of a completed form. Please contact the Health Boards Secretariat for a copy of the latest claim form.

Part-time Per Diem Appointee Travel Expenses

Ministry of Health and Long Term Care
Health Boards Secretariat

Print Form | Clear Form | Instructions

Page 1 of 3

Name of Board/College/Agency	Date (DD-MMM-YY)
College of Audiologists and Speech Language Pathologists of Ontario	8-Apr-16

Claimant Contact Information

Last Name *	First Name *	MI	Telephone	Ext.	Email Address *
Doe	Jane		416-555-5555		Jane.Doe@Example.ca

Unit/Apt.#	Street # *	Street Name *	City/Town *	Province *	Postal Code *
	100	Main Street	Ottawa	ON	A1Z 2A3

Travel Expenses — Add/Remove rows: + -

Date (DD-MMM-YY)	Particulars	Distance (KM) S. Ont. 0.40	Distance (KM) N. Ont. 0.41	Meals B	Meals L	Meals D	Accom.	Travel	Receipt No.	Row Total
4-Apr-16	Air Travel (Ott-Tor, return)							$320.00	1	$320.00
4-Apr-16	Subway (Airport-Hotel, return)							$6.00		$6.00
4-Apr-16	Hotel (1 night)						$215.00		2	$215.00
4-Apr-16	Dinner					$20.00			3	$20.00
5-Apr-16	Breakfast			$6.25					4	$6.25
5-Apr-16	Subway (Hotel-College, return)							$6.00		$6.00
Sub-Total (HST Inclusive)				$6.25		$20.00	$215.00	$332.00		$573.25
Sub-Total (HST Exclusive)				$5.53		$17.70	$190.27	$293.81		$507.30
HST				$0.72		$2.30	$24.73	$38.19		$65.95

Claimant Name	Signature	Date (DD-MMM-YY)
Jane Doe		8-Apr-16

Authorized by (*I authorize this claim, being satisfied as to* | Approved by | (Health Boards Secretariat Use Only)

Page 1: Travel Expenses

Your personal information is required. Where expenses are being claimed, you must ensure original, itemized receipts are attached. Number your receipts and ensure the corresponding number is noted in the "Receipt No." column of the claim form.

TAKE NOTE: Where expenses are being claimed, you are required to sign page 1 (see red arrow in the screen-shot above).

Helpful tip: When your personal information has been entered on page 1, save the form. This saved copy can be used again for future claims, and will avoid typing in your basic information at each claim submission.

Ontario

Part-time Per Diem Appointee Renumeration Detail

Ministry of Health and Long Term Care
Health Boards Secretariat

Print Form | Clear Form | Instructions

Page 2 of 3

Honoraria — Add/Remove rows: + -

Date (DD-MMM-YY)	Meeting/Hearing Details	File Name/No. and/or Committee	Actual Meeting Time Begin	Actual Meeting Time End	No. of Days /No.Hours	Per diem Rate/ Hourly Rate	Amount
1-Apr-16	Preparation	Executive	5 PM	7 PM	1/2	150.00	$75.00
5-Apr-16	Attendance	Executive	9 AM	1 PM	1	150.00	$150.00
							$0.00
							$0.00
							$0.00
	Other (specify below)						
							$0.00
							$0.00
					Total Honoraria (Pre-WHT)		$225.00

Honoraria Summary

Per Diem Description	Amount (Pre-WHT)
Attendance	$150.00
Preparation	$75.00
Total Honoraria	$225.00

v 3.2

Page 2: Detail of Remuneration

Where remuneration is being claimed, you must select the appropriate drop-down fields for meeting details, Committee name, start/end times and the appropriate per diem rate.

TAKE NOTE: The total honoraria on page 2 is "Pre-WHT". In other words, the amount listed is subject to withholding tax prior to payment to you.

Ontario

Part-time Per Diem Appointee Statement of Remuneration

Notes

The personal information you provide on this form is collected by Ontario Shared Services (OSS), Ministry of Government and Consumer Services, for the purpose of administering remuneration payments to you, and to remit any taxes payable to the Canada Revenue Agency pursuant to section 153 of the *Income Tax Act* (R.S.C, 1985, c. 1). If you have questions about the collection and use of your personal information, please contact the OSS Contact Centre at:

	Telephone Number	Teletypewriter (TTY)
Within the Greater Toronto Area	416 212-2345	416 327-3851
Toll Free	1 866 320-1756	1 866 310-7259

Fields marked with an asterisk (*) are mandatory.

Claimant Information (To be completed by Part-time Per Diem Appointee)

Last Name *	First Name *	Middle Initial
Doe	Jane	

Mailing Address

Unit/Apt. Number	Street Number *	Street Name *
	100	Main Street

City/Town *	Province *	Postal Code *
Ottawa	ON	A1Z 2A3

Ministry *	Agency *
Ministry of Health and Long-Term Care	College of Audiologists and Speech Language Patholo

Telephone Number	Email Address *
416-555-5555 ext.	Jane.Doe@Example.ca

Part-time Per Diem Appointee Remuneration *

Date (dd/mmm/yyyy)	Number of Hours or Days	Particulars (Details of service performed)	Hourly Rate or Per Diem Rate	Amount
08/Apr/2016	1.50	Various - See attached for particulars	150.00	$225.00
			Total Remuneration Amount ►	$225.00

Claimant Certification

This is to certify that the above remunerations were incurred by me while on government business.

Signature of Claimant * Sign here

Date (dd/mmm/yyyy) * 08/Apr/2016

Please visit www.ontario.ca/directpayment to download the application form to enrol for electronic payment.

Ministry/Agency Use Only

Ministry/Agency Contact

Page 3: Statement of Remuneration

This page summarizes the remuneration information you entered on page 2. In addition, it pulls your personal information from page 1 to automatically populate at the top of the page.

Where remuneration is being claimed, you are required to sign page 3 (see red arrow in the screen-shot above).

TAKE NOTE: The only action required on page 3 is to sign, once printed. All other fields auto-populate from the first two pages. Your personal information is pulled from page 1 and your remuneration is pulled from page 2. Your signature is required for page 3.

Appendix 4: EFT Sign-Up

Payment is made only by Electronic Funds Transfer (EFT, or Direct Deposit). Below is an example of the application that must be submitted in order to have EFT initiated. This form is periodically updated; please contact the Health Boards Secretariat for a copy of the latest version.

Ontario Ministry of Government Services

Application for Electronic Funds Transfer (Direct Deposit) and Remittance Advice Notification for Suppliers

The authority for the collection of this information as a lawfully authorized activity is the *Ministry of Government Services Act*, R.S.O. 1990, c.M25, s.6 (2) (c.1), and will be used solely for the purposes of depositing your payments into your bank account, and providing payment notifications by e-mail.
For information about collection, use and disclosure practices, write to the Senior Manager, Expenditure Management Branch, at the address listed below.
For frequently asked questions please visit our web page www.ontario.ca/directpayment. For further assistance please call 416 212-2345 or toll free at 1 866 320-1756.

Instructions

- Select the Type of Authorization and complete all requested information below.
- Attach an **original void cheque** displaying your name or an **original signed and/or bank stamped letter** from your financial institution. Supplier name must also match name on invoice.
  Note: Bank counter cheques are not acceptable.
- Enter the e-mail address you wish to receive Remittance Notification.
  Note: It is advisable to use a secured generic e-mail address that will not be affected by the change of staff in your organization.
  Void cheque/bank letter is required for all banking and remittance e-mail changes.
- Mail the **SIGNED** completed application to:

  Ministry of Government Services
  Ontario Shared Services
  Expenditure Management Branch
  Central Control Unit
  77 Wellesley St. West, Box 700
  Toronto ON M7A 1N3

Type of Authorization *(check ☒ one only)*

☐ New Banking/E-mail Information ☐ Change Banking/E-mail Information

Supplier Information

Supplier Name *(as printed on invoice)*			Business/GST No.
Supplier Address: Street No.	Street Name		Unit/Suite
City/Town	Province		Postal Code
Remittance E-mail Address *(You will receive a verification e-mail upon setup.)*	Supplier No. *(optional)*	Site No. *(optional)*	

Financial Institution Information

Name of Financial Institution

Branch No. | Institution No.

Account No.

ATTACH ORIGINAL VOID CHEQUE OR BANK LETTER

Authorization

I/We authorize the Province of Ontario to make all payments by direct deposit into the above account (I/We have attached a void cheque/bank letter). I have the authority to provide the above information on behalf of the corporation/organization/payee.

Name	Job Title	
Signature	Phone No. *(Incl. Area Code, Ext.)*	Date *(dd-mmm-yy)*

For Expenditure Management Branch use only		ORG : ☐ ODOE ☐ TP ☐ MAG	
Supplier No.	Site Name	Date	Rep Initials

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Ontario College of Pharmacists
Putting patients first since 1871

COUNCIL BRIEFING NOTE
MEETING DATE: *JUNE 2016*

FOR DECISION	FOR INFORMATION	X

INITIATED BY: Executive Committee

TOPIC: Physician-Assisted Death/Medical Assistance in Dying

ISSUE: College Guidance on physician-assisted death as of June 6, 2016 given the current status of federal legislation and provincial implementation.

BACKGROUND:

- On February 6, 2015 the Supreme Court of Canada (SCC), in the *Carter v. Canada*[1] decision, ruled that the criminal law must permit some form of physician-assisted death.
- The SCC suspended its decision and granted federal and provincial governments one year to develop federal and provincial legislation to accommodate its decision, with a deadline of February 6, 2016.
- The SCC then extended the deadline by four months, to June 6, 2016, and allowed those wishing to seek assistance in dying to apply to a court of superior jurisdiction for individual authorization to proceed with physician-assisted death during the interim period.
- The College developed a Preliminary Guidance to Pharmacists and Pharmacy Technicians to provide guidance to members during this interim period. The documents were made available to the public and pharmacy professionals on February 6, 2016.
- As of June 6, 2016, federal legislation has been introduced but has not yet been finalized. Therefore, as of this date, physician-assisted death is lawful by virtue of the SCC decision in *Carter v. Canada*.

DISCUSSION:

The Carter Decision

- The Carter decision requires that to be eligible for physician-assisted death an individual must:
    - Be a competent adult;
    - Clearly consent to the termination of life;
    - Have a grievous and irremediable medical condition (including an illness, disease or disability); and

[1] Carter v. Canada (Attorney General), 2015 SCC 5.

    - Experience enduring suffering that is intolerable to the individual in the circumstances of his or her condition.

- The *Carter* decision is ambiguous regarding involvement of the overall health team in physician-assisted death, and does not explicitly provide non-physician health care providers, including pharmacists and pharmacy technicians, an exemption from criminal liability.

- Until legislators through new legislation, or the courts through judicial decision determine otherwise, the current provisions of the Criminal Code still apply to pharmacists.

College Activity

- The College has been actively collaborating with the Ministry of Health and Long-Term Care (the Ministry), other regulatory bodies and applicable stakeholders on this topic.

- In relation to Bill C-14, the College has been following the Bill's progression carefully and meeting regularly with the Ministry and other stakeholders to discuss the status of physician-assisted death both federally and provincially.

- The College has published an updated Guidance to Pharmacists and Pharmacy Technicians to provide guidance to pharmacy professionals based on the requirements outlined in the *Carter* decision. (Appendix A)

- This guidance is substantively consistent with the Preliminary Guidance released on February 6, 2015, with updates to reflect that at the close of the interim period individuals are no longer required to seek jurisdictional authorization for physician-assisted death from a superior court.

- At this time the College recommends that, due to the ambiguity regarding criminal liability for pharmacists and pharmacy technicians, prior to aiding in physician-assisted death pharmacy professionals consult with their own legal counsel.

- The College has also updated the position statement on Refusal to Fill for Moral or Religious Reasons to more clearly reflect the expectations in practice as outlined in the Code of Ethics. (Appendix B)

NEXT STEPS:

- The College will continue to collaborate with government and stakeholders to clarify outstanding issues in the absence of federal legislation.

- The College will continue to monitor the status of Bill C-14 and has developed a draft guidance which will reflect federal law.

- Once the federal law is finalized, the draft guidance will be updated as required to ensure alignment with finalized federal law and will replace the existing Physician Assisted Death: Guidance for Pharmacists and Pharmacy Technicians.

Appendix A: Physician-Assisted Death: Guidance to Pharmacists and Pharmacy Technicians

Consideration for Pharmacists and Pharmacy Technicians Prior to Participating in Physician-Assisted Death

As of June 6, 2016, the interim court approval process established by the Supreme Court in February 2016 is no longer required for physician-assisted death. This process enabled specific exemption of pharmacists from criminal liability through court orders. In the absence of this process, the *Carter* decision is ambiguous regarding involvement of the overall health team in physician-assisted death, and does not explicitly provide pharmacists and pharmacy technicians an exemption from criminal liability. Until legislators through new legislation, or the courts through judicial decision determine otherwise, the current provisions of the Criminal Code still apply to pharmacists.

As such, the College recommends that a pharmacist or pharmacy technician consult with their own legal counsel before providing services to support a physician's prescription for physician-assisted death.

It is important for all pharmacy professionals to continually monitor information from the College about physician-assisted death, as the following guidance is based on the information available to the College at the time of publishing. Future development of policies, legislation or regulations may impact this guidance, and will be communicated to the profession as it unfolds.

Background

Assisting with death has historically been considered a crime under the Criminal Code. In the context of the *Carter v. Canada*[2] decision, the Supreme Court of Canada (SCC) found that this absolute prohibition violated an individual's *Charter* right to life, liberty and security of person. Accordingly, the SCC ruled that the criminal law must permit some form of physician-assisted death.

[2] *Carter v. Canada* (Attorney General), 2015 SCC 5.

The SCC suspended its decision to allow federal and provincial governments time to develop a framework to support the provision of physician-assisted death. The deadline for the federal government to bring a new law regulating MAID was June 6, 2016. However, the new legislation is not yet in force. Therefore, as of June 6, 2016 physician-assisted death is lawful where it is in accordance with the parameters set out by the SCC *Carter v. Canada*[3] decision.

The College of Physicians and Surgeons of Ontario has released a Policy on Physician-Assisted Death. The Ontario College of Pharmacists guidance document is aligned to this policy.

Guidance in the Absence of Federal and Provincial Legislation

The *Carter* decision deals with the rights of individuals to request physician-assisted death under specific conditions and does not explicitly address the involvement of the overall health team in this process. Under the *Carter* decision, only physicians are exempted from criminal liability when providing physician-assisted death.

The Carter decision is ambiguous regarding involvement of the overall health team in physician-assisted death and does not explicitly provide pharmacists and pharmacy technicians an exemption from criminal liability[4].

Therefore, at this time the College advises that pharmacists must make their own measured and informed decisions about whether to support physician-assisted death.

- **It is important that the pharmacist does not, or is not perceived to, undertake any of the following responsibilities:**
    - **Perform any activity that may imply that they are leading physician-assisted death**. This includes assessing an individual to determine whether their condition is "grievous or irremediable."
    - **Collect consent for physician-assisted death**. Pharmacists are not responsible for assessing whether a patient is capable of providing informed consent or for collecting and documenting that the patient consents to assisted death;

[3] Carter v. Canada (Attorney General), 2015 SCC 5.

[4] As of June 6, 2016, the interim court approval process established by the Supreme Court in February 2016 is no longer required for physician-assisted death. This process enabled specific exemption of pharmacists from criminal liability through court orders. In the absence of this process, the Carter decision is ambiguous regarding involvement of the overall health team in physician-assisted death and does not explicitly provide pharmacists and pharmacy technicians an exemption from criminal liability. As such, the College recommends that a pharmacist or pharmacy technician consult with their own legal counsel before providing services to support a physician's prescription for physician-assisted death.

- **Dispense drugs intended for physician-assisted death for "Office Use" by the physician**. Prescriptions for medications to assist in death cannot be dispensed unless prescribed to a specific patient.

- **Where a pharmacist or pharmacy technician makes the decision to participate in physician-assisted death, he or she should:**
  - **Engage in a collaborative process at an early stage,** to ensure that patients who have met the criteria and are eligible for physician-assisted death are able to access required medications and supplies in a timely manner;
  - **Be confident that the physician has affirmed that the patient meets the required eligibility criteria and has provided informed consent;** where a physician has not indicated that all criteria have been met and that the patient has provided appropriate consent, the pharmacist should follow-up with the physician.
  - **Confirm the indication for the prescription**, if not known or already communicated by the physician.
  - **Be aware that that a pharmacist cannot adapt prescriptions for physician-assisted death.**
  - **Dispense prescriptions written for a specific patient.** While it is appropriate to provide the prescription directly to the prescribing physician, the medication MUST only be dispensed under that patient's name and appropriately recorded in the patient's record of care.
  - **Practice in accordance with the Standards of Practice** with respect to dispensing a prescription when supporting physician-assisted death. Pharmacists are also encouraged to discuss appropriate disposal of unused medications with the patient or his/her agent.
  - **Ensure appropriate documentation according to the College's Documentation Guidelines**, such as indication and pertinent patient dialogue, on the patient record.

Appendix A: Ethical Considerations

The Code of Ethics must be considered holistically and in context with all ethical principles and standards. When providing services to support physician-assisted death pursuant to the consent of a patient and the prescription of a physician, you should pay particular attention to these principles and standards:

Principle 1: Beneficence

Pharmacists and Pharmacy Technicians serve and benefit the patient and society's best interests.

- Ensure the primary focus at all times is the well-being and best interests of the patient.
- Apply therapeutic judgment in order to assess the appropriateness of current or proposed medication therapy given individual patient circumstances.
- Provide patients with the relevant and sufficient information they need in order to make more informed decisions about their healthcare.
- Participate in consultation, communication and documentation with colleagues or other healthcare professionals to facilitate quality patient care.

Principle 2: Non-Maleficence

Pharmacists and Pharmacy Technicians refrain from participating in behaviours that may harm patients or society and whenever possible prevent harm from occurring.

- Practice only within their scope of practice, recognize their limitations and when necessary, refer the patient to a colleague or other healthcare professional whose expertise can best address the patient's needs.
- In circumstances where they are unwilling to provide a product or service to a patient on the basis of moral or religious grounds, ensure the following:
    i. that the member does not directly convey their conscientious objection to the patient;
    ii. that the member participates in a system designed to respect the patient's right to receive products and services requested;
    iii. that there is an alternative provider available to enable the patient to obtain the requested product or service, which minimizes inconvenience or suffering to the patient.
- Assume responsibility for making reasonable efforts to ensure continuity of patient care when they are unable or unwilling to provide requested pharmacy services.

Principle 3: Respect for Persons

Pharmacists and Pharmacy Technicians respect their patients as self-governing decision-makers in their healthcare and treat all patients fairly and equitably.

- Respect and value the autonomy and dignity of patients.
- Practice patient-centered care and treat patients with sensitivity, caring, consideration and respect.
- Listen to patients to seek understanding of their needs, values and desired health goals and respect their right to be an active decision-maker in their healthcare.
- Respect the patient's values, customs and beliefs and their right to hold these as self-governing decision-makers.

Principle 4: Accountability

Pharmacists and Pharmacy Technicians maintain the public trust by ensuring that they act in the best interest of their patients and society.

- Assume responsibility for all decisions and actions they undertake in professional practice, including failure to make a decision and take appropriate action when necessary.
- Ensure that all professional documentation is accurately maintained in accordance with practice standards.

Appendix B: Guideline on Professional Obligations when Declining to Provide a Pharmacy Product or Service due to Conscience or Religion

Professional Obligations when Declining to Provide a Pharmacy Product or Service due to Conscience or Religion

Guideline

Published: March 2001(originally a position statement: Refusal to Fill for Moral or Religious Reasons); Revised: X 2016

College Contact: Pharmacy Practice

Introduction

The Code of Ethics (the Code) outlines the ethical principles and standards that pharmacists and pharmacy technicians are accountable to in practice. In a circumstance where a pharmacist or pharmacy technician declines to provide a product or service due to a conscientious objection, he or she is required to meet the expectations outlined in standard 2.13 of the Code.

Background

Pharmacy professionals are required to act in their patients' best interests and provide an environment where the rights, autonomy, dignity and diversity of all patients are respected. The Supreme Court of Canada has determined that, although all persons right to freedom of conscience and religion are protected by the *Canadian Charter of Rights and Freedoms,* no rights are absolute.[5,6] The rights of patients must be balanced with those of healthcare providers, and rights can be limited, as necessary, to protect pubic safety, order, health, morals, or the fundamental rights and freedoms of others.[7,8] While the *Charter* entitles a health care professional to limit the health services he or she provides for reasons of conscience or religion, this choice cannot impede, either directly or indirectly, access to these services for existing patients, or those seeking to become patients.

Guideline

Designated managers are required to ensure that there is a system in place that, where a pharmacist or pharmacy technician has a conscientious objection, respects the patient's dignity and enables the patient to access desired services in a timely manner.

The information presented in the Code of Ethics and this guideline must be considered holistically and in context with all ethical principles and standards. The following provides further information regarding the expectations of any pharmacy professional in circumstances where they are unwilling to provide a service or product for reasons of conscience or religion as outlined in Standard 2.13:

[5] Canadian Charter of Rights and Freedoms, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11, s 2(a).
[6] R. v. Big M Drug Mart Ltd., [1985] 1 S.C.R. 295 at para 95.
[7] R. v. Big M Drug Mart Ltd., [1985] 1 S.C.R. 295 at para 95.
[8] Carter v. Canada (Attorney General), 2015 SCC 5 [Carter].

Standard 2.13	**Further Clarification of Expectation in Practice**
Members must, in circumstances where they are unwilling to provide a product or service to a patient on the basis of moral or religious grounds, ensure the following:	• A pharmacist or pharmacy technician is permitted to decline providing certain pharmacy products or services if it appears to conflict with the pharmacy professional's morality or religious beliefs.
i. that the member does not directly convey their conscientious objection to the patient;	• Any communication with the patient must be in a sensitive and respectful manner that does not impose any personal moral judgements about the beliefs, lifestyle, identity or characteristics of the patient. Furthermore, personal religious beliefs must not be promoted to the patient.
ii. that the member participates in a system designed to respect the patient's right to receive products and services requested;	• Objecting pharmacists and pharmacy technicians have a responsibility to inform their designated manager of their conscientious objection and participate in a system designed to respect a patient's right to receive pharmacy products and services.
iii. that there is an alternative provider available to enable the patient to obtain the requested product or service, which minimizes inconvenience or suffering to the patient.	• A pharmacist or pharmacy technician must not impede a patient's access to care. An effective referral meaning, a referral made in good faith, to a non-objecting, available, and accessible alternate provider in a timely manner must be provided to the patient. • A pharmacist or pharmacy technician must not withhold information about the existence of any treatment because it conflicts with their conscience or religious beliefs. • A pharmacist or pharmacy technician must provide care in an emergency, where it is necessary to prevent imminent harm, even where the care conflicts with their conscience or religious beliefs. • A pharmacist or pharmacy technician must make reasonable efforts to ensure continuity of patient care when they are unable or unwilling to provide requested pharmacy services.

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uwaterloo.ca/pharmacy

Improving Pharmacy Practice 5 Minutes at a Time

We invite the Ontario College of Pharmacists to join us in offering an innovative teaching tool to pharmacists and pharmacy technicians across Ontario designed to assist in optimizing scope of practice.

Pharmacy 5 in 5

Dr. Kelly Grindrod and her team from the University of Waterloo School of Pharmacy have developed an online, multimodal teaching tool called “Pharmacy 5 in 5”. The tool is designed to help pharmacists and pharmacy technicians develop their skills and acquire a deeper understanding of a variety of clinical and professional topics. These include changes to the scope of practice, implementation of new services, remuneration and clinical management. Pharmacy 5in5 allows users to audit their knowledge and provides them with feedback on their knowledge level compared to their peers.

Using the web-based platform, pharmacists and technicians perform rapid 5-minute self-audits of their knowledge and confidence. The tool is complementary to other learning modalities and is ideally suited for the busy practitioner who has limited time available for professional development. Pharmacy 5 in 5 includes short videos, infographics and flash cards and can be used on computers, tablets and smartphones. Using Pharmacy 5 in 5, users are able to test their knowledge on a topic by answering 5 questions in 5 minutes. When a gap is identified, they can quickly and easily use one or more of the learning modalities to build their knowledge and identify topics that require deeper self-study.

At its core, Pharmacy 5in5 is a research and assessment tool with the ability to capture baseline knowledge and track progress over time. The tool was developed using educational psychology and health services research, including theories of behaviour change, multimedia learning, audit, feedback and game-based learning. In addition, the back end of Pharmacy 5in5 captures data that will allow us to study how different groups are using the app and learning about scope of practice. For example, Pharmacy 5in5 can be used to compare understanding of scope of practice between Canadian and international pharmacy graduates, or between new and experienced graduates. We can also identify if users are more inclined to use written material or to watch videos and use this information to tailor content to specific groups or to develop focused educational campaigns on specific topics.

Why Partner with Waterloo?

The University of Waterloo School of Pharmacy is uniquely positioned to assist in OCP’s efforts to promote effective and high quality care in Ontario. The University of Waterloo is situated in a technology hub and we have strong connections with our growing technology community. In addition to our expertise in research, education, and assessment, our focus on new and emerging technologies provides us with a foundation unlike any other institution or company. We have created the Pharmacy 5in5 tool by combining emerging technologies with evidence based research and the local technology community.

Game-based learning and serious gaming are emerging as new strategies for clinician behavior change. The University of Waterloo is a leader in this area. Dr. Grindrod and her team work with both UW's Games Institute and with the local technology community to better understand and incorporate emerging learning strategies and technologies.

The University of Waterloo is fortunate to have an extensive network of pharmacy practitioners throughout the province who are engaged in educating our students. Access to this network as well as our own students provides us with a large number of individuals who are available to test new modules and features of Pharmacy 5in5.

Working together, we can develop a tool that combines the College's expertise in pharmacy practice with the University of Waterloo's expertise in technology-enhanced learning and practice based research. In addition, much of the work done in Pharmacy 5in5 has emerged from ongoing research by the OPEN pharmacy research collaboration—the largest network of pharmacy practice-based researchers in Canada.

Opportunity and Budget

The Pharmacy 5in5 tool has been developed over the last eight months with in-kind support from the School of Pharmacy and seed funding from OPEN (Ontario Pharmacy Research Collaboration) totaling $70,000. Future costs relate to refining the web-based platform including apps, development of modules, and building assessment and tracking components.

For an investment of $400,000 over three years, the University of Waterloo School of Pharmacy will work with OCP to further develop Pharmacy 5 in 5, make it available to pharmacists and pharmacy technicians across the province, and explore the development of complementary resources.

With OCP support, we will refine the platform including apps for Apple and Android operating systems, create a diverse suite of educational modules, and further develop assessment components. The topics for new modules will be selected based on input from OCP and from ongoing needs assessments within our experiential pharmacist network. Topics suggested to date include Documentation, Patient assessment, Counseling, and Narcotics Regulations. Modules will be created by an expert, reviewed by stakeholders, peer-reviewed by pharmacists and user tested through our extensive network of pharmacists, technicians and students.

A graphic designer will develop the videos, infographics and case examples. The graphic designer is expected to user test the content with practicing pharmacists before inclusion in a module. In addition the website must be updated regularly to ensure compatibility with major web browsers and operating systems. The current platform will evolve to meet the needs of practicing pharmacists and new features added to further support pharmacy practice.

Waterloo Pharmacy will also work with OCP to develop a communication and distribution plan to disseminate the Pharmacy 5 in 5 tool to pharmacists and technicians throughout Ontario. In addition, we will explore emerging technologies for opportunities to create resources for pharmacists and pharmacy technicians that complement the 5 in 5 tool and support OCPs work in the areas of coaching, mentoring and monitoring.

Dr. Grindrod will manage the project and provide oversight and strategic guidance.

Total Budget (3 years) $400,000

Year One – Platform Development $50,000

- The website was built by the Tuq design firm and they will be retained to modify and improve the website and build a mobile app for the Apple and Android phones.
- User testing conducted
- 3 modules developed in priority areas identified by OCP

Year Two – Module Development and Roll Out $200,000

- Up to 12 new modules will be developed
- Conceptual user testing of new features with practicing pharmacists, technicians and pharmacy students
- Work with OCP to disseminate Pharmacy 5in5 to all Ontario pharmacists and technicians
- Develop an assessment plan to provide the College with data related to baseline understanding of fundamental topics by pharmacists and pharmacy technicians

Year Three – Assessment, Module Development/New Features $150,000

- Up to 12 new modules developed
- Continue to user test and improve the existing website and apps
- Explore new and emerging learning strategies such as simulations, game-theory and persuasive technologies that can be added to the Pharmacy 5 in 5 system
- Provide the College with a comprehensive analysis of data which documents use of the tool and improvements in skills and knowledge in critical areas

Acknowledgement

The School of Pharmacy will be pleased to work with OCP to determine appropriate acknowledgment of support and expert assistance.

Terms

The University of Waterloo School of Pharmacy retains all copyright and intellectual property rights associated with the learning tool platform and app.