



ONTARIO COLLEGE OF PHARMACISTS

COUNCIL MEETING AGENDA

MONDAY, MARCH 20, 2017– 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 CouncilAppendix 1
 - 4.2 Briefing Note - December 2016 Council Meeting Evaluation.....Appendix 2
5. **Approval of Minutes of Previous Meeting**
 - 5.1 Minutes of December 2016 Council MeetingAppendix 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**
10. **For Decision**
 - 10.1 Briefing Note – Finance and Audit CommitteeAppendix 4
- *Audited Financial Statements for 2016 (includes Presentation of Audited Financial Statements by Auditor)*
 - 10.2 Briefing Note – Medication Safety Task ForceAppendix 5
- *Continuous Quality Improvement (CQI) for Medication Safety*
 - 10.3 Briefing Note – Executive CommitteeAppendix 6
- *Bill 87, Proposed Amendments to the Regulated Health Professions Act*

11. For Information

- 11.1 Briefing Note - Registrar's Report to Council Appendix 7
- Strategic Priorities Progress Update
 - Ministry Activities
 - Legislative Initiatives
 - Federal/Provincial Initiatives
 - Inter-Professional Relationships
 - Other Stakeholder Meetings
 - Miscellaneous Items
- 11.2 Briefing Note –Registrar - *Pharmacy Technician Strategy*..... Appendix 8

12. Other Matters

- 12.1 Presentation by Dr. Robert Bell, Deputy Minister of Health and Long-Term Care
Re: "Patients First" Time: 11:30 a.m. to noon
- 12.2 Presentation by Ms. Tina Perlman, Manager, Community Practice
Re: Strategic Plan Update
- 12.3 Motion respecting Future Council Meeting Dates

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.



COUNCIL BRIEFING NOTE

MEETING DATE: MARCH 2017

FOR DECISION

FOR INFORMATION

X

INITIATED BY: Régis Vaillancourt, President

TOPIC: President's Report to March 2017 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 December 2016 Council Meeting. In addition to regular meetings and phone calls with the interim Registrar, 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:

January 5th University of Waterloo White Coat Ceremony
January 11th University of Toronto White Coat Ceremony
February 16th Meeting with Public Health Agency of Canada Pharmacist on opioids crisis and the role of pharmacists

College Meetings:

January 26th Conference call - New Council Member Orientation (Elnora Magboo)
January 31st Discipline Committee Meeting
February 4th - 7th CSHP Professional Practice Conference 2017
February 27th Finance and Audit Committee Meeting
March 2nd OCP-OPA Conjoint Executive Committee Breakfast Meeting
Executive Committee Meeting



COUNCIL BRIEFING NOTE
MEETING DATE: MARCH 2017

FOR DECISION	FOR INFORMATION	X
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INITIATED BY: Régis Vaillancourt, President

TOPIC: December 2016 Council Evaluation Report to March 2017 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 December 2016 Council meeting, we provided Council members with the opportunity to provide their feedback. 17 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	14	1	1	0	0	16
2. Members were well prepared to participate effectively in discussion and decision making	11	4	1	0	0	16
3. In accordance with the governance philosophy, Council worked interdependently with staff	14	2	0	0	0	16
4. There was effective use of time	14	2	0	0	0	16
5. There was an appropriate level of discussion of issues	14	2	0	0	0	16
6. The discussion was focused, clear, concise, and on topic	13	2	1	0	0	16

2. Did the meeting further the public interest?

YES = 16 = 100%

NO = 0 = 0%

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

- Giving everyone fair chance to voice their opinions
- Reporting on prescription errors
- Medication errors. People had lots of feedback about this
- Mandatory reporting of errors
- Enhancing CQI program for med incidents
- Excellent discussion on a variety of topics particularly the new medication safety initiative
- The discussion on reporting prescription errors was very fulsome; everyone was given an opportunity to participate. Good presentation setting the stage, very productive discourse

- Discussion about reporting errors
- The discussion regarding the CQI was informative and provided some useful guidelines on what members are looking for in the development of this taskforce

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.

- None during this session
- None
- None
- The entire meeting was well chaired and fruitful
- I could not identify one

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	15
Mostly Satisfied	1
Neither Satisfied Nor Dissatisfied	0
Mostly Dissatisfied	0
Completely Dissatisfied	0
Total Responses	16

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

- None for now
- Please remember that we have valuable public members in the room. Many do not live in the pharmacy world we are familiar with. Take care to explain as new practice issues or terms are discussed
- Another well run meeting by Regis. Anne Resnick did an excellent job of presenting the Acting Registrar's report. The staff presentations done by Maryan and Judy were very informative and comprehensive - Karen Riley
- Suggest that Strategic Plan be on screen and highlight achievements in past months and/or reflect where focus has shifted (e.g. due to new Regs approved)
- Very good meeting with everyone participating. Keep it up - Sylvia Moustacalis
- Great meeting. Anne did a very thorough job getting us up to date with issues. Presentations from staff and Zubin most informative. Everything moved along smoothly. Thanks Regis - Joy
- No, I felt that the meeting was both informative and educational

Respectfully submitted,

Régis Vaillancourt, President



**Ontario College
of Pharmacists**

Putting patients first since 1871

MINUTES OF MEETING

OF COUNCIL

DECEMBER 12, 2016

Draft

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MONDAY, DECEMBER 12, 2016 – 9:06 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 Ms. Tracey Phillips, Westport
District L Mr. Billy Cheung, Markham
District L Mr. James Morrison, Burlington
District L Dr. Sony Poulose, Hamilton
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 - **Regrets**
District N Mr. Chris Leung, Windsor
District N Dr. Karen Riley, Sarnia
District P Mr. Jon MacDonald, Sault Ste. Marie - **Regrets**
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
Ms. Carol-Ann Cushnie, Toronto
Mr. Naj Hassam, North York - **Regrets**
Mr. Javaid Khan, Markham
Mr. John Laframboise, Ottawa
Mr. James MacLaggan, Bowmanville - **Regrets**
Ms. Sylvia Moustacalis, Toronto
Mr. Shahid Rashdi, Mississauga
Ms. Joy Sommerfreund, London
Mr. Ravil Veli, North Bay
Mr. Wes Vickers, LaSalle

Staff present

Ms. Connie Campbell, Director, Finance and Administration
Ms. Susan James, Director, Competence
Ms. Ushma Rajdev, Council and Executive Liaison
Ms. Anne Resnick, Interim Acting Registrar

Invited Guests

Dr. Zubin Austin, Murray Koffler Chair in Pharmacy and Academic Director, Centre for Practice Excellence, Leslie Dan Faculty of Pharmacy, University of Toronto

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 Vaillancourt welcomed Council members to the meeting. He also introduced to Council Ms. Nancy Lum-Wilson, who was observing the proceedings at today's meeting. Ms. Lum-Wilson was appointed CEO and Registrar of the College on November 24 at the Special Council Meeting and will assume her role at the College on January 9, 2017.

The President advised that a new Public Member Mr. Najmudin (Naj) Hassam from North York, was appointed to College Council on October 5, 2016 for a period of 3 years. An Orientation was held on October 27 and Mr. Hassam has been appointed to the Discipline, ICRC and Registration Committees. Mr. Hassam was unable to participate in today's meeting and will be formally introduced to Council at the March 2017 Council Meeting.

The President went on to advise that Mr. Farrell, Public Member from Sundridge, tendered his resignation effective December 2, 2016, and that Ms. Al-Zand has been appointed to replace him on the Executive Committee.

President Vaillancourt also advised Council that in an effort to address concerns from staff about clean air in the workplace, and to promote a healthy work environment and reduce the potential for adverse health effects related to the use of fragrances at the College, policies have

been created to ensure a scent-free environment. These policies are similar to those in place at hospitals and other regulatory bodies.

4.1 Briefing Note - President's Report to December 2016 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 Acting Registrar and the Vice President. President Vaillancourt added that amended regulations under the *Pharmacy Act* that permit pharmacist administration of certain vaccines were announced by the Minister of Health and Long-Term Care on December 1, 2016 and will take effect on December 15, 2016.

The Briefing Note was received by Council for information.

4.2 Briefing Note – September 2016 Council Meeting Evaluation

Referring to the September 2016 Council Meeting Evaluation, President Vaillancourt was pleased to note the increase in the number of respondents to the survey and thanked Council for taking the time to provide feedback.

The Briefing Note was received by Council for information.

5. Approval of Minutes of Previous Meeting

5.1 Minutes of Special Meeting of Council (November 24, 2016)

It was moved and seconded that the Minutes of the Special Meeting of Council held on November 24, 2016 be approved. CARRIED.

5.2 Minutes of September 2016 Council Meeting

It was moved and seconded that the Minutes of the September 2016 Council 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 – Acting Registrar’s Report to December 2016 Council

President Vaillancourt asked the Acting Registrar, Ms. Resnick, to address Council.

Ms. Resnick highlighted the salient points from her report and responded to questions posed by Council. Referring to the Mandate letter provided by the Premier to the Minister of Health and Long-Term Care, Ms. Resnick noted the various priorities outlined therein. She advised Council that on December 7, the government introduced the *Medical Assistance in Dying Statute Law Amendment Act, 2016*. The Act consists of a series of amendments that will provide more clarity on medical assistance in dying for patients, families and health care providers. It will ensure that appropriate coroner oversight of medical assistance in dying situations will continue.

Also introduced by the government was legislation to prevent sexual abuse of patients. The legislation, if passed, will strengthen and reinforce Ontario's zero tolerance policy on sexual abuse of patients by any regulated health professional. The *Protecting Patients Act, 2016* includes legislative amendments that would, among others, (1) clarify the time period after the end of a patient-provider relationship; (2) expand the list of acts of sexual abuse that will result in the mandatory revocation of a regulated health professional's license; (3) remove the ability of a regulated health professional to continue to practice on patients of a specific gender after an allegation or finding of sexual abuse; (4) increase access to patient therapy and counselling as soon as a complaint of sexual abuse by a regulated health professional is filed; (5) ensure that all relevant information about regulated health professionals' current and past conduct is available to the public in an easy-to-access and transparent way; and (6) improve colleges' complaints, investigations and discipline processes.

Council noted that in anticipation of these amendments, the College began work in some of these areas, and has already implemented changes to the public register that support the transparency initiative.

Council next noted that on October 7, Minister Hoskins released a letter he wrote to Ed Clark, the Premier's Business Advisor and Chair of the Advisory Council on Government Assets in which he requested Mr. Clark's expert advice in valuing public and private assets with respect to Ontario's digital health strategy. Currently, most family physicians in Ontario have electronic medical records in their practice and nearly all hospital-based diagnostic imaging is digital and key lab results are available through a provincial information system. Ms. Resnick advised that as part of this initiative, if/when pharmacists have access to more information, there will be a need for new policy development to help guide the profession. In anticipation, she continued, we are working with the College of Physicians and Surgeons of Ontario to develop complementary policies for continuity of care to help serve and meet patient needs. It is anticipated that signage required to be displayed in pharmacies will be amended to reflect the change in access by pharmacists and other health professionals to patients' health information.

Ms. Resnick next referred to the section in her report regarding opioid abuse, noting that in addition to Ontario's own strategy to prevent addiction and overdose, on November 19, the Federal Minister of Health and Ontario's Minister of Health and Long-Term Care released a "Joint Statement of Action to Address the Opioid Crisis". The statement reflects the combined commitment both federally and provincially to address this crisis. Council noted for information that the College is establishing a working group to provide guidance in the development of a comprehensive opioid dependence treatment (ODT) policy. This will include guidance from a regulatory perspective as well as providing input on both best practices and challenges in the delivery of addiction services. In response to a comment from the floor, Ms. Resnick advised that consideration has been given to include non-pharmacists, in particular, patients, as members of this working group, in order to assist the College in developing a comprehensive understanding of this issue.

Ms. Resnick advised that the National Association of Pharmacy Regulatory Authorities (NAPRA) had met in Saskatoon on November 8. Referring to Mr. Scanlon's (College representative on the NAPRA Board) report, she noted that on the issue of medical marijuana, NAPRA continues to support the existing evidence-based process for drug review, evaluation, and approval and does not support a separate process for this product. She added that due to the complex nature of regulation development and enforcement in this area, CPRC (the Council of Pharmacy Registrars of Canada) would like to consider the broader issue of distribution in greater detail and it is anticipated that this discussion will occur some time in February 2017.

Ms. Resnick added that in addition to various other discussions, a significant portion of the Board meeting was taken up with the discussion on governance. Since its inception over 20 years ago, there has been recognition that a governance review was needed to examine challenges related to structure and function of NAPRA in order to strengthen the organization to better serve its members. An Ad-hoc Committee was created in April 2016 and with the support of the Institute on Governance, at this November meeting, the Committee put forth recommendations for the Board's consideration and subsequently, for member organizations feedback.

Ms. Resnick provided an overview of the current structure and concerns which are that: member organization representatives are voting directors of the Board (14 people) of which many are past members of provincial boards/councils; the Council of Pharmacy Registrars of Canada (CPRC) meets separately (also comprises 14 people); meetings are infrequent due to numbers and logistics; and there is duplication of discussion by both groups.

The proposed structure/recommendation is that the Board be comprised of 17 members (14 Registrars from provincial/territorial colleges and Canadian Forces Pharmacy Services and up to three Directors-at-Large [a pharmacist to be drawn from outside provincial boards/councils, a pharmacy technician and a public member]). Among other elements, the Board is expected to continue to operate with existing consensus decision-making model and meet six times a year (four of which will be in-person). This structure will not only ensure a strong strategic focus but will remove duplication of effort between the Registrars' group and the Board. It will also enable NAPRA to be more nimble.

Council members discussed the recommendation, noting that feedback was expected by NAPRA by February 20, 2017. Comments from the floor included that lack of elected member involvement may result in loss of practice perspective (although it was explained that NAPRA

will rely on expert groups made up of practitioners when dealing with practice issues); assurance that the 3 members at large adequately represent the demographics (it was noted that implementation details, which will include by-law changes, are currently being considered to support the Board decision in April); expression of strong support for public member representation; and a question as to whether this proposed structure would result in budgetary changes (it was noted that no changes to budget were anticipated). Ms. Resnick invited members at the table to provide her with further feedback, if any, before the submission deadline.

Council also noted that NAPRA developed the draft Model Standards for Pharmacy Compounding of Non-Sterile Preparations which the College had recently posted for consultation. Responses were received from a number of stakeholder groups including pharmacists, pharmacy technicians and pharmacy organizations. Ms. Resnick advised that the submissions had generally been supportive and suggestions had been provided to aid clarity. It was noted that this feedback will be submitted to NAPRA, who will review submissions from across the country and determine what changes to make, if any. When NAPRA has completed work on the standards, Council will consider their adoption as well as timing of implementation.

The Registrar's (Acting Registrar's) reporting activity also includes regular program updates/presentations from the program managers and accordingly, Ms. Judy Chong, Manager, Hospital Practice, followed by Ms. Maryan Gemus, Manager, Investigations and Resolutions, were invited to present to Council.

10. For Decision

10.1 Briefing Note – Executive Committee

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

Vice President Donaldson, was invited to address Council. Following a recent tragic incident linked to a compounded medication error, the College reviewed how medication incident reporting is addressed in practice and what resources are available to improve and strengthen existing measures. This review also included the protocols and reporting requirements of other provincial regulatory authorities, specifically Nova Scotia's SafetyNET-RX and Saskatchewan's COMPASS CQI programs that enable community pharmacies to anonymously report medication incidents to a third party (such as the Institute for Safe Medications Practices [ISMP] Canada). The objective of this approach, which includes analysis of factors contributing to the error, is to ensure that all practitioners learn from these incidents and review and enhance their policies and procedures to reduce the likelihood of recurrence thereby improving patient safety.

Ms. Donaldson added that although the College continuously reminds practitioners of their responsibility to appropriately manage medication incidents in their practice through broad communications, and as part of discussions during regular pharmacy practice assessments in hospitals and community pharmacies, it does not currently mandate the reporting of medication errors to an external body. Accordingly, in considering this matter, the Executive Committee made the recommendation that Council approve a motion to expand on the existing expectation for continuous quality improvement for medication safety, by requiring reporting of errors to a

third party, with the expectation that aggregate reports will be received by the College for targeted practice improvement initiatives. It was noted that a Task Force will be established to fully examine this subject and that it is anticipated that a model will be developed for consultation during January and February 2017, after which the model will be presented to Council for approval at its meeting in March 2017.

Council members expressed overwhelming support of implementing such reporting requirements. Comments and suggestions included: that reporting would increase accountability; an analysis of the systems currently in place (i.e. Nova Scotia and Saskatchewan) be conducted to determine the best model for Ontario; that this was good for the profession as it showed an openness to learn; that reporting promoted a culture of continuous improvement and that everyone can win from this; that it was important to learn from mistakes; assurance that data and outcomes would be transparent in order to learn from them; that it was important to discern the contributing factors to errors and determine trends; that a possible result could be the development of further standards and/or guidelines; assurance that anonymous reporting is protected; and encouragement of reporting by public/patients.

Following discussion, **it was moved and seconded that the College take initial steps to examine expansion of existing expectation for continuous quality improvement for medication safety, by requiring reporting of errors to a third party, with the expectation that aggregate reports will be received by the College for targeted practice improvement initiatives.** Council members voted unanimously in favour of the motion. **The motion CARRIED.**

11. For Information

There were no matters for information.

12. Other Matters

12.1 Presentation by Drs. Zubin Austin and Heather Boon, Leslie Dan Faculty of Pharmacy, University of Toronto

Following introduction by Ms. Resnick, Dr. Austin made his presentation to Council. Council noted that in the fall of 2012, the College signed an agreement with the University of Toronto to establish a Program that will address, through extensive research, the underlying behavioral issues and characteristics of pharmacists that are inhibiting pharmacists from confidently embracing/adopting an expanded scope of practice in the health care system. Dr. Austin provided a status report to College Council on the research activities undertaken by the University over the past year, as well as their results and the plan for the upcoming year.

With Dr. Austin's appointment of the Murray B. Koffler Chair in Pharmacy Management, Dr. Boon, Dean, Faculty of Pharmacy, University of Toronto, announced that Dr. Lisa Dolovich would be assigned the professorship at the faculty in January 2017 and will provide an update on the accomplishments at a future Council meeting.

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.

President Vaillancourt encouraged Council members to continue to provide feedback which will serve to ensure efficiency and enhance Council members' participation at these meetings.

14. Motion of Adjournment

It was moved and seconded that the Council meeting be adjourned at 2:06 p.m. and to reconvene on Monday, March 20, 2017, or at the call of the President. CARRIED.

**Ushma Rajdev
Council and Executive Liaison**

**Régis Vaillancourt
President**

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COUNCIL BRIEFING NOTE
MEETING DATE: MARCH 2017

FOR DECISION	X	FOR INFORMATION
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INITIATED BY: Finance and Audit Committee

TOPIC: Audited Financial Statements

ISSUE: Approval of 2016 Audited Financial Statements

BACKGROUND: The audit was conducted in accordance with Canadian generally accepted auditing standards. The statements reflect the values for reserve funds agreed to by the Finance and Audit Committee which appropriately replenishes the Fee Stabilization Reserve Fund drawn down last year and adjusts the Investigations and Hearings Reserve Fund to reflect current obligations.

The Management Letter issued by the auditor is also attached for Council information.

ANALYSIS: The opinion of the auditor is that the financial statements present fairly, in all material respects, the financial position of the College as at December 31, 2016 and its financial performance and its cash flows for the year then ended in accordance with Canadian accounting standards for not-for-profit organizations.

RECOMMENDATION: That Council approve the attached Audited Financial Statements and Summary Statements for the operations of the Ontario College of Pharmacists for 2016 as prepared by management and audited by Clarke Henning LLP, Chartered Accountants.

EXECUTIVE COMMITTEE RECOMMENDATION AND COMMENTS (if any):

ONTARIO COLLEGE OF PHARMACISTS
FINANCIAL STATEMENTS
YEAR ENDED DECEMBER 31, 2016

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Draft - Mar 3/17

INDEPENDENT AUDITOR'S REPORT

TO THE MEMBERS OF COUNCIL OF THE ONTARIO COLLEGE OF PHARMACISTS

We have audited the accompanying financial statements of the Ontario College of Pharmacists, which comprise the statement of financial position as at December 31, 2016 and the statements of operations, changes in net assets and cash flows for the year then ended and a summary of significant accounting policies and other explanatory information.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with Canadian accounting standards for not-for-profit organizations, and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with Canadian generally accepted auditing standards. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements present fairly, in all material respects, the financial position of the Ontario College of Pharmacists as at December 31, 2016 and its financial performance and its cash flows for the year then ended in accordance with Canadian accounting standards for not-for-profit organizations.

Toronto, Ontario
March 20, 2017

CHARTERED ACCOUNTANTS
Licensed Public Accountants

ONTARIO COLLEGE OF PHARMACISTS

STATEMENT OF FINANCIAL POSITION

AS AT DECEMBER 31, 2016

	2016	2015
ASSETS		
Current assets		
Cash balances with banks	\$ 252,197	\$ 500,614
Short-term investments (note 4)	1,500,000	-
Accounts receivable and cost recoveries (note 3)	206,893	163,871
Prepaid expenses	312,764	115,487
	<u>2,271,854</u>	<u>779,972</u>
Long-term investments (note 4)	7,731,305	8,242,634
Property and equipment (note 5)	4,149,710	4,333,685
	<u>14,152,869</u>	<u>13,356,291</u>
LIABILITIES		
Current liabilities		
Accounts payable and accrued liabilities	1,204,528	1,515,775
Deferred revenue	61,550	59,887
	<u>1,266,078</u>	<u>1,575,662</u>
NET ASSETS		
Invested in property and equipment	4,149,710	4,333,685
Internally restricted (note 6)	8,480,000	7,125,000
Unrestricted	257,081	321,944
	<u>12,886,791</u>	<u>11,780,629</u>
	<u>\$ 14,152,869</u>	<u>\$ 13,356,291</u>

Approved on behalf of the Council:

_____, President

_____, Chair of Finance Committee

ONTARIO COLLEGE OF PHARMACISTS

STATEMENT OF OPERATIONS

YEAR ENDED DECEMBER 31, 2016

	Budget	Actual	
	2016	2016	2015
	(note 2)		(note 12)
Revenues			
Member fees - Pharmacists	\$ 9,106,500	\$ 9,175,702	\$ 8,825,392
Member fees - Pharmacy Technicians	1,876,000	1,713,306	1,501,194
Community Pharmacy fees	4,278,700	4,417,290	3,856,597
Hospital Pharmacy fees	1,440,000	908,000	-
Registration fees and income	696,500	792,555	1,603,841
Investment income	203,000	245,374	246,042
	17,600,700	17,252,227	16,033,066
Expenses (Schedules)			
Council and committees	2,468,900	2,112,062	2,550,401
Administration	14,827,426	13,530,375	13,325,673
Property	213,508	125,841	137,703
Niagara Apothecary	24,725	26,557	27,638
	17,534,559	15,794,835	16,041,415
Excess (deficiency) of revenues over expenses from operations for the year before depreciation	66,141	1,457,392	(8,349)
Depreciation	182,000	351,230	365,708
Excess (deficiency) of revenues over expenses for the year	\$ (115,859)	\$ 1,106,162	\$ (374,057)

Draft - Mar

ONTARIO COLLEGE OF PHARMACISTS

SCHEDULE OF EXPENSES

YEAR ENDED DECEMBER 31, 2016

	Budget	Actual	
	2016 <i>(note 2)</i>	2016	2015 <i>(note 12)</i>
Council and Committees			
Council	\$ 130,000	\$ 91,207	\$ 133,572
District/Regional	50,000	-	700
Committees			
Accreditation	70,000	48,786	53,053
Communication	12,500	6,270	69,159
DPP Committee	5,000	-	-
Discipline	1,510,000	1,527,823	1,628,794
Discipline - cost recoveries	(100,000)	(144,300)	(123,350)
Executive	24,000	32,206	26,327
Finance and Audit	7,000	7,044	8,367
Fitness to practice	62,000	69,739	61,981
ICRC	153,000	184,588	146,881
Patient relations	5,000	5,071	1,101
Professional practice	4,000	-	5,661
Quality assurance	502,400	264,242	488,400
Registration	14,000	19,143	22,821
Special	20,000	243	26,934
	\$ 2,468,900	\$ 2,112,062	\$ 2,550,401

Draft - Mar 31, 2017

ONTARIO COLLEGE OF PHARMACISTS

SCHEDULE OF EXPENSES

YEAR ENDED DECEMBER 31, 2016

	Budget	Actual	
	2016 <i>(note 2)</i>	2016	2015 <i>(note 12)</i>
Administration			
Personnel <i>(note 9)</i>	\$ 11,648,441	\$ 11,124,386	\$ 10,602,475
General			
Association fees	135,000	138,368	115,902
Audit	20,000	16,000	17,500
Bank charges	389,201	369,443	373,364
Communication initiatives	204,000	94,374	-
Consulting - general	317,850	142,889	376,051
Continuing education initiatives	10,000	471	12,273
Courier and delivery	6,050	5,902	5,508
Donations, contributions and grants	205,000	252,300	202,150
DPP Inspection Costs	5,000	361	242
Election expenses	5,000	3,930	2,703
Examinations, certificates and registrations	183,000	138,566	206,180
Government Relations	42,000	42,000	42,000
Information systems, leasing and maintenance	260,050	219,885	265,256
Insurance - errors and omissions	5,800	5,503	5,412
Legal	250,000	136,955	189,562
Office services - equipment leasing and maintenance	29,000	23,224	30,033
Postage	36,000	27,493	33,070
Professional health program	160,000	148,636	128,089
Practice input initiatives	110,000	17,902	9,624
Publications - Annual Report and Pharmacy Connection	51,500	42,687	36,014
Structured practice training	114,500	83,386	108,273
Subscriptions and publications	4,800	10,614	5,867
Supplies	28,414	14,499	22,159
Telecommunication	186,470	167,549	150,723
Travel and conferences	420,350	303,052	385,243
	\$ 14,827,426	\$ 13,530,375	\$ 13,325,673

ONTARIO COLLEGE OF PHARMACISTS

SCHEDULE OF EXPENSES

YEAR ENDED DECEMBER 31, 2016

	Budget	Actual	
	2016 <i>(note 2)</i>	2016	2015 <i>(note 12)</i>
Property			
483 Huron Street	\$ 216,167	\$ 227,276	\$ 228,272
186 St. George Street	141,486	128,703	127,080
	357,653	355,979	355,352
Rental income - 186 St. George Street	(144,145)	(230,138)	(217,649)
	213,508	125,841	137,703
Niagara Apothecary			
Salaries and administration	31,900	30,892	30,696
Insurance	5,700	5,700	8,222
Utilities	5,900	6,774	6,039
Building maintenance and repairs	500	-	433
Publicity	225	130	125
Miscellaneous	500	2,284	1,913
Cost of sales	9,000	10,876	11,196
	53,725	56,656	58,624
Sales, grants and donations	(29,000)	(30,099)	(30,986)
	\$ 24,725	\$ 26,557	\$ 27,638

Draft - Mar 31, 2017

ONTARIO COLLEGE OF PHARMACISTS

STATEMENT OF CHANGES IN NET ASSETS

YEAR ENDED DECEMBER 31, 2016

	2016			2015	
	Invested in Property and Equipment	Internally Restricted	Unrestricted	Total	Total
Balance - at beginning of year	\$ 4,333,685	\$ 7,125,000	\$ 321,944	\$ 11,780,629	\$ 12,154,686
Excess (deficiency) of revenues over expenses for the year	(351,230)	-	1,457,392	1,106,162	(374,057)
	3,982,455	7,125,000	1,779,336	12,886,791	11,780,629
Inter-fund transfers representing:					
Purchase of capital assets (net of disposals)	167,255	-	(167,255)	-	-
Investigations and hearings reserve fund					
- net expenses in the year	-	(1,383,523)	1,383,523	-	-
- inter-fund transfer	-	2,738,523	(2,738,523)	-	-
	167,255	1,355,000	(1,522,255)	-	-
Balance - at end of year	\$ 4,149,710	\$ 8,480,000	\$ 257,081	\$ 12,886,791	\$ 11,780,629

Draft - May 2017

ONTARIO COLLEGE OF PHARMACISTS

STATEMENT OF CASH FLOWS

YEAR ENDED DECEMBER 31, 2016

	2016	2015
Cash flows from operating activities		
Excess (deficiency) of revenues over expenses for the year	\$ 1,106,162	\$ (374,057)
Item not requiring a current cash outlay		
Depreciation	351,230	365,708
	1,457,392	(8,349)
Changes in non-cash working capital balances		
Accounts receivable and cost recoveries	(43,022)	44,970
Prepaid expenses	(197,277)	108,383
Accounts payable and accrued liabilities	(311,247)	(190,473)
Deferred revenue	1,663	(41,250)
	907,509	(86,719)
Cash flows from investing activities		
(Purchase) disposal of investments	(988,671)	343,623
Purchase of capital assets	(85,192)	(341,022)
Building renovations	(82,063)	(16,345)
	(1,155,926)	(13,744)
Change in cash during the year	(248,417)	(100,463)
Cash - at beginning of year	500,614	601,077
Cash - at end of year	\$ 252,197	\$ 500,614

Draft - Mar 31/17

ONTARIO COLLEGE OF PHARMACISTS

NOTES TO THE FINANCIAL STATEMENTS

YEAR ENDED DECEMBER 31, 2016

Mission: The Ontario College of Pharmacists (the "College") regulates pharmacy to ensure that the public receives quality services and care. The vision of the College is to lead the advancement of pharmacy to optimize health and wellness through patient centred care.

The College is the registering and regulating body for pharmacy practice in Ontario. All persons within Ontario who wish to dispense prescriptions and sell products defined as drugs to the public must first have met the professional qualifications set by the College, and be registered as a pharmacist or pharmacy technician. Likewise, all pharmacies must meet certain standards for operations and be accredited by the College. In addition to setting initial standards, the College ensures ongoing adherence to the professional and operational standards.

The College is a not-for-profit organization, incorporated as a non-share capital corporation in 1871 under the laws of Ontario and, as such, is generally exempt from income taxes.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

These financial statements have been prepared using Canadian accounting standards for not-for-profit organizations and include the following significant accounting policies:

Financial Instruments

The College initially measures its financial assets and financial liabilities at fair value. The College subsequently measures all its financial assets and financial liabilities at amortized cost.

Financial assets and liabilities measured at amortized cost include cash balances with banks, short-term investments, long-term investments, accounts receivable and cost recoveries and accounts payable and accrued liabilities.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided over the estimated useful lives of the assets at the following annual rates:

Buildings	- 4% declining balance
Furniture and equipment	- 15% declining balance
Computer equipment	- straight line over 3 years
Computer software	- straight line over 2 years

The above rates are reviewed annually to ensure they are appropriate. Any changes are adjusted for on a prospective basis. If there is an indication that the assets may be impaired, an impairment test is performed that compares carrying amount to net recoverable amount. There were no impairment indicators in 2016.

ONTARIO COLLEGE OF PHARMACISTS

NOTES TO THE FINANCIAL STATEMENTS

YEAR ENDED DECEMBER 31, 2016

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Revenue Recognition

Fees

The College's principal source of revenue is membership and pharmacy fees which are recognized as revenue in the period to which these fees relate. Membership and pharmacy fees received in the current year, applicable to a subsequent year are recorded as deferred revenue on the statement of financial position and will be accounted for in income in the year to which they pertain.

Investment Income

Investment income consists of interest and is recorded as earned.

Other Revenues

All other revenues being registration and other fees, rental income and other miscellaneous income are recognized as revenue when services are provided or as earned.

Use of Estimates

The preparation of the College's financial statements in conformity with Canadian accounting standards for not-for-profit organizations requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the year.

Key areas where management has made difficult, complex or subjective judgments, often as a result of matters that are uncertain, include, among others, accounts receivable valuation, useful lives for depreciation and amortization of property and equipment and other assets and liabilities valuation. Actual results could differ from these and other estimates, the impact of which would be recorded in future periods.

2. BUDGET FIGURES

The budget figures in the Statement of Operations and the Schedule of Expenses are provided for information purposes, are unaudited and are approved by the Council.

3. ACCOUNTS RECEIVABLE

As at December 31, 2016 the carrying amount of impaired receivables totalled \$205,000 (\$205,000 in 2015). The accounts receivable are presented net of the impairment.

ONTARIO COLLEGE OF PHARMACISTS

NOTES TO THE FINANCIAL STATEMENTS

YEAR ENDED DECEMBER 31, 2016

4. INVESTMENTS

Details of investments are as follows:

	2016	2015
Short-Term		
Guaranteed investment certificates - BMO Bank of Montreal 1.10% maturing March 13, 2017	\$ 1,500,000	\$ -
Long-Term		
Guaranteed investment certificates - BMO Bank of Montreal 2.30% to 2.55% (2.30% to 2.55% in 2015), maturing April 27, 2019 to October 18, 2019 (April 27, 2019 to October 18, 2019 in 2015)	7,731,305	8,242,634
	\$ 9,231,305	\$ 8,242,634

Investment Risk Management

Risk management relates to the understanding and active management of risks associated with all areas of the College's activities and operations. Investments are primarily exposed to interest rate risk. The College has formal policies and procedures for investment transactions and investments are made on the advice of portfolio manager.

Interest Rate Risk

Interest rate risk arises from the possibility that changes in interest rates will affect the value of fixed income securities held by the College. The value of fixed income investments will generally rise if interest rates fall and decrease if interest rates rise. The College is exposed to interest rate risk on its fixed rate investments.

5. PROPERTY AND EQUIPMENT

Details of property and equipment are as follows:

	Cost	Accumulated Depreciation	<u>Net Book Value</u>	
			2016	2015
Land	\$ 363,134	\$ -	\$ 363,134	\$ 363,134
Buildings	6,104,041	2,775,254	3,328,787	3,383,714
Furniture and equipment	1,452,610	1,186,568	266,042	308,273
Computer equipment and software	2,550,060	2,358,313	191,747	278,564
	\$ 10,469,845	\$ 6,320,135	\$ 4,149,710	\$ 4,333,685

ONTARIO COLLEGE OF PHARMACISTS

NOTES TO THE FINANCIAL STATEMENTS

YEAR ENDED DECEMBER 31, 2016

6. NET ASSETS - INTERNALLY RESTRICTED

The Council of the College has internally restricted net assets to be used for specific purposes. These funds are not available for unrestricted purposes without approval of the Council. The internally restricted net assets at December 31 are as follows:

	2016	2015
Investigations and hearings reserve fund	\$ 2,280,000	\$ 2,000,000
Contingency reserve fund	4,670,000	4,250,000
Fee stabilization fund	1,530,000	875,000
	\$ 8,480,000	\$ 7,125,000

Investigations and Hearings Reserve Fund

The Investigations and Hearings Reserve Fund is designated to cover costs including legal costs, for the conduct of inquiries, investigations, discipline hearings, fitness to practice hearings, appeals and payments under the program for funding for therapy and counselling which exceed annual budget provisions for those activities.

Contingency Reserve Fund

The Contingency Reserve Fund is designated to provide for extraordinary expenses that exceed or fall outside of the provisions of the College's operating budget and to fund the College's obligations in extreme circumstances as determined and approved by the Council.

Fee Stabilization Fund

The Fee Stabilization Fund is designated to minimize or delay the impact of year-over-year changes in revenues or expenses on membership renewal fees.

7. FINANCIAL INSTRUMENTS AND RISK EXPOSURE

The College is exposed to various risks through its financial instruments. The following analysis provides a measure of the College's risk exposure at the statement of financial position date.

Credit Risk

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation. The College's main credit risks relate to accounts receivable and cost recoveries. The College monitors this risk and has included an adequate provision for doubtful accounts in the financial statements.

Liquidity Risk

Liquidity risk is the risk that the College will encounter difficulty in meeting obligations associated with financial liabilities. The College is exposed to this risk mainly in respect of its accounts payable and accrued liabilities and commitments. The College expects to meet these obligations as they come due by generating sufficient cash flow from operations.

Market Risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises three types of risk: currency risk, interest rate risk and other price risk. The College is not exposed to currency or price risks. The interest rate risk is disclosed in note 4.

ONTARIO COLLEGE OF PHARMACISTS

NOTES TO THE FINANCIAL STATEMENTS

YEAR ENDED DECEMBER 31, 2016

8. COMMITMENTS

(a) The College is committed to payments of \$200,000 in 2017 and \$150,000 in 2018 to the University of Waterloo to support the Pharmacy 5in5 program in the Faculty of Science, School of Pharmacy.

(b) The College contracted the Professional Health Program Services of the Centre for Addiction and Mental Health ("CAMH") effective October 1, 2014 (prior to October 1, 2014, these services were provided by the Ontario Medical Association) to monitor members deemed to be incapacitated in accordance with the provisions of the legislation. Members are monitored over a period of time, depending on the nature of their incapacity. During fiscal year 2016, the College expended \$128,000 (\$103,000 - 2015) towards the monitoring of identified members. The remaining commitment of the College is as follows:

2017	\$	128,333
2018		108,499
2019		74,666
2020		57,166
2021		28,000
	\$	<u>396,664</u>

(c) The College is committed to annual rental payments under leases for office equipment and a vehicle, expiring from January 2019 to December 2020 as follows:

		<i>Equipment</i>	<i>Automobiles</i>
Fiscal year ending December 31	2017	\$ 23,422	\$ 10,188
	2018	23,422	10,188
	2019	23,422	10,188
	2020	23,422	-
		\$ 93,688	\$ 30,564

9. PENSION PLAN

The College sponsors a defined contribution pension plan for its employees. The contribution required by the College is a function of qualified employees' annual earnings. The pension expense recognized by the College for the year was \$455,693 (\$421,414 - 2015).

10. CREDIT FACILITY

The College has a credit facility available in the amount of \$1,500,000 bearing interest at bank prime rate, subject to certain terms and conditions. At December 31, 2016, the facility had not been drawn upon.

ONTARIO COLLEGE OF PHARMACISTS

NOTES TO THE FINANCIAL STATEMENTS

YEAR ENDED DECEMBER 31, 2016

11. GUARANTEES AND INDEMNITIES

The College has indemnified its past, present and future directors, officers and volunteers against expenses (including legal expenses), judgments and any amount actually or reasonably incurred by them in connection with any action, suit or proceeding, subject to certain restrictions, in which they are sued as a result of their involvement with the College, if they acted honestly and in good faith with a best interest of the College. The College has purchased directors' and officers' liability insurance to mitigate the cost of any potential future suits and actions, but there is no guarantee that the coverage will be sufficient should any action arise.

In the normal course of business, the College has entered into agreements that include indemnities in favour of third parties, either express or implied, such as in service contracts, lease agreements and purchase contracts. In these agreements, the College agrees to indemnify the counterparties in certain circumstances against losses or liabilities arising from the acts or omissions of the College. The terms of these indemnities are not explicitly defined and the maximum amount of any potential liability cannot be reasonably estimated.

12. COMPARATIVE FIGURES

Certain comparative figures in the Statement of Operations and Schedule of Expenses have been reclassified to conform with the financial statement presentation for the current year.

Draft - Mar 2017

ONTARIO COLLEGE OF PHARMACISTS
SUMMARY FINANCIAL STATEMENTS
YEAR ENDED DECEMBER 31, 2016

Independent Auditor's Report	Page 1
Summary Balance Sheet	2
Summary Statement of Operations and Net Assets	3

Draft - Feb 10/17

**INDEPENDENT AUDITOR'S REPORT ON
SUMMARY FINANCIAL INFORMATION**

TO THE MEMBERS OF COUNCIL ONTARIO COLLEGE OF PHARMACISTS

The accompanying summary financial statements of the Ontario College of Pharmacists, which comprise the summary balance sheet as at December 31, 2016 and the summary statement of operations and net assets for the year then ended, are derived from the audited financial statements of the Ontario College of Pharmacists for the year ended December 31, 2016. We expressed an unmodified audit opinion on those financial statements in our report dated March 20, 2017.

The summary financial statements do not contain all the disclosures required by Canadian accounting standards for not-for-profit organizations. Reading the summary financial statements therefore, is not a substitute for reading the audited financial statements of the College.

Management's Responsibility for the Summary Financial Statements

Management is responsible for the preparation of a summary of the audited financial statements in accordance with Canadian accounting standards for not-for-profit organizations.

Auditor's Responsibility

Our responsibility is to express an opinion on the summary financial statements based on our procedures, which were conducted in accordance with Canadian Auditing Standard (CAS) 810, "Engagements to Report on Summary Financial Statements".

Opinion

In our opinion, the summary financial statements derived from the audited financial statements of Ontario College of Pharmacists for the year ended December 31, 2016 are a fair summary of those financial statements, in accordance with Canadian accounting standards for not-for-profit organizations.

Toronto, Ontario
March 20, 2017

CHARTERED ACCOUNTANTS
Licensed Public Accountants

ONTARIO COLLEGE OF PHARMACISTS

SUMMARY BALANCE SHEET

AS AT DECEMBER 31, 2016

	2016	2015
ASSETS		
Current assets		
Cash and short-term investments	\$ 1,752,197	\$ 500,614
Accounts receivable and cost recoveries	206,892	163,871
Prepaid expenses	312,764	115,487
	2,271,853	779,972
Long-term investments	7,731,305	8,242,634
Property and equipment	4,149,710	4,333,685
	14,152,868	13,356,291
LIABILITIES		
Current liabilities		
Accounts payable and accrued liabilities	1,204,528	1,515,775
Deferred revenue	61,550	59,887
	1,266,078	1,575,662
NET ASSETS		
Net assets invested in property and equipment	4,149,710	4,333,685
Internally restricted		
Investigations and hearings reserve fund	2,280,000	2,000,000
Contingency reserve fund	4,670,000	4,250,000
Fee stabilization fund	1,530,000	875,000
Unrestricted	257,080	321,944
	12,886,790	11,780,629
	\$ 14,152,868	\$ 13,356,291

Approved on behalf of the Council:

_____, President _____, Chair of Finance Committee

ONTARIO COLLEGE OF PHARMACISTS
SUMMARY STATEMENT OF OPERATIONS AND NET ASSETS
YEAR ENDED DECEMBER 31, 2016

	2016	2015
Revenues		
Member fees - Pharmacists	\$ 9,175,702	\$ 8,825,392
Member fees - Pharmacy Technicians	1,713,306	1,501,194
Community Pharmacy fees	4,417,290	3,856,597
Hospital Pharmacy fees	908,000	-
Registration fees and income	792,555	1,603,841
Investment and other income	245,374	246,042
	17,252,227	16,033,066
Expenses		
Council and committees	2,138,929	2,563,076
Administration	13,530,066	13,340,636
Property	125,841	137,703
	15,794,836	16,041,415
Excess of revenues over expenses from operations for the year before depreciation	1,457,391	(8,349)
Depreciation	351,230	365,708
Excess of revenues over expenses for the year	1,106,161	(374,057)
Net assets - at beginning of year	11,780,629	12,154,686
Net assets - at end of year	\$ 12,886,790	\$ 11,780,629

Draft - Feb 10/17

**Clarke
Henning
LLP**

Chartered Accountants

801 - 10 Bay Street
Toronto, Ontario
Canada M5J 2R8
Tel: 416-364-4421
Fax: 416-367-8032



February 27, 2017

Members of the Finance and Audit Committee
Ontario College of Pharmacists
483 Huron Street
Toronto, ON M5R 2R4

Dear Members of the Finance and Audit Committee:

**ONTARIO COLLEGE OF PHARMACISTS
AUDIT OF 2016 FINANCIAL STATEMENTS**

To identify and assess the risks of material misstatement in the financial statements, we are required to obtain an understanding of internal control relevant to the audit. This understanding is used for the purpose of designing appropriate audit procedures. It is not used for the purpose of expressing an opinion on the effectiveness of internal control. The limited purpose also means that there can be no assurance that all significant deficiencies in internal control, or any other control deficiencies, will be identified during our audit.

A deficiency in internal control exists when a control is designed, implemented or operated in such a way that it is unable to prevent, or detect and correct, misstatements in the financial statements on a timely basis, or when a control necessary to prevent, or detect and correct, misstatements in the financial statements on a timely basis is missing.

A significant deficiency in internal control is defined as a deficiency or combination of deficiencies in internal control that, in the auditor's professional judgment, is of sufficient importance to merit the attention of those charged with governance.

During the course of our audit of the financial statements of Ontario College of Pharmacists for the year ended December 31, 2016, we did not identify any of the following matters:

- (a) any control deficiencies that, in our judgment, would be considered significant deficiencies;
- (b) misstatements, other than trivial errors;
- (c) fraud, intentional misstatements, errors;
- (d) misstatements that may cause future financial statements to be materially misstated; or
- (e) illegal, or possibly illegal acts.

This communication is intended solely for the information and use of the Finance and Audit Committee, the Council and management and is not intended to be, and should not be, used by anyone other than these specified parties. Accordingly, we assume no responsibility to any other party who may rely on it.

We would like to express our appreciation for the co-operation we received from management and staff with whom we worked during the audit.

Yours very truly,
CLARKE HENNING LLP

Liana Bell, CPA, CA
Partner
lbell@clarkehenning.com

Copy: Ms. Nancy Lum-Wilson, Registrar & CEO
Ms. Connie Campbell, Director, Finance & Administration

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COUNCIL BRIEFING NOTE

MEETING DATE: MARCH 2017

FOR DECISION

X

FOR INFORMATION

INITIATED BY: Medication Safety Task Force

TOPIC: Continuous Quality Improvement (CQI) for Medication Safety

ISSUE: Circulation of a proposed model for a standardized continuous quality assurance program for pharmacies, including the collection of medication incident data.

BACKGROUND:

- Following an incident linked to a compounded medication error, the College reviewed the current processes for medication incident reporting in Ontario and completed a jurisdictional review to identify similar processes across Canada.
- The College's current approach is to rely on policies and Standards of Practice for designated managers and pharmacy professionals related to management of medication errors to improve patient safety. The College provides additional guidance to pharmacy professionals through multiple communication channels (e.g. articles, practice tools, practice advisors).
- In December 2016, Council directed the formation of a Task Force to develop a model for a standardized continuous quality improvement program.
- The composition of the Task Force included a public member, a patient representative, a pharmacy technician, a hospital pharmacist and two pharmacists from varying community practices.
- The jurisdictional review confirmed that Nova Scotia is the only province with a requirement for mandatory reporting to an external third party and that Saskatchewan recently approved full implementation of a mandatory reporting requirement for November 2017.
- Manitoba has recently approved a pilot program that began in January 2017 and PEI has committed to reviewing this topic in 2017.
- The College has consulted with the Nova Scotia College of Pharmacists and The Saskatchewan College of Pharmacy Professionals to gather information about SafetyNET-Rx and COMPASS, which are the standardized CQI programs that have been implemented in these jurisdictions.
- The Task Force also invited the Institute for Safe Medication Practice (ISMP) to present to the Task Force on Medication Safety and Continuous Quality Improvement (CQI) in Pharmacy Practice.

DISCUSSION:

- Media and public attention regarding the recent medication incident in Ontario has been focused on the issue of mandatory reporting of medication errors.
- Dr. Eric Hoskins, Ontario's Minister of Health and Long-Term Care has expressed his support for mandatory reporting and has requested that the College follow-up with Nova Scotia to better understand their processes.

Model for Continuous Quality Improvement

- Based on information provided by ISMP, as well as the other jurisdictions, the Task Force determined that an effective Continuous Quality Assurance (CQA) Program would support a CQI model that focuses on systemic review of processes and root cause analysis of individual incidents to inform quality improvement initiatives.
- The objective of this CQA approach, which includes analysis of how the error came to be and reporting the error to an external body, is to ensure that all practitioners learn from these incidents and review and enhance their policies and procedures to reduce the chances of recurrence thereby improving patient safety.
- Medication error reporting provides the data required to support a systemic review of errors in individual pharmacies as well as an aggregate review of national trends.
- All jurisdictions consulted stated that mandatory standardized CQA programs have resulted in numerous benefits such as; reduction in blame and fear in discussing medication errors, more open discussions about near misses to prevent similar incidents from reaching a patient, increased practitioner accountability, clearer practice expectations with respect to CQI, increase in shared learnings and increased awareness of safety issues.

Medication Incident Reporting

- Based on feedback and recommendations from Saskatchewan and Nova Scotia, the Task Force determined that including a specified third party for incident reporting would maintain the quality of aggregate data and prevent data dilution in the event of multiple third party providers.

Sharing Learnings

- Feedback from Saskatchewan and Nova Scotia indicated that annual Medication Safety Self-Assessment (MSSA) completion was a barrier for many pharmacies due to time restrictions and that one year may not be sufficient to implement and monitor all quality improvement initiatives identified. ISMP recommends completion of an MSSA every one to three years.
- The Task Force proposed requirements for the completion of a MSSA every 2 to 3 years, or more frequently if needed, concluding that the recommended schedule would best support success and uptake of a CQA program.

- To support maximal uptake and reduce barriers presented by formal face-to-face meetings, the Task Force included a requirement that pharmacies implement regular communication between pharmacy staff regarding medication incidents and safety initiatives (i.e. would not always require face-to-face meetings) to encourage increased frequency of discussions.

Implementation

- The Task Force recommends that the College implement a mandatory standardized CQA program that outlines program requirements all pharmacy professionals must meet, including a requirement for medication incident reporting.
- Saskatchewan and Nova Scotia highlighted the need to implement in phases to allow for the development of peer champions that can support a more seamless full implementation by acting as mentors or coaches.
- Based on this feedback, the Task Force recommends that implementation occur over two phases, the initial phase to include volunteer pharmacies that are representative of pharmacy practice across Ontario (e.g. independent, chain, rural, urban) and the second phase to build upon the initial volunteers to further strengthen the peer champion network.
- As part of the enhanced practice assessments, practice advisors will review adherence to pharmacy CQA requirements and individual practice standards related to continuous quality improvement, as well as the requirements outlined in the mandatory standardized Continuous Quality Assurance Program (Appendix A).

NEXT STEPS:

- Should Council recommend that the College release the proposed model for public consultation, the proposed model (Appendix A) will be posted on the College website for 30 days following which the results will be presented to Council at its June meeting.
- Consultation would be framed by presenting specific questions to guide feedback on the concept the College is proposing to best ensure successful adoption by pharmacists.
- The College will develop a comprehensive implementation and monitoring plan including an expected date of full achievement.
- The College will develop a comprehensive communication plan to support successful implementation. Stakeholders, including educators, are being identified.

DECISION FOR COUNCIL:

- Recommend that Council support public consultation on the proposed model for a Continuous Quality Assurance Program in Pharmacies in order to determine potential barriers to full implementation as well as factors to support successful rollout.
- Does Council have any feedback on the proposed model prior to posting for consultation?



Continuous Quality Assurance Programs in Pharmacies

Recent studies on the prevalence of medication errors have brought increased attention to continuous quality improvement (CQI) in healthcare in North America. These reports have identified the need for increased efforts to create a safer healthcare delivery system.¹

In 2015, as part of its commitment to CQI, the College introduced enhancements to the long-standing pharmacy inspection process. Now referred to as practice assessments, the new process is designed to increase adherence to both pharmacy operational and individual practice standards. In an ongoing effort to improve patient safety, community pharmacies are required to implement a mandatory standardized continuous quality assurance program that enables enhancement of the safety culture of pharmacies.

Continuous quality improvement (CQI) involves an ongoing and systematic examination of an organization's work processes to identify and address the root causes of quality issues and implement corresponding changes.² Effective CQI programs involve implementation of quality improvements as a result of both proactive review of work processes to identify areas of risk and retrospective review of specific medication incidents. The objective of CQI is to ensure that all practitioners learn from medication incidents and review and enhance their policies and procedures to reduce the chances of recurrence, thereby improving patient safety.

According to the Standards of Practice, all pharmacists and pharmacy technicians have the responsibility and obligation to manage medication incidents and address unsafe practices. This includes documenting and communicating all medication incidents and near misses with the rest of the staff in the pharmacy, and as appropriate to the patient and other health care providers if the incident reaches the patient. It is the responsibility of the Designated Manager (DM) to ensure that there is an appropriate mechanism in place for this to occur, and that learnings are continuously being documented, identified and applied to improve processes within the pharmacy.

To achieve safer care for patients, CQI must focus on both systemic improvements and the tasks that individual practitioners perform. The CQI model supports shared accountability; it holds pharmacies accountable for the systems they design and for how they respond to staff behaviours fairly and justly. It holds pharmacy professionals accountable for the quality of their choices and for reporting both their errors and system vulnerabilities. To enable a culture that supports learning and accountability over blame and punishment, individuals must be comfortable to discuss medication incidents without fear of punitive outcomes.

A critical element in safe medication practices is the sharing of lessons learned from medication incidents through medication error and near miss reporting, to support sustainable changes in practise. Using the lessons learned from both medication incidents and near misses enables continuous process improvements to minimize errors and maximize health outcomes to improve the quality of care provided in pharmacies.

¹ A Systemic Review of Medication Errors. International Journal of Drug Development and Research (2015). Retrieved on January 31, 2016 from <http://www.ijddr.in/drug-development/a-systematic-review-on-medication-errors.php?aid=7947>

² Boyle TA, Bishop AC, Duggan K, Reid C, Mahaffey T, MacKinnon NJ, et al. Keeping the "continuous" in continuous quality improvement: Exploring perceived outcomes of CQI program use in community pharmacy. *Res Social Adm Pharm* 2014 Jan-Feb; 10(1): 45-57.

The required components of an effective standardized quality assurance program for pharmacies addresses both medication errors that reach the patient as well as near misses that are intercepted prior to dispensing, and must achieve all of the following four elements:

Report

- Enable and require *anonymous* reporting of all medication incidents by pharmacy professionals to a specified independent, objective third-party organization for population of an aggregate incident database to identify issues and trends to support patient safety improvement.

Document

- Require pharmacy professionals to document appropriate details of medication incidents and near misses in a timely manner to support the accurateness of information reported.
- Document CQI plans and outcomes of staff communications and quality improvements implemented.

Analyze

- Necessitate that when a medication incident occurs pharmacy professionals analyze the error in a timely manner for causal factors and commit to taking appropriate steps to minimize the likelihood of recurrence of the incident.
- Require completion of a medication safety self-assessment (MSSA) within the first year of implementation of the Standard, then at least every 2-3 years. The Designated Manager may determine an MSSA is required more frequently if a significant change occurs in the pharmacy.
- Analyze individual and aggregate data to inform the development of quality improvement initiatives.

Share Learning

- Require prompt communication of appropriate details of a medication incident to all pharmacy staff, including causal factors of the error and actions taken to reduce the likelihood of recurrence.
- Ensure the scheduling of regular CQI communication with pharmacy staff to educate pharmacy team members on medication safety, encourage open dialogue on medication incidents, complete an MSSA, and develop and monitor quality improvement plans.
- Support the development and monitoring of CQI plans, outcomes of CQI communications and quality improvements implemented.



COUNCIL BRIEFING NOTE

MEETING DATE: MARCH 2017

FOR DECISION

X

FOR INFORMATION

INITIATED BY: Executive Committee

TOPIC: Bill 87: Proposed Amendments to the *Regulated Health Professions Act*

ISSUE: To obtain Council's feedback on the Ontario College of Pharmacists' proposed amendments to Bill 87 to inform the College's response and ongoing involvement in the legislative process.

BACKGROUND:

In December 2016, in response to the recommendations made by the Minister's *Sexual Abuse Task Force*, the government introduced an omnibus bill amending five statutes, including the *Regulated Health Professions Act*. Proposed amendments will:

- Confer additional powers on the Minister to:
 - a. Make regulations affecting statutory committee structure and function
 - b. Require Colleges to gather and disclose additional information, and
 - c. Provide for additional authority for Patient Relations Committees;
- Increase transparency;
- Improve the response to sexual abuse; and
- Enact miscellaneous revisions to strengthen patient protection and uphold the public interest.

Health regulators support the majority of the measures proposed in the Bill; however, the proposals within the legislation will impact the College and the profession. The College plans to submit a response to the proposed legislation calling for additional review and discussion in several areas, including:

1. The impact of changes to committee and panel structures;
2. Providing immediate funding to a patient alleging abuse;
3. Defining additional circumstances for mandatory reporting and revocation;
4. The definition of 'patient'; and
5. The impact of time-limited ADR.

The Ministry has indicated the following next steps:

- The legislative process will continue and proclamation is anticipated to be in Spring 2017;
- The work on the regulation-making authorities proposed in the Bill will proceed as soon as possible;
- An Expert Advisor, Deanna Williams, will begin work on reviewing best practices for processes related to complaints, investigations and discipline within the regulatory colleges; and
- The ministry will begin additional work on outstanding Sexual Abuse Task Force Recommendations.

DISCUSSION:

The College supports the objectives of Bill 87 which are to increase patient protection and to ensure that the process for investigating and adjudicating allegations of sexual abuse is robust, transparent and consistent among all health regulators. A response to the Minister may be formed by the following recommendations:

1. *Committee and Panel Structures:*

The structure of committees and panels may be changed through circumscribing the qualifications, training and experience of members and adopting measures, such as changes to quorum provisions which may limit participation by professional members and increase the participation of public members.

Recommendations:

- Support the addition of public members and recommend taking an outcome- based approach to framing the regulations, establishing the criteria that would define the qualifications of potential members;
- Recognize the difficulty in recruiting public members through the public appointments process and suggest other options that utilize the established criteria be considered;
- Recommend that new public members, if any, be provided with training and education to ensure an efficient and effective committee/panel process; and
- With respect to potential changes to the functions of the Patient Relations Committee, recommend that consultation be undertaken, including seeking and incorporating feedback from existing committee members.

2. *Funding for Sexual Abuse:*

Providing patients with earlier access to funding for therapy and counselling and expanding the purposes to which funding can be applied

Recommendations:

- Support the principle of providing earlier funding to a complainant and to providing flexibility on the types of expenses for which funding is available;
- Recommend flexibility in eligibility for funding in cases where complainants may wish for their name to be withheld from a mandatory report;
- Recommend that the College propose the regulations be outcome-based in order to permit patients to exercise choice over how funding is applied;
- Address the possibility that measures may remove the ability to provide funding to patients through the alternative criteria established by current regulation.

3. *Mandatory Revocation:*

The criteria for mandatory revocation will be expanded to include additional sexual acts and to permit the Minister to add additional non-sexual grounds.

Recommendation:

- Support both potential changes which would permit the College to take measures to protect the public in the face of egregious proprietary misconduct, such as fraud or drug offences, in addition to sexual misconduct.

4. The Definition of 'Patient' for Sexual Abuse Purposes:

Criteria for the definition of 'patient' will be established in relation to professional misconduct through the sexual abuse of a patient, including setting a time period of a year in which a professional may not have a sexual relationship with a former patient.

Recommendations:

- Support the measure and recommend that a criteria-based approach be applied, allowing sufficient latitude among health regulators to establish a definition that aligns to practice and the type of contact between health professionals and patients;
- Provide feedback related to a recent jurisdictional review of pharmacy regulators that failed to identify a definition that could be applied in all circumstances of patient contact; and
- Reflect that the time period of one year, regardless of when it begins and ends, might not be sufficient.

5. Alternate Dispute Resolutions and Withdrawals of Complaints

Providing the Registrar with the authority to approve ADR resolutions and withdrawals of complaints within approved time limits

Recommendations:

- Support the measure while suggesting that further review be conducted to ensure that the time periods established do not present barriers to reaching an agreement where parties are negotiating in good faith.

Additional Legislative Changes

Early Interim Suspension

An interim order for suspension may be made prior to a referral to discipline in cases where the public is at risk.

The College supports this measure and recommends, in the context of this omnibus bill, that this approach is extended to actions that may be taken under the *Drug and Pharmacies Regulation Act* (DPRA). Patient safety and protection will be served by permitting the Accreditation Committee to take immediate steps to order a pharmacy's certificate of accreditation to be immediately suspended when warranted.

Non-Council Public Members

The College recommends that changes be enacted to permit non-council public members to be included in the Quorum for the Inquiries, Complaints and Reports Committee and the Discipline Committee to ensure that matters before these committees can be addressed in a timely, efficient and effective manner.

It is recommended that the College propose that public members be compensated to support them in their public service.

Permit Discretion to Provide Information to the Police

At present, the College can only provide information to police about members. In the event that criminal activity involving non-members is uncovered in a pharmacy, additional discretionary measures are needed to protect the public.

It is recommended that the College be permitted to share information about non-members to police, when it is in the public interest to do so.

Drafting Suggestions

It is recommended that the College indicate support for the drafting suggestions proposed by the *Federation of Health Regulatory Colleges of Ontario* in Appendix 1 of their letter of submission.

KEY MESSAGES

- The College supports actions that provide better patient protection and strengthen its role to serve and protect the public.
- The proposed regulatory changes align with the College's value of and commitment to transparency, and support many of the actions the College has already undertaken to share more information with the public.
- As with any changes to established processes, clarity will be required around how the College may provide input and how any new responsibilities or priorities will be balanced with existing ones.
- The College supports the definition of a "patient", and any measures that establish the existence of a pharmacist- patient relationship and prevent sexual abuse. It is important that the description of a "patient" is broad enough to take into account the wide variety of ways that pharmacy professionals and patients interact.

NEXT STEPS:

Letter to Minister of Health and Long-Term Care

- From President and Registrar, content based on this Briefing Note;

Monitor the Legislative Process

- College staff will monitor the legislative process, make submissions and participate in committee hearings;

Collaborate with Health Regulators

- College staff will continue to meet with health regulator partners to consider the proposed amendments and their impact on health professionals; and

Prepare for Implementation

- On an ongoing basis, the impacts of the proposed amendments on College processes and finances will be identified, and the College will begin preparation for implementation.

RECOMMENDATION: That Council approve the Next Steps.



Federation of Health Regulatory Colleges of Ontario (FHRCO)
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February 27, 2017

Hon. Dr. Eric Hoskins, Minister
Ministry of Health and Long-Term Care
Hepburn Block, 10th Flr
80 Grosvenor St
Toronto ON M7A 2C4

TRANSMITTED BY FAX AND EMAIL

Dear Minister Hoskins:

Re: Submissions of the Federation of Health Regulatory Colleges of Ontario on Bill 87

The Federation of Health Regulatory Colleges of Ontario welcomes the opportunity to make submissions on the proposed amendments to the *Regulated Health Professions Act (RHPA)* found in Schedule 4 of Bill 87, *Protecting Patients Act, 2016*.

Introduction

The Federation is the provincial organization that brings together the 26 health regulatory Colleges for the health professions governed under the *RHPA*. Under the statutory mandate to protect the public interest through regulation, the Colleges govern more than 300,000 health professionals in Ontario.

The members of the Federation are committed to having the strongest legislative framework available to support patients and prevent sexual abuse. The Federation supports the intent and assumed goals of Bill 87; many of the provisions in Bill 87 that pertain to transparency have already been implemented by many *RHPA* Colleges. In some areas, Bill 87 could go further to protect the public and support the effectiveness of College complaints, investigations, and discipline processes.

The Federation's members, with their expertise in regulating health professionals in the public interest, can provide a unique perspective in ensuring that the proposals are effective and able to achieve the outcomes that will protect the public. As such, the Federation is making a number of suggestions, collating the amendments into four substantive topics dealing with:

1. Reducing and Eliminating Sexual Abuse;
2. Enhancing Transparency;
3. Increased Powers of the Minister; and
4. Miscellaneous Amendments.

We have also provided an appendix which addresses drafting issues. The Federation understands and supports the intentions behind these revisions to the *RHPA* and the *Health Professions Procedural Code* (the “Code”) but there are some matters that we believe are quite significant and need to be carefully considered in order to avoid unintended negative consequences.

While we have provided as much feedback as possible in this early submission, we know that more could be achieved through ongoing discussion as the Bill moves through the legislative process.

1. Reducing and Eliminating Sexual Abuse

a. Minister Prescribed Functions: RHPA s. 43(1)(w). This amendment permits the Minister to make regulations specifying how Colleges are to investigate and prosecute sexual misconduct cases. In addition, the Minister can make regulations providing for further “functions and duties” for Colleges.

Federation member Colleges, with experience in sexual abuse matters, are continually working to improve their procedures for dealing with such cases; many of the proposals relating to sexual abuse in Bill 87 and in the Sexual Abuse Task Force report have already been implemented. Federation members, who operationalize legislation, are offering to work with the Ministry on regulations as they are developed. Federation members also look forward to working with the external advisor who will be appointed. Our suggestions in this area are put forward to strengthen the legislative framework to ensure that the provisions will achieve the desired outcome and avoid unintended negative consequences.

The Federation will have additional comments to make about this amendment and would welcome further information from the Ministry about the intent of the legislative amendments.

b. Funding for Sexual Abuse: RHPA s. 43(1)(y), Code s. 1.1, 85.7, 95(1)(q). The intention of this amendment is to expand funding for individuals who may have been sexually abused. As we understand it, eligibility for funding for a person who makes a complaint, or is the subject of a report that alleges sexual abuse, commences when the complaint or report is made. In addition, the Minister may make regulations expanding the types of expenses for which funding will be provided. The amendments also state that awarding funding will not be taken as a finding that sexual abuse occurred and cannot be considered by any other committee of the College, which reduces the likelihood that an appearance of bias challenge could be successfully made.

While the Federation supports broader access to funding, we note that these amendments may have a contrary effect in some instances.

Under the amendments, Colleges will no longer be able to maintain (or create) alternative criteria for funding by regulation (e.g., criminal findings of sexual assault of a patient; where the patient has not been named in a complaint or report). Accordingly, where Colleges intended to go beyond the criteria established in the Code, it might not be possible to do so. We urge revisions to avoid this.

c. Mandatory Revocation: RHPA s. 43(1)(u) and (v), Code 51(5) and (5.1), 71.1. The criteria for a mandatory revocation (and the corresponding inability to apply for reinstatement for at least five years) will be expanded to include a list of additional sexual acts. Additional grounds can be enacted through a Minister's regulation. The mandatory revocation also applies where a regulator outside of Ontario makes a finding of professional misconduct that involves the expanded list of revocable sexual acts. In addition, the Minister can make a regulation designating certain offences (e.g., sexual assault, fraud) as also requiring mandatory revocation.

The Federation supports the expansion of mandatory revocation for frank acts of sexual abuse. We are concerned about whether using a prescribed list of sexual acts is too restrictive an approach to take and would welcome the opportunity to discuss other approaches which might afford a higher level of protection without unintentionally excluding some acts that are potentially no less egregious than those on the list.

d. Other Orders by the Discipline Committee in Sexual Abuse Cases: Code s. 51(4.1) and (4.2), 51(5).2, 51(5).3(vi) and (vii). A discipline panel will be prevented from ordering gender-based restrictions in any case (not just sexual abuse cases). Where a discipline panel makes a finding of sexual abuse that requires mandatory revocation and defers the penalty portion of the hearing, it must immediately suspend the member's certificate of registration until the mandatory revocation is ordered. In addition, where a finding of sexual abuse is made and mandatory revocation is not required, a suspension must be ordered.

The Federation supports these changes. In our view, the requirement to suspend a member immediately where there is a finding that requires mandatory revocation is essential to public protection. We note that beyond sexual abuse findings, there are other situations in which mandatory revocation arises and this provision should be expanded to cover all such findings (i.e., offence findings resulting in mandatory revocation discussed in submission 1(c) above). There is no reason to permit a practitioner to keep practising where revocation will inevitably result when the penalty hearing is held. In fact, permitting the practitioner to practise in the interim could encourage attempts by the member to delay the penalty hearing.

e. Definition of Patient for Sexual Abuse Purposes: RHPA s. 43(1)(o), Code s. 1(6). These amendments address the definition of persons who constitute patients in the context of sexual abuse. A "patient" will include former patients for a period of one year after the professional relationship ends (or such longer time as prescribed in a College's regulation). In addition, the Minister can make regulations setting additional criteria for the definition of a "patient".

The Federation supports the intent of these proposed amendments, but urges an approach that will reduce the risk of unintended consequences. The Federation appreciates the need to prevent a practitioner from circumventing the mandatory penalty provisions in this amendment. The ambiguity in the proposed wording could prevent Colleges from fully addressing the goals of this amendment.

Colleges recognize that defining a "patient" is challenging and many have worked on defining a patient as appropriate for professions' practices and practice settings. We concur that there can be

value in consistency across professions but note that the provider/patient interface is highly variable. The nature of a “patient” may even vary considerably within a single profession (e.g., a radiologist viewing an x-ray as compared to a psychiatrist, both of whom are physicians).

In order to recognize this variability, courts show deference to the contextual approach taken by College Discipline Committees (e.g., *College of Physicians and Surgeons of Ontario v. McIntyre*, 2017 ONSC 116, and *Clokie v. Royal College of Dental Surgeons (Ontario)*, 2016 ONSC 4164).

We note, as well, that there are implications to having a different definition of “patient” for sexual abuse purposes and other purposes (e.g., abandonment of patients, billing, record retention, conflicts of interest) and this warrants further exploration.

Instead of a “one size fits all” approach, we believe that there would be value in prescribing criteria for defining “patient” for the purposes of sexual abuse (e.g., sharing of personal health information; circumstances where the person might reasonably rely on the practitioner in making health care decisions; reasonable expectation of being able to obtain additional services).

We also note that the proposed wording is ambiguous as it does not identify when the one-year period begins. It might be anticipated that this ambiguity could lead to unnecessary legal proceedings.

The Federation looks forward to further discussion of these issues.

e. Fines Increased for Failing to Make a Mandatory Report: Code s. 93(2) and (3). The maximum fine on a first offence for an individual who fails to make a mandatory report relating to sexual abuse will be doubled to \$50,000. For corporations, it will be quadrupled to \$200,000.

The Federation takes the mandatory reporting provisions seriously and supports these amendments.

2. Enhancing Transparency

The Federation believes that increased transparency, including the proposals in Bill 87, will enhance Ontario’s health professional regulatory system, which is recognized as having one of the most open professional regulation statutes in the world.

a. Expansion of the Public Register: RHPA s. 43(1)(t), Code s. 23, 94(1)(l.2). The mandatory, universal content of the Colleges’ public registers will be expanded. New information would include: the date a former member died if known, cautions, Specified Continuing Education and Remediation Programs (SCERPs), the date and status of referrals to discipline, a copy of the specified allegations, a synopsis of disciplinary and incapacity decisions even where the finding was that the allegations were not proved, acknowledgements and undertakings, and any inspection outcomes. Also, the Minister will be able to make a regulation requiring additional information to be placed on the public register. The Registrar will now have an explicit duty to post all information promptly. The Registrar will also be required to correct information that is incomplete or inaccurate. The “pardon” provision,

permitting the removal of less serious findings after six years, will be amended to prevent the deletion of any findings of sexual abuse, not just those where there has been sexual touching.

Colleges already have made by-laws placing most, if not all, of this information on their public registers and we support the provisions related to transparency in Bill 87. These provisions will bring consistency in the details of precisely how this information is posted on the register. We do note, however, that the expansion of the public register does not appear to include items that some Colleges currently post, such as relevant pending charges, bail conditions, and convictions. Those items appear to remain within the discretion of individual Colleges.

We also note that our ability to ensure that information related to criminal proceedings is complete and up-to-date is hampered by our own access to information. It would be a tremendous advance in the protection of the public interest to require the Attorney General to promptly notify Colleges of these events when they relate to registered practitioners.

In relation to this section, the Federation is quite concerned with the inclusion of an explicit requirement to correct information that is incomplete or inaccurate. Colleges already correct information that they learn is inaccurate or is no longer accurate. The current drafting of this section could allow for court challenges by members who might consider it their legal “right” to dilute the content of the wording on the public register, making the usefulness of the information negligible for the public. The outcome will be public register postings that are of less assistance to the public accessing them. This is a prime example of unintended consequences.

The Federation also raises whether the proposal to place a synopsis of incapacity determinations on the public register has been fully analyzed for compliance with the Ontario *Human Rights Code* and section 15 of the *Canadian Charter of Rights and Freedoms*. These determinations relate to whether the member has a disability that interferes with the safe practice of the profession, e.g., mental illnesses or substance abuse disorders that impair judgment. Even if this provision is found to be legal, there needs to be consideration regarding how public protection is enhanced by publishing details of those proceedings or determinations as opposed to the terms, conditions, and limitations that arise from them which are posted on the public register.

The Federation also notes that Bill 87 does not address transitional issues such as whether the posting of additional information applies to the date of the conduct, the date of the referral to discipline, or to the date of the disposition that occurs after the enactment. This lack of clarity is likely to result in legal challenges that will delay implementation and may lead to inconsistency of interpretation amongst Colleges.

b. New Mandatory Self-Reporting Obligations: Code s. 85.6.3, 85.6.4. Two new self-reporting obligations will be created. The first will require members to report all other regulatory bodies they are registered with and any findings of professional misconduct or incompetence (but not incapacity) made by those bodies. The second will require members to report all charges for an offence and any resulting bail conditions.

Many Colleges already require the reporting of this information through their by-laws. While the Federation generally supports the inclusion of these provisions, it would be desirable also to require the Attorney General to notify Colleges of charges for an offence and release conditions of practitioners.

c. Posting Council Meeting Information on the College Website, Code s. 7(1.1) and (1.2). Colleges will be required to post the dates and agendas for upcoming Council meetings on their websites.

Many Colleges already post this information. Currently the wording of the proposed amendments does not require the posting of Council meeting materials, which would enhance this provision. We note, however, that if Council meeting materials are added to the amendments, explicit exceptions should be specifically included for privileged materials (e.g., legal advice) as well as information that relates to any part of the meeting that it is anticipated will be closed to the public.

3. Increased Powers of the Minister

a. Committee Structure: RHPA s. 43(1)(p) to (s), Code s. 10(3), 17(2) and (3), 25(2) and (3), 38(2), (3) and (5), 64(2) and (3), 73(3).3, 94(1)(h.1) to (h.4). The Minister will have the power to make regulations controlling all aspects of the structure of the statutory committees. This authority will place in the hands of the Minister, and beyond the purview of the Legislature, the power to make fundamental changes to the very essence of self-regulation. Further submissions, including submissions from individual Colleges, will be made on this issue. At this point, the Federation believes it is impossible to assess the significance and impact of these broad ranging amendments without first seeing the proposed Minister's regulations. If enacted, the Federation trusts that the Minister will consult with the Colleges before making any regulations.

4. Miscellaneous Amendments

a. Disclosure of Information where there is a Compelling Public Interest: RHPA s. 36(1)(g). There are significant issues with the confidentiality provisions of the RHPA beyond the ability to disclose confidential information with regulators of long-term care homes (discussed below). For example, some Colleges have experienced media reports to the effect that someone told the College of a threat to public safety "and the College did nothing". Currently a College is generally not able to say anything other than that the matter is under investigation. This inability to respond to the assertion, particularly where it is incorrect, undermines public confidence in the College. Clause 36(1)(g) of the RHPA should be amended to read, "...if, in the opinion of the Registrar, there is a compelling public interest in the disclosure of that information".

b. Earlier Interim Suspensions: Code s. 25.4, 37, 62, 63(1). The ICRC will now be able to make an interim order prior to a referral to discipline. The criteria for making an interim order is expanded to include situations where the member's physical or mental state places the public at risk even in non-incapacity cases. This amendment will enable the earlier protection of the public in urgent cases, especially where an extensive investigation still needs to be done. Interim orders cannot include

gender-based restrictions. There are a number of significant drafting issues with these provisions which are described in the Appendix.

c. Disclosing Information to Regulators of Long-Term Care Homes: RHPA s. 36(1)(d). The confidentiality provision will be amended to permit disclosure of College information to the regulators of long-term care homes. The Federation recommends that this duty should be expanded to include regulators of other similar facilities and would suggest that a corresponding duty be created for the long-term care home (and related) regulators to disclose information to the Colleges.

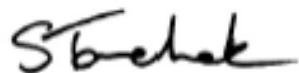
Conclusion

The members of the Federation are offering to work with the Ministry to share their experience and expertise in the regulation of healthcare professionals in Ontario. Daily, Federation members operationalize legislation, and we can help to prevent any undesirable implications of legislative amendments before unintended consequences occur.

Generally, the Federation supports the overarching objectives of the proposed amendments contained in Bill 87. In some cases, members have already implemented the changes that would follow through enactment of these legislative amendments and, as has been identified, some of the proposed changes do not go far enough. The Federation has also made a number of suggestions to ensure that the intent of the Bill is achieved. Finally, the Federation has identified a number of drafting issues, some of which are quite significant, and would ask that these be given close scrutiny.

The Federation appreciates the opportunity to be part of the process to ensure that the public is fully protected.

Sincerely,



Shenda Tanchak, President
Federation of Health Regulatory Colleges of Ontario¹

cc. Dr. Bob Bell, Deputy Minister, Ministry of Health and Long-Term Care
Ms. Denise Cole, Assistant Deputy Minister
Allison Henry, Director, Health System Labour Relations and Regulatory Policy Branch
Stephen Cheng, Manager (Acting), Regulatory Policy Unit
FHRCO Board of Directors

¹ *The College of Naturopaths of Ontario has not approved the letter but has agreed to stand aside and allow the Federation's response to proceed.*

Appendix 1

Drafting Suggestions (In Sequential Order)

Drafting Suggestions for Amendments to the Act

- S. 5(2) the proposed wording is that the Minister can require Council to disclose the personal or personal health information of a member. It is suggested that the “Council” be replaced with “Registrar” as the current wording would require that Council be informed of the personal or personal health information of a member.
- S. 5(2.2) requires Colleges not to disclose personal information “if other information is sufficient for the purposes set out in subsection (2.1)”. It would be difficult for Colleges to determine these purposes since they are so broad. It might be better to rephrase s. 5(2.2) so that the Minister is not permitted to request personal information or personal health information if it is unnecessary for the purpose since the Minister is more familiar with the purposes.
- S. 43(1)(w) it is unclear whether the phrase “functions and duties” relates only to allegations of sexual misconduct or whether it could relate to anything the Colleges do. While the context is about sexual misconduct it would enhance clarity if the phrase “with respect to matters involving allegations of a member’s misconduct of a sexual nature” was repeated after the words “functions and duties”.

Drafting Suggestions for Amendments to the Code

- S. 7(1.2) indicates that if the Council intends to exclude the public from a Council meeting, the website posting should indicate this and the grounds for doing so. However, we note that decisions to exclude the public must be made by Council at the meeting. Accordingly, before the meeting is held, one can only speculate as to whether portions of the meeting will be closed and why. Council will not have considered the issue yet. The provision should probably begin with: “If the Registrar anticipates that Council will exclude the public from any meeting or part of a meeting under subsection (2), the anticipated grounds for doing so ...”.
- S. 23(2).2 relates to former members. The phrase “The name of each former member of the College” implies that, without this authorizing provision, information about former members could not be posted on the public register². That undermines the approach taken by most Colleges that information about former members can and should remain on the public register. To eliminate this possible unintended consequence, the provisions should simply begin: “2. Where a member is deceased, ...”.³ This drafting concern is potentially of enormous significance.

² There is sometimes an inference in law that making a list (here, a list of information about former members that is on the public register) implies that items not on the list are excluded (i.e., the “*exclusio unius*” rule).

³ Or, in the alternative, at least separate out the two items so that the names of all former members are one paragraph and the date of death is a separate paragraph. This would reinforce the interpretation that additional items about former members could be added through College by-laws.

- S. 23(2).9 refers to the “notice of specified allegations against a member”. There is no such document at most, if not all, Colleges. It should be reworded to read: “A copy of the specified allegations ...”.
- S. 23(2).11 requires acknowledgements and undertakings (A&U’s) to be posted if they are “in relation to professional misconduct and incompetence”. The intent is probably to differentiate them from A&U’s for incapacity and quality assurance. However, the language is unclear as to whether they include ICRC A&U’s or apply just discipline A&U’s. Perhaps the following phrase might be clearer: “in relation to concerns of professional misconduct or incompetence before the Inquiries, Complaints and Reports Committee or the Discipline Committee”.
- S. 23(2) refers to a number of dispositions of the ICRC (e.g., cautions, SCERPs, A&U’s) that stay on the public register permanently. However, some Discipline Committee dispositions are eligible to come off the public register after six years (see S. 23(11)). It seems inconsistent to make less serious ICRC dispositions appear on the register permanently while some discipline dispositions are potentially temporary. The two provisions should be reconciled, perhaps by repealing s. 23(11).
- S. 23(14) defines the results of a hearing using the phrase “and where the panel has made no finding, includes the failure to make a finding”. This language is confusing as a finding is always made. Preferable language would be similar to the following: “and including any finding that professional misconduct or incompetence has not been proved”.
- S. 25.4(1) permits interim orders to be made upon receipt of a complaint or “report”. In this context, the “report” refers to the s. 79 report of the Registrar to the ICRC at the conclusion of an investigation. The obvious intent of the amendments is to permit the ICRC to make an interim order immediately upon the concern being identified as urgent, not after a lengthy investigation is undertaken. To achieve this intent, the word “report” should be changed to “the appointment of an investigator under section 75”. This drafting concern is potentially of enormous significance.
- S. 25.4(4) deals with the duration of interim orders. There are two drafting issues with this provision:
 - The language in the Bill says that the order ends upon the “disposition” of the matter by the ICRC which, conceivably, could end the interim suspension upon a referral to discipline. To reduce ambiguity, the provision could be worded: “(4) An order under subsection (1) continues in force until the matter is finally determined.” An alternative, but less satisfactory, solution would be to change the phrase “otherwise disposed of by a panel of the Inquiries, Complaints and Reports Committee” to read: “otherwise *finally* disposed of by a panel of the Inquiries, Complaints and Reports Committee”.
 - It is unclear whether an interim order can be amended if necessary. For example, additional information may come to the attention of the College indicating that a more restrictive interim order is needed to protect the public. On the other hand, the practitioner may propose amendments that would protect the public as much as, or even more than, the original order while having a less severe impact on the member.These drafting concerns are potentially of enormous significance.
- S. 51(5.1) requires a mandatory revocation lasting at least five years where a regulatory body outside of Ontario has made a finding of professional misconduct involving revocable sexual acts. However, this provision does not apply to findings made by regulatory bodies inside Ontario. For

example, if a practitioner was also registered with the Ontario College of Social Workers and Social Service Workers or the Ontario College of Teachers and was revoked by one of them for frank sexual acts, the practitioner would not necessarily be revoked by the *RHPA* College. This result could also conceivably occur where a practitioner is registered with two *RHPA* Colleges. The solution would be to amend 51(1)(b) to remove the requirement that the misconduct finding must be for a regulator outside of Ontario. Including other Ontario regulators is also more consistent with the drafting approach taken in s. 85.6.3. This drafting concern is potentially of enormous significance.

- S. 85.6.4 requires members to self-report when they are charged with an offence and every bail condition imposed. There are a number of drafting issues with this provision.
 - Unlike the other self-reporting duties, the provision does not include a requirement to disclose the location of the entity laying the charges or imposing the bail conditions (i.e. the location of the courthouse where any information has been laid or any indictment has been preferred in relation to the member). This omission will make it difficult for Colleges to verify the accuracy and completeness of the self-report (which sometimes minimizes the conduct).
 - S. 85.6.4 requires members to self-report every bail condition. Not all relevant restrictions on conduct flowing from a charge are contained in bail conditions. Other instruments that contain similar restrictions include terms of release and peace bonds, for example. A more precise list of relevant restrictions might read as follows:

“A member shall file a report in writing with the Registrar if the member has been charged with an offence, and the report shall include information about every condition of release imposed on the member as a result of the charge including, but not limited to, information regarding any summons, appearance notice, promise to appear, undertaking or recognizance whether with or without sureties. A member shall also file a report in writing with the Registrar if the member has entered into a common law peace bond or a recognizance pursuant to s. 810, s. 810.01, s. 810.011, s. 810.02, s. 810.1, s.810.2 or s. 83.3 of the *Criminal Code*.”

In the alternative a broader provision could be used such as: “every bail condition or other restriction imposed on or agreed to by the member relating to the charge”.



COUNCIL BRIEFING NOTE
MEETING DATE: MARCH 2017

FOR DECISION	FOR INFORMATION	X
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INITIATED BY: Nancy Lum-Wilson, CEO and Registrar

TOPIC: Report to March 2017 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: As CEO and Registrar, I respectfully submit a report on the activities that have taken place since the December 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.

Strategic Priorities Progress 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 December 2016 Council meeting.

Also attached is the College's Risk Management Report. As outlined in the Council Governance Manual, the Registrar is to develop a risk management program and report annually 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.

Ministry Activities

Since joining the College in January, I have spent a significant portion of my time meeting with several officials from the various branches of the Ministry to not only understand and learn about their priorities and concerns but also to inform about the College's strategic priorities and plans. The meetings serve to foster relationships that will ultimately help the College work proactively on various initiatives that will continue to strengthen our capacity to effectively meet our public protection mandate.

During more recent meetings and phone calls, our discussion topics have included: development of communication protocols, data sharing, immunization, amendments to the RHPA, Bills 84 and 87, and expanded scope. Updates on some of these issues are expanded upon later in my report.

Government Stakeholders

During this reporting period, there has been increased activity and collaboration not only with the Ministry but the Minister's office. This has provided the College with the opportunity to guide important changes to policy decisions and potential changes to existing legislation and regulations that impact the College and patients.

Auditor General/Audits

The Office of the Auditor General is conducting a value-for-money audit of the Ontario Public Drug Program at the Ministry of Health and Long-Term Care and identified the college as a key stakeholder. The same office is doing audit research on cancer treatment and services in Ontario, including cancer drugs. The College has had discussion with both teams.

Digital Health

On October 7, 2016, Minister Hoskins, asked Ed Clark, the Premier's Business Advisor and Chair of the Advisory Council on Government, to review the value of public and private assets with respect to Ontario's digital health strategy. In his response on November 22, 2016, Mr. Clark stated that while eHealth Ontario has provided value, it "needs to do more and faster". To that end, Mr. Clark made recommendations that would, within a 5-7 year timeframe, enable all Ontarians to have online access to their own health information, such as test results, and to proven tools that enable them to book appointments, request prescription refills/renewals, connect with health care providers, manage their health, and share information as they choose to with others involved in their care.

Furthermore, Mr. Clark recommended the establishment of a Digital Health Strategy Secretariat, with part of its mandate to include:

- Working with health care regulatory colleges, associations, and other partners to identify opportunities and incentives for health care providers and practitioners to improve care by employing new approaches for the adoption of and increased use of digital health technology, and the adoption of common standards relating to the input of patient data.

The entire report can be found at: <https://www.ontario.ca/page/value-and-opportunities-created-ontarios-digital-health-assets#section-3>

A staged launch of the Digital Health Drug Repository (DHDR) Project is underway, beginning in the Guelph area. Information available to health care providers includes Ontario Drug Benefit publicly funded drugs and professional pharmacy services provided by a pharmacist in Ontario and paid for by the Ministry of Health, as well as monitored drugs (narcotics and controlled substances) dispensed in Ontario when the approved identification used was a valid Ontario Health Card number.

Further opportunities have been identified for collaborative digital health solutions such as investigating integration of the DHDR with Pharmacy Management Systems, access to the provincial immunization repository and Canada Health infoway's PrescribeIT project for e-prescribing.

Legislative Initiatives

Pharmacy Act

Amendments to the Professional Misconduct regulation were approved by Council in 2013. The amendments addressed the addition of a new class of registrants, the expanded scope of practice, and the expectation that members will exercise professional judgement in choosing to

deliver services and/or referring patients to another health professional as needed. The regulation, in addition to giving members further clarity regarding ethical practice and professional boundaries, provides Council, committees and staff with a valuable screening mechanism to support and guide decisions when considering potential professional misconduct. We were informed by the Ministry that due to some minor outdated references, there was a need to unseal the previously signed regulation. I am pleased to report that the President and I signed the updated version of the sealed regulation on February 1, 2017.

Bill 84, *Medical Assistance in Dying Statute Law Amendment Act, 2016*

The Ontario legislature adjourned for its winter break on December 8, 2016. Just prior to its adjournment, the government introduced two new pieces of legislation that are of significance to the College: *Bill 87, Protecting Patients Act* (Briefing Note and discussion to follow later on the agenda) and *Bill 84, Medical Assistance in Dying Statute Law Amendment Act*. Legislature resumed on February 21, 2017.

On December 7, *Bill 84, Medical Assistance in Dying Statute Law Amendment Act*, was introduced to support the implementation of medical assistance in dying by providing more protection and greater clarity for patients, their families and their health care providers. This Bill complements the federal government's medical assistance in dying (MAID) legislation (Bill C-14), and seeks to address issues that fall within provincial jurisdiction. It consists of narrow amendments to Ontario statutes that would provide clarity and legal protections for clinicians and patients navigating MAID. The legislation, if passed, will also establish a new role for the Coroner in overseeing MAID deaths.

In particular, the amendments seek to:

- Ensure that having a medically-assisted death would not affect a right or benefit that would otherwise exist under a contract or statute (i.e., life insurance);
- Provide immunity to physicians, nurse practitioners and persons assisting them in the lawful provision of MAID, from civil actions or proceedings for damages;
- Bolster privacy protections for clinicians and health care facilities;
- Require that the Coroner be notified of all MAID deaths, but allow the Coroner to determine whether to investigate the death; and
- Clarify application of the Vital Statistics Act and related regulations, consistent with the Coroners Act amendments.

The College does not have any concerns with respect to the legislative amendments proposed by Bill 84, which passed second reading on February 21 and is currently being debated. Discussion has centred on the role of health regulatory colleges in establishing policies that strike an appropriate balance between the rights of clinicians to conscientiously object and the rights of eligible patients to access this legal service. We will continue to follow its progression and consult with the Ministry and other stakeholders to clarify outstanding issues related to the implementation of the bill and the delivery of MAID services. Initial challenges for pharmacists related to interprofessional collaboration and involvement have largely been addressed with the support of the Ministry, other Colleges, and through increased practitioner familiarity with the process.

Quality Assurance and Registration Regulation Update

Following discussion at the September 2016 Council meeting, drafting of the revised Quality Assurance and Registration Regulations was initiated. The College is awaiting Ministry direction.

Expanded Scope of Pharmacy Practice (Vaccinations)

As of December 15, 2016, Ontario pharmacists have the authority to administer certain additional vaccines to anyone over the age of five years.

MOHLTC Framework for Expansion of Scope

On February 13, 2017, the Health Workforce Planning & Regulatory Affairs Division, Ministry of Health & Long-Term Care, presented their new Model for the Evaluation of Scopes of Practice in Ontario (MESPO) to the Federation of Health Regulatory Colleges of Ontario (FHRCO). The framework uses a patient and system-centred approach that considers alignment with Ministry priorities, patient need, system need and value. Provider competencies, integration with the overall health system and funding will also be key criteria for consideration. The Ministry will be sharing a broad communication in the coming weeks.

Common Ailments

During my discussions with the Ministry on this particular initiative, the Ministry has indicated that further due diligence needs to be completed before moving further on this initiative. As well, we have been advised that any new request for expansion of scope will be assessed against the new MESPO framework developed by the Ministry.

Federal/Provincial Initiatives

Cannabis

In June, 2016 the federal government released a Discussion Paper “Toward the Legalization, Regulation and Restriction of Access to Marijuana” for a 60 day public consultation and announced a Task Force on Cannabis Legalization and Regulation. The Final Report of the Task Force was released in December and addressed five themes:

- Minimizing Harms of Use
- Establishing a Safe and Responsible Supply Chain
- Ensuring Public Safety and Protection
- Medical Access
- Implementation

The government is expected to table legislation in spring 2017 but it is also expected that further study will be required before any legislation is passed. There have been varying perspectives on pharmacy distribution of medical marijuana ranging from strong support to no support.

NAPRA (National Association of Pharmacy Regulatory Authorities) has for some time held the position that only products that have gone through the drug approval process in Canada for safety, efficacy and quality should be sold by pharmacists. As there is limited evidence on cannabis, it has not undergone this process. As such, NAPRA will convene at the end of March to develop a national consensus on the pharmacist’s role in the medical use of cannabis, from the perspective of its mandate of public protection.

In September, 2016 the OCP engaged Dr. Jake Thiessen to research and recommend possible approaches to addressing the impact of the legislation on members and accredited pharmacies. This research will inform the approach that the College will take forward to discussions with the NAPRA.

Opioid Misuse

In November 2016, Federal Health Minister Jane Philpott and Ontario Health Minister Eric Hoskins convened a two-day Summit in Ottawa to address the ongoing opioid crisis in Canada. The meeting included other provincial health ministers, addiction experts and affected families.

The outcome of the discussion was the issuance of a joint statement signed by both the federal and provincial Ministers of Health (http://www.healthycanadians.gc.ca/healthy-living-vie-saine/substance-abuse-toxicomanie/opioids-opioides/conference-cadre/statement-declaration-eng.php?_ga=1.78833436.988591637.1459974481) that included), commitments from each province and Health Canada. Ontario's commitment, which was reported to Council in December 2016, was to implement a comprehensive Opioid strategy that focuses on enhancing data collection, modernizing prescribing and dispensing practices, and connecting patients with high quality addiction treatment services. As well, Dr. David Williams, Ontario's Chief Medical Officer of Health, was designated as Ontario's first-ever Provincial Overdose Coordinator to launch a new surveillance and reporting system to better respond to opioid overdoses in a timely manner and inform how best to direct care.

In response to the Ontario commitment, and in alignment with NAPRA's goal to develop a national opioid strategy, I have agreed to serve as a co-lead with Bev Zwicker, Registrar of the Nova Scotia College of Pharmacists, to assist with development of NAPRA's leadership role on the regulatory issues pertinent to opioid misuse. This will allow the College to support and align both the Ontario and national strategy to improve patient safety in the use of opioids.

In April, the Ontario and Nova Scotia Registrars will lead a half-day discussion of the Council of Pharmacy Registrars of Canada (CPRC) and NAPRA to develop a national approach to opioid misuse.

NEXT STEPS

During the Executive Committee meeting on March 2nd, it was noted that pharmacists are at the forefront of this issue and could make an important contribution to support the provincial and national strategies. Given the importance of the issue, the Committee considered the idea of creating an Opioid Task Force to support the development of a College Opioid Strategy that would serve to define, coordinate and evaluate the range of initiatives that could be undertaken in relation to this issue. Council will be asked for comment.

Health Canada – Mifegymiso

In December 2016, this College, together with the College of Physicians and Surgeons of Ontario (CPSO) wrote a letter to Health Canada (attached), regarding Mifegymiso (a drug product to be used sequentially for the termination of a developing intra-uterine pregnancy up to a gestational age of 49 days and which became available to the Canadian public in January 2017). In particular, the Colleges requested clarification, and were provided with a response (also attached) by Health Canada on the requirements contained in the product monograph which could impact patient access to the drug. Distributor Celopharma Inc. (see attached article) has applied to Health Canada for permission for pharmacists to dispense directly to the patient if indicated by the prescriber, and to increase gestational limit to 63 days (the FDA extended the limit to 70 days in 2016). The company expects a response by the fall. In the interim, the College has created a guidance document outlining the options for dispensing this product. http://www.ocpinfo.com/regulations-standards/policies-guidelines/dispensing_mifegymiso/

Inter-Professional Relationships

Federation of Health Regulatory Colleges of Ontario (FHRCO) Update

The Federation of Health Regulatory College of Ontario (FHRCO) maintains a strategic focus on regulatory matters while promoting effective communication and cooperation among its members. During this reporting period, much of the focus was on Bill 87. A special meeting was held in mid-January to discuss Bill 87, where the member colleges reviewed and discussed a detailed analysis of the many valuable recommendations of the Sexual Abuse Task Force that will significantly affect the RHPA colleges. As previously stated, our position continues to be that the College is committed to serving and protecting the public, and demonstrating our values of transparency, accountability and excellence at all times. We look forward to working with the government and stakeholders throughout the development and implementation of this legislation.

A Federation Working Group has been researching available training and planning new videos/online modules that Colleges will be able to use to train their Councils, Committees and staff on issues related to the sexual abuse of patients. Six key areas are under development, including the following:

- Understanding the dynamics of abuse
- Understanding diversity as it relates to sexual abuse
- Understanding legislation as it relates to sexual abuse
- Understanding and managing your own beliefs, attitudes, and response to sexual abuse
- Setting up appropriate intake and investigation processes (staff focus)
- Fashioning appropriate dispositions and remedial programs

The modules are planned to be produced this spring for availability in summer 2017.

AGRE - Governance

Since its formation in 2012, the Advisory Group for Regulatory Excellence (AGRE) has had considerable success in collaborating together to develop the AGRE Transparency Principles, engaging with the provincial government regarding these principles and having them adopted in bylaw by the AGRE regulators.

In anticipation that Bill 87 (*Protecting Patients Act, 2016*), will make significant changes to the RHPA (*Regulated Health Professions Act*) which in turn will impact how the Colleges govern themselves, and building on the work of the College of Nurses of Ontario, AGRE recognized an opportunity to proactively and positively influence system change for the RHPA.

The AGRE Registrar's group voiced their support for support for CNO's "Vision: The College of Nurses of Ontario's Board of Directors for 2020" and communicated their offer of assistance as the Ministry moves forward with Bill 87, should it pass. The group also engaged Blais Consulting to develop a "Governance Discussion Paper" on best practices in governance to perhaps begin a higher level conversation on governance in an environment of changing public expectations. The documents are attached for your information.

Deputy Minister Bob Bell, from the Ministry of Health and Long-Term Care will be sharing his views with Council on the modernization of the governance of regulated health professionals at the March 20th Council meeting..

Other Stakeholder Meetings

National Association of Pharmacy Regulatory Authorities (NAPRA) Update

As reported at the December 2016 Meeting, the NAPRA Board requested feedback from member organizations regarding the proposed governance model. The College has shared comments made by Council members at its December 2016 meeting with NAPRA and all feedback will be considered by the Board at its meeting in April. It is expected that further information will be forthcoming by the June 2017 Council Meeting.

The Council of Pharmacy Registrars of Canada (CPRC) has continued informal discussions on issues of mutual concern to foster communication and collaboration on pan-Canadian trends.

Ontario Pharmacists Association (OPA)

The resignation of OPA's CEO, Dennis Darby, took effect January 27, 2017, and an announcement regarding the new CEO is anticipated. In the meantime, on March 2, the Executive Committee and senior staff at the College as well as selected Board members and staff at the OPA met to discuss issues of mutual concern. Although our mandates are different, this annual meeting benefits both organizations as we inform each other of priorities and initiatives for moving forward.

Miscellaneous Items

Beyond Use Date (BUD)

In response to a request by the President regarding Beyond Use Dates, staff researched the issue in detail and a memorandum from Ms. Chong, Manager, Hospital Practice, is attached for Council's information.

Pharmacy 5 in 5

Attached for Council's information is an update report from the University of Waterloo regarding Pharmacy 5 in 5.

RN Prescribing

Attached for Council's information is an announcement by the Minister of Health and Long-Term Care regarding changes to legislation to allow RN prescribing.

Quality Assurance and Practice Review Program

On a related matter, attached for Council's information is an article that was published in December 2016 in the Journal of Medical Regulation which is a peer-reviewed publication focusing on issues of licensing and regulation. It traces the twenty-year history of the College's Quality Assurance and Practice Review Program since 1997, the results of which have informed ongoing considerations as QA for Pharmacy continues to evolve in Ontario.

Appointment of Inspectors

The duties of the Registrar also include those set out under the *Drug and Pharmacies Regulation Act* as they pertain to inspection of pharmacies and drug preparation premises. As such, and as required under the by bylaws, I am reporting that my name has been added to the list of inspectors for the College.

Program Updates/Presentations

This reporting activity also includes regular program updates/presentations from the program managers. At this March Council meeting, I will invite Ms. Tina Perlman, Manager, Community Practice, to present her program update to Council.



Strategic Priorities 2015 - 2018

Progress Update – March 2017

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

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 Accomplishments (Sept – Nov 2016)	Noteworthy Accomplishments this Quarter (Dec 2016 – Feb 2017)
		PF	EC	CQI		
Fair and objective assessment framework.	<p>Refine assessment tools and activities.</p> <p><u>Premises:</u> Current authority and others i.e. long-term care, family health teams.</p> <p><u>Members:</u> Pharmacists - at entry, in practice, (site based and standardized). Pharm techs – as above.</p>	High	Med	High	<ul style="list-style-type: none"> 36% of practice assessments now scheduled (target of 95% by end of 2017) as previously reported. Behavioral based interview tool to promote consistency in QA practice assessments drafted and being calibrated. QA coaches completed initial training and supervised coaching sessions. PACE milestones reached: <ul style="list-style-type: none"> Implementation and evaluation plans for 2017 pilot complete Policies and resources for pilot launch posted on website Technology for records delivered and tested On target to achieve 90% of required Assessors in place by December 31 Assessment criteria (domains and elements) to support the Pharmacy Technician Standardized Assessment Tool (entry-to-practice) on track – draft shared with national stakeholders for input. Breakfast meeting piloted to assist in preparation for upcoming assessments. Data to be collected to determine effectiveness of this strategy over next quarter. 85% of 2016 hospital assessments completed using revised assessment document. Community and Hospital Practice Advisors and QA Remediation staff completed Vital Smarts Influencer training to enhance coaching skills for practice assessments. 	<ul style="list-style-type: none"> PACE successfully launched for student registrants January 18, 2017 Assessment rubric for Pharmacy Technician Standardized Assessment Tool ready for validation. Behavioral based interview tool for the QA practice assessments calibrated and ready for piloting. QA coaches fully trained and initiated coaching with members 55% of practice assessments now scheduled (on target for 95% by end of 2017). Data from first breakfast meeting, demonstrates the strategy is very effective. <ul style="list-style-type: none"> 100% made practice adjustments based on meeting attendance alone 70% used the assessment criteria to conduct a Self Assessment 70% made improvements prior to assessment.

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 Accomplishments (Sept – Nov 2016)	Noteworthy Accomplishments this Quarter (Dec 2016 – Feb 2017)
		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	<ul style="list-style-type: none"> Benchmarks developed for I&R Dashboard for consistent reporting, tracking and data analysis. Established a checklist for investigations into allegations of sexual abuse. Developed a scoring system for screening Intakes for member specific matters coming to the attention of I&R. Streamlined the internal process for data submission to CIHI for improved data quality. Delivered an Advanced Management Program to build management capacity and skills for leadership team decision making. Developed staff skills inventory bank for technical and transferable skills within the College. Established internal mechanism to manage ongoing development of the Public Register, and initiated development of criteria to determine when information may be deleted/removed from the Register. 	<ul style="list-style-type: none"> Annual statistics compiled for program evaluation and annual report. Upgraded Records Management System to enable Outlook integration; enables implementation of the zone approach to email management.
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	<ul style="list-style-type: none"> Professional development and remediation approach moving forward with a communication plan and the identification of a lead and program area coordinators. 	<ul style="list-style-type: none"> Professional Development and Remediation technology for resource catalogue finalized.

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 Accomplishments (Sept – Nov 2016)	Noteworthy Accomplishments this Quarter (Dec 2016 – Feb 2017)
		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	<ul style="list-style-type: none"> Baseline data collected for 76% of 2016 target for pharmacist assessments by 31/10/2016. Consulted on and responded to draft NAPRA model standards of practice for non-hazardous compounding and initiated member communication on implementation of hazardous sterile compounding standards. Completed 2nd and 3rd Code of Ethics learning modules and 2nd and 3rd interactive learning videos. Launched 5in5 project with UWaterloo to create Advisory Group, review annual deliverables and reporting analytics. 	<ul style="list-style-type: none"> Baseline data collected for 95% of 2016 target for pharmacist assessments by 31/12/2016. Project Charter for Practice Based assessments for Hospital Pharmacists completed. Completed last 3 Code of Ethics learning modules. Implemented the Code of Ethics declaration for 2017 membership renewal.
Pharmacy Technicians 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	<ul style="list-style-type: none"> Presentation to CCAPP program coordinators on NAPRA model standards for sterile compounding. Four presentations to pharmacy buyers to educate about hospital assessments including compounding standards and future practice based assessments. 	<ul style="list-style-type: none"> Underway – see Strategic Priority #1.

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 Accomplishments (Sept – Nov 2016)	Noteworthy Accomplishments this Quarter (Dec 2016 – Feb 2017)
		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	<ul style="list-style-type: none"> Achieved 79% of 2016 target to assess 2500 community pharmacies, on track for 100% by year end. 	<ul style="list-style-type: none"> Achieved 95% of 2016 target to assess 2500 community 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	<ul style="list-style-type: none"> Established cataloguing system to align professional development and remediation activities with competencies to identify and eliminate gaps in training. 	None.

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 Accomplishments (Sept – Nov 2016)	Noteworthy Accomplishments this Quarter (Dec 2016 – Feb 2017)
		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	<ul style="list-style-type: none"> Initiated identification of reporting analytics and new content needed for Pharmacy 5in5 to enhance and assess scope of practice of pharmacy teams. 	<ul style="list-style-type: none"> Mined pharmacy assessment data to determine baseline of pharmacies reporting integration of pharmacy technicians (currently about 25%). Initiated a study within U of T Practice Optimization project to identify factors that support pharmacy technicians practicing to their full scope.
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	None.	<ul style="list-style-type: none"> Developed and posted joint guideline with CPSO on Mifegymiso.

Ontario College of Pharmacists Risk Management Report – March 2017

In accordance with the expectations outlined in the Council Governance Manual, a Risk Management Plan was created by staff and reported to Council in 2015. As indicated in the manual, the Registrar is to report to Council annually on the status of the risk management plan and any updating that is required. Accordingly, a Risk Management Report was included in the Registrar's report in March 2016. The Plan continues to appropriately represent the philosophy, intentions and high level activity undertaken to manage risks to the College and its operations. This report highlights the activity undertaken over the past year that contributes to risk mitigation and management.

Overview

While the College's Risk Management Plan is appended below for reference, the philosophy, goals and approach are repeated herein for guidance on this Risk Management Report:

Risk Management Philosophy

The College has embraced a collaborative, strategic approach to risk management, which includes identifying and addressing the threats and opportunities the organization faces. The views and participation of personnel at all levels of the organization, including Council, will be sought as the College identifies risk management priorities and implements strategies for modifying, retaining and/or financing risk. This collaborative effort will culminate in the creation of a Risk Management Plan. The Plan will be reported to Council annually.

Risk Management Goals

Any and all risk management activities should be designed to enable, rather than impede the mission of Ontario College of Pharmacists.

Approach to Risk Management

The College takes a multi tiered approach to risk management:

- *Strategic - organization-wide*
- *Operations - statutory obligation (committee and/or program)*
- *Operations – corporate services and support*

The Registrar/CEO works with the various entities in the organization to identify and evaluate risks and create appropriate risk management plans.

Activity – 2016

Strategic – Organization Wide

- Following the launch of the redesigned Public Register that clearly displays more information about members and the outcomes of college proceedings, the College is carefully weighing the requests for removal of information as it develops a framework for consideration of removal to appropriately balance the rights of the public to be informed and the desire of members to clear their record after a period of time.
- The College expressed support for the concepts introduction in Bill 87 recognizing the need for decisive action to be taken to recover public trust of professional self regulation.
- Council and Committee orientations were further revised to reflect the increased emphasis on transparency.

Operations, Statutory Obligations (Committees/Programs)

- Rigorous psychometric assessment of the new Practice Assessment of Competence at Entry (PACE) process undertaken to ensure the validity and reliability of assessment results.
- Facility assessment tools were further refined and tested to improve reliability, consistency and relevance to increase defensibility.
- Similarly, the site based member assessment tools and processes were refined and tested and data is being mined to establish benchmarks against which practice improvement can be measured. The ability to demonstrate value to society will be critical to public trust.
- Work processes that support the new site based member assessments were reviewed to mitigate against unintended breaches of confidentiality.

Operations, Corporate Services and Support

Staff Operations

- JHSC reassessed safety risks across all departments and recommended enhancements to security protocols and updates to the Workplace Discrimination Violence and Harassment Policy (WDVHP).
- All staff and council members were re-trained on WDVHP as Bill 132 introduced greater protections against sexual violence and harassment in the workplace.
- Staff driven Pension Committee continues to review fund performance and recommend changes to the fund portfolio.
- Documentation completed to ensure AODA compliance with design of public spaces and maintenance of accessible parts of public spaces.
- Instituted a new policy regarding “Use of fragrances” on OCP property to promote a healthy environment and minimize absenteeism.
- Continued commitment to Continuous Quality Improvement (CQI) initiative using PDSA model to improve work process and department structures to increase effectiveness, timeliness and accountability – sample projects include: HR Onboarding, Elections Process, Investigation Backlog and Hearings and Alternative Dispute Resolutions.

Technology and Information Management

- The report of the external IT Security Threat Risk Assessment (STRA) commissioned last year to examine the effectiveness of existing protocols and identify areas for improvement was reviewed. Immediate action was taken on all areas identified as Critical. Non-Critical concerns were then addressed on a priority basis; all issues classified as High Risk – Non Critical were addressed within three weeks following receipt of the report.
- Plans are in place to systematically address other recommendations made in the STRA report. Implementation of changes aimed at strengthening Disaster Recovery is scheduled throughout the coming year.

Facility/Site Safety and Security

- The catch basin in the 483 parking lot was reconstructed to repair the decayed concrete wall.
- Door Operator System for the elevator at 483 Huron building replaced and upgrade to hands free emergency telephone system installed.
- New motion sensor lights in 186 parking lot for enhanced security.
- Recommendations from the Joint Health and Safety Committee (JHSC) implemented to improve safety and security – indicator light installed on door opening to third floor landing.

Emergency Response Planning and Crisis Management

- Table top exercise created by the JHSC undertaken in 2016 verified workability of the Emergency Response Plan (ERP) and general strategy for business continuity.



Risk Management Plan

Change Creates Opportunity
Opportunity Creates Risk
Optimized Risk Creates Value

If we only have a compliance focus, we will miss opportunity.

Version date: February 29, 2016

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Section 1 - Risk Management Program

Risk Management Philosophy

The College has embraced a collaborative, strategic approach to risk management, which includes identifying and addressing the threats and opportunities the organization faces. The views and participation of personnel at all levels of the organization, including Council, will be sought as the College identifies risk management priorities and implements strategies for modifying, retaining and/or financing risk. This collaborative effort will culminate in the creation of a *Risk Management Plan*. The Plan will be reported to Council annually.

Risk Management Goals

Any and all risk management activities should be designed to enable, rather than impede the mission of Ontario College of Pharmacists.

Approach to Risk Management

The College takes a multi tiered approach to risk management:

- Strategic - organization-wide
- Operations - statutory obligation (committee and/or program)
- Operations – corporate services and support

The Registrar/CEO works with the various entities in the organization to identify and evaluate risks and create appropriate risk management plans. Working together, these leaders develop protocols, program standards, policies and incident response plans.

Section 2 - Responsibility for Risk Management

Council

Receives periodic reports from the Registrar/CEO concerning the priority risks facing the organization and its risk management framework.

Contributes to a shared understanding of the enterprise level and strategic risks.

Receives periodic reports on the organization's risk financing and insurance strategies.

Receives and periodically reviews the organization's *Risk Management Plan*.

Registrar/Chief Executive Officer (CEO)

Keeps the Council apprised of staff-led risk assessment and risk management activity.

Presents a periodic summary of the critical risks facing the organization for Council discussion and feedback.

Monitors and reports on the compliance obligations of the organization.

Delegates responsibility for specific risk areas and tasks to appropriate staff.

Director, Finance & Administration

Champions organization-wide effort to protect the vital assets of the College and engage key stakeholders in risk management activities.

Keeps the Registrar/CEO apprised of changes in critical risks and risk management strategies.

Engages staff throughout the organization in risk assessment and risk management activities.

Evaluates the insurance program.

Committee Chairs/ Program Managers

Responsible for complying with the obligations outlined in the Health Professional Procedural Code respecting procedure, timeliness, transparency, objectivity and fairness.

Section 3 - Governance Structure

Incorporation

The College was incorporated in the province of Ontario in February 1871. Its duties and objects are set out in *Regulated Health Professions Act (RHPA)*, *Pharmacy Act (PA)* and *Drug and Pharmacies Regulation Act (DPRA)*. Annual not-for-profit corporate filings are submitted annually as required by provincial law.

The Council of the College serves as the Board of Directors. The role of the Council, Committees and staff are outlined in the Governance Manual approved by Council and posted to the College website and serve to guide the various entities in fulfilling their obligations.

The authority to establish by-laws is prescribed in statute. The by-laws are reviewed and amended by Council periodically to support the governance approach and operational requirements.

The Council is committed to having the minutes accurately reflect the actions of Council. The minutes are circulated between meetings and approved at the next scheduled meeting after which they are posted to the website for public viewing.

Indemnification

The Council, committee members and staff are protected from action or other proceeding for damages under the immunity provisions of S. 38 of the RHPA for acts done/or intended to be done in good faith in the performance of a duty or exercise of power under the various statutes.

Council, Committees and staff are educated on their obligations through orientation and training at the council, committee and staff levels.

Council Operations

OCP has adopted a Governance Manual containing the key assumptions and expectations of Council, Committees, Chairs and staff. The Manual will be reviewed annually during Council orientation and updates will be made on an as needed basis.

Orientation - To ensure that the members of the Council/Committees are properly trained and prepared for their service, the organization conducts orientation training for all members on an annual basis. Legal Counsel/s (with staff support) delivers the orientation at the Council and Committee levels and experienced members share their insights and coach the new members.

Development - The College strives to enhance the ability of its Council members to govern the organization by providing training for council members and chairs. Periodically the Council will assess the educational needs of the members and offer training, support or assistance as needed.

Assessment - The Council is committed to evaluating and improving its performance as a responsible, accountable and effective governing body. The Council periodically evaluates its performance and adopts a work plan to address any weaknesses.

A Code of Conduct for Council and Committee Members was adopted by Council in September 2014. Every year each Council/Committee member completes and signs a statement declaring any known conflicts and agreeing to comply with the policy. These annual statements are gathered in September of each year.

Staff Operations

The Registrar as CEO assembles the staff necessary to carry out the work of the College. Staff are organized as appropriate to carry out the duties in an efficient manner, accountable ultimately for implementation of the strategic priorities identified by Council, statutorily prescribed in the legislative framework and consistent with the culture and values of the organization. A Deputy Registrar is assigned to fulfill the duties of the Registrar if he is unable to do so.

Structure - The College has developed job descriptions for all paid positions in the organization to clearly communicate staff work objectives. These documents are created with input from line managers and are finalized before the recruitment process begins. Job descriptions help to establish pay structure between positions by evaluating responsibility and value to the College.

Organizational Accountability – The College views effective staff supervision as an essential component of risk management. Supervisory staff are expected to communicate their expectations of direct reports clearly and consistently and hold employees accountable with regard to key tasks and responsibility and compliance with the organization's employment policies. All employees are encouraged to raise concerns or questions about work priorities and assignments with their direct supervisor.

Employees may be assigned to projects operating under a matrix management or team approach. Major projects involve personnel from various units in the organization who work under the direction of a team leader. The team leader for a project is responsible for holding team members accountable. The team leader may impose discipline on a team member who fails to meet performance requirements or violates the code of conduct for the organization.

Orientation – The Human Resource department staff at the College are responsible for coordinating an orientation session for all new employees within the first week of employment. During this session, there is an overview of the mandate and organizational structure of OCP, key provisions of OCP's policies, procedures and guidelines are discussed, a benefits summary is provided along with forms which require completion by the employee. The employee is encouraged to ask questions about any aspect of employment policy or operations.

Employee Policies – The College believes that written employment policies are an essential risk management tool. The organization has compiled its key employment policies and publishes them on the intranet. The College reviews and updates its policies every two years or as new legislation is introduced in order to ensure that policies remain suitable for the organization and in compliance with provincial and federal employment laws. Policy updates are vetted through legal counsel where appropriate.

New policies are communicated via email and through the intranet to employees. Staff are provided with ample time to review policies and are required to confirm their understanding of and willingness to abide by any new policies. For legislated policies, the College will organize staff training sessions.

Assessment - The College requires annual reviews for all employees. Staff are asked to complete self assessments of key objectives and competencies outlined in the performance plan. Supervisors are responsible for scheduling review meetings and completing the performance review form in the dedicated Performance Management system. The performance review is tied into career development counselling and training. Supervisors conduct reviews with employees within six months of the hire date and thereafter on an annual basis as a minimum.

If needed, performance improvement plans can be used to facilitate constructive discussion between an employee and supervisor to clarify the work performance to be improved.

Section 4 - Strategic, Organization Wide Risk

The College recognizes that it must not only act in the public interest but be seen to act in the public interest. Failure to do so exposes the College to the risk of losing the right to self regulation through the appointment of a Supervisor under the provisions of the RHPA.

The College further recognizes that while it is incorporated as an independent body, it is established by statute and its duty to serve and protect the public interest while regulating the profession of pharmacy are delegated by the government.

The College also recognizes that it, as well as the profession it regulates, operates within the broader context of a healthcare system. It is imperative to take this perspective into account and ensure that the interests of the broader system and its delivery of quality service to the public of Ontario take precedence over the interest of the College.

The College further recognizes that innovation, evolution and continuous improvement in its programs and services and those of the profession we regulate are necessary to meet the changing demands and expectations of our stakeholders.

Section 5 - Statutory Programs and Services

OCP undertakes their statutory obligations outlined in the legislation in accordance with the provisions set out in the various Acts. These obligations must balance timeliness with process and quality outcomes. Failure to do so could result in successful appeals and an erosion of confidence in the College and its effectiveness as a self regulatory organization.

- Committee orientations are developed and delivered with the input from legal expertise.
- Legal support is available to guide decisions and practices.
- Statistical data is compiled and reported to monitor adherence.
- Committees report to Council annually.

Section 6 - Operations Support

Financial Management

On the recommendation of the Finance and Audit Committee, the Council approves an annual budget that represents the financial plan for operations for the coming year. The Finance and Audit Committee establishes policies in relation to contract execution and cash reserves, whereas the Council establishes a policy for investment of surplus funds of the College. Staff, under the direction of the Director of Finance and Administration, establish policies to ensure the consistent treatment of financial transactions in accordance with sound accounting principles.

Council reviews the operations and activities of the College. This oversight responsibility is delegated to the Finance and Audit Committee. The Registrar acts as the primary fiscal agent. The Registrar may delegate to the Director of Finance and Administration the responsibility for implementing all financial management policies and procedures and managing the various aspects of financial management.

The financial management objectives of the Ontario College of Pharmacists are to:

- preserve and protect financial assets needed for mission critical activities;
- exercise appropriate care in the handling of incoming funds and disbursement of outgoing funds;
- strive for transparency and accountability in fiscal operations.

Financial Responsibilities and Objectives

The Director of Finance and Administration shall be responsible for developing and presenting to the Finance and Audit Committee a proposed budget for the upcoming fiscal year. The Finance and Audit Committee shall consider the budget and present it to the Council. The budget shall contain detailed projections for revenues and expenditures.

The College's financial statements shall be prepared on an accrual basis in accordance with Generally Accepted Accounting Principles (GAAP). The net assets of the organization and changes shall be classified as unrestricted or internally restricted to be used for specific purposes.

The presentation of the Financial Statements shall follow the Canadian accounting standards for not-for-profit organizations.

The Director of Finance and Administration shall direct the preparation of quarterly Financial Statements and presentation of these statements to the Finance and Audit Committee.

The College has adopted a number of internal control measures as part of an overall effort to safeguard financial assets.

In addition, and to the extent possible given its size and circumstances, the organization strives to segregate the duties so that a single staff member isn't required to perform two or more incompatible functions

It is the policy of the College to engage the services of a reputable, independent CPA firm to conduct an annual audit of the organization's financial statements. The audit is completed as soon as practical after the end of each fiscal year. The audit firm is selected by and reports to the College's Finance and Audit Committee. The Council shall approve the appointment at a Council meeting in the year for which the books are to be audited. A representative of the audit firm is requested to make an annual presentation to the Council by the Finance and Audit Committee.

The College's Investment Policy establishes the principle that all investments shall ensure preservation of capital and sets out the restrictions and limitations of investments vehicles. The primary objectives of such investments shall be, in order of importance, preservation of capital and yield.

In addition to the Investment Policy established by Council and the Reserve Fund and Contract Execution Policy established by the Finance and Audit Committee, internal accounting policies are in place to ensure consistency in processing, e.g. expense authorization, purchasing, corporate credit card use. Fraud Protection services offered by the College's financial services provider were recently added. Policies are reviewed annually and new policies added as necessary in response to suggestions from the Auditors.

Technology and Information Management

Technology Policy

The College's information and office technology systems (networks, software, computers, telephones, printers, copiers, etc.) are tools provided to employees and volunteers to enhance productivity and performance on the job. Limited non-business use is permitted when on personal time (e.g. during lunch hour or after work). Regardless of the type of use, employees must not have any expectation of privacy to data, information or files that are created, stored or used on the College's systems. College Management reserves the right to access the employee's computer or files at any time. Staff are expected to use good judgment in their use of the College's information and office technology systems, especially electronic mail. Access to all systems, including electronic mail and the Internet, is a privilege, not a right.

The failure to use good judgment or the abuse of the organization's policies may result in suspension of privileges or disciplinary action. If any employee discovers he or she has unintentionally violated this policy, that employee should notify his or her supervisor immediately.

Policy on Systems Inventory and Documentation

To safeguard its office and technology assets, the College maintains a complete inventory of its electronic equipment and computer and technology systems, including hardware, software, media and data. The inventory process includes documentation of how the networks and systems are configured. Responsibility for maintaining the inventory has been assigned to a regular staff member. The inventory is updated at least quarterly or whenever new equipment, media or software are acquired or discarded. The inventory is stored on-site as well as off-premises.

Physical Security for Technology Assets

The College is committed to protecting its office technology assets. The organization takes all reasonable steps to protect and safeguard systems and equipment from damage due to power fluctuations, water damage, dust, extreme temperature change and other environmental factors. In addition, the organization guards against threats due to viruses, worms, malicious software and hackers. The Manager, Information Technology is responsible for overseeing the security of office systems.

The College maintains numerous files containing personal data, financial information, and other confidential or proprietary information. These files may be in paper or electronic form. The systems administrator will limit access to certain electronic files based upon individuals' responsibilities and job tasks. Confidential documents will be secured in locked filing cabinets. Any employee whose work requires access to confidential documents should ensure that files are returned to their secure location. Persons who knowingly obtain unauthorized access to confidential information will be subject to discipline, up to and including termination. All incoming employees will be required to execute a Confidentiality Undertaking concerning access to and use of confidential information prior to being given access to any confidential information.

Disaster Recovery Plan

Information technology is critical to the College's ability to provide its programs and services. As a key component of our operations, the Manager, Information Technology is responsible for establishing a disaster recovery plan for our network and computer operations. All employees and volunteers will support this staff person in developing, maintaining and testing the plan. All personnel involved with the disaster response must be familiar with the plan and their assigned roles and responsibilities.

Internet Security

In order to protect personal information, the College uses technologies and processes such as encryption, access control procedures, network firewalls and physical security. These measures increase the security and privacy of information traveling to, from and within our website. Only our authorized employees or agents carrying out permitted business functions are allowed to access personal information. Employees who violate our privacy access policies may be subject to disciplinary actions, up to and including termination.

Website Functionality

The College depends on its website to distribute information and meet its reporting and public register obligations. An inoperable website or one functioning less than optimally can have serious consequences with regard to the organization's reputation and service delivery. To ensure that the website remains fully operational at all times, the Communications Department has established a monitoring procedure which includes a complaint or notice feature allowing visitors/users to report problems encountered while using the website. The Communications Department has also established a goal of responding to all complaints or notices of site errors or problems within eight hours. The Communications Department has also provided detailed instructions to staff about their role in reporting website irregularities or other malfunctions.

Web Content

To maintain the integrity of the organization's website, the Communications department staff oversee the content and look and feel of the site. They are responsible for ensuring that content meets the organization's quality standards and due diligence has been completed to ensure that the organization is within its rights to use any material it posts.

Website Disclaimer

All materials posted on this site are subject to copyrights owned by Ontario College of Pharmacists or other individuals or entities. Any reproduction, retransmission, or republication of all or part of any document found on this site is expressly prohibited, unless Ontario College of Pharmacists or the copyright owner of the material has expressly granted its prior written consent to so reproduce, retransmit or republish the material. All other rights reserved.

Facility/Site Safety and Security

Facility Needs

Ontario College of Pharmacists seeks to utilize its resources and assets fully in achieving its mission. The prudent use of facilities and resources is required to protect the safety and well-being of all personnel - including staff, volunteers and service recipients - while safeguarding the organization's financial assets.

Building Security

The College buildings are configured to provide light of site surveillance of individuals entering the buildings. Monitored access cards enable the College to identify traffic in off-hours. The buildings are monitored 24/7 through an external alarm monitoring service. Security cameras are installed at entry points and in the parking areas. Policies are in place to communicate expectations of staff and visitors during and after hours. Additional procedures are enacted during periods of high alert as required.

Preventative Maintenance and Inspections

The College undertakes preventive maintenance for all its building and related facilities. Maintenance protocols are in place for fire safety, mechanical and electrical equipment, cleaning, grounds maintenance, elevator maintenance, waste disposal, food handling, etc. In accordance with legislation, the College maintains a joint Workplace Health and Safety

Committee comprised of staff and management. Workplace inspections are conducted monthly. Issues brought forward by the Committee are addressed promptly, or where investment is required, are implemented in a timely manner.

Policy Concerning Invitees

The College will permit other organizations affiliated with the College (Federation of Health Regulatory Colleges of Ontario (FHRCO), National Association of Pharmacy Regulatory Authorities (NAPRA)) to use College property for meetings provided that the events will not interfere with the business of the College. College facilities staff will be present to manage security and equipment issues and respond in the event of an emergency. Where facilities staff are unavailable, a meeting designate will be trained on the fire, safety, and evacuation procedures.

As a facility owner, Ontario College of Pharmacists is committed to providing outside users of its premises with a safe environment. This commitment includes, but is not limited to meeting building code requirements, making timely repairs, and providing and maintaining appropriate security.

Section 7 - Emergency Response Planning and Crisis Management

Emergency Response Policy

Ontario College of Pharmacists has adopted an Emergency Response policy whose purpose is to provide direction to the stakeholders of the organization in the wake of an emergency that may threaten the mission of the organization and the safety of its personnel and stakeholders. The Registrar/CEO is responsible for managing the organization's emergency response in accordance with the following priorities:

- to save lives;
- to protect health and to provide for the safety and health of all responders;
- to protect property and infrastructure;
- to protect the environment; and
- to restore the principle functions of the organization.

Business Continuity Planning Policy

The College's Emergency Response Plan addresses business continuity by assessing the potential impact to core and ancillary business functions and outlining impacts. The members of the ER team are responsible for developing strategies for crisis communication, financing a business interruption incident and for implementing mitigation strategies.

A table top exercise is executed every second year to test the plan and remind members of the ER team of the procedure.

Vital Records, Data and Documents Backup Policy

In order to ensure the continuity of mission-critical services, Ontario College of Pharmacists will duplicate and store off site all information identified as essential to fulfilling its business continuity plan.

Crisis Communications Policy

The College is committed to taking a pre-emptive approach to public relations crises, using disclosure whenever possible as the preferred strategy for preventing or minimizing a crisis. No one is authorized to speak to the news media during a crisis without clearance from the Registrar/CEO. The Registrar/CEO or his designee will be responsible for developing crisis communication strategies.

When a crisis unfolds, the designee will gather and verify information about the crisis, and with the Registrar/CEO, will assess the severity of the matter and determine how information is to be released, who should speak for the organization and who is to be notified.

Section 8 - Insurance Program

Insurance/Risk Financing Strategy

To safeguard the assets and resources of the College the organization maintains insurance for those insurable risks of major importance to mission-critical operations and the financial health of the organization. It is the Director, Finance and Administration's responsibility to oversee the organization's insurance program and report annually to the Registrar/CEO.

Insurance Program for Ontario College of Pharmacists

The College relies on HIROC (Health Insurance Reciprocal of Canada) under umbrella coverage through FHRCO for insurance advice and services relating to:

Errors and Omissions/Directors and Officers Liability.....	\$5 Million
Liability Insurance.....	\$5 Million
• Bodily Injury	
• Property	
• Tenant Coverage	
• Healthcare Professional	
• Contingent Employer	
• Employee Benefits	
• Cyber Threats	
• Environment Impairment	
• Non-Owned Automobiles	
Crime Insurance – Employee Dishonesty.....	\$2 Million
• Loss, money order and counterfeit paper, depositors forgery.....	\$200,000
Travel Accident Coverage.....	\$100,000
Property.....	\$9.8 Million
Property coverage extensions	
• rental income.....	\$228,000
• business interruption/valuable paper and records.....	\$100,000
Company leased vehicles (Ed Johnstone and Sons, brokerage).....	\$.1 Million

Relationship with Insurance Advisors

Selection Process

The College works cooperatively with the members of FHRCO to realize efficient, cost effective coverage for our common operations.



See more news releases in [Health Care & Hospitals](#) | [Pharmaceuticals](#)
| [Federal Executive Branch & Agency](#) | [Public Safety](#)

Statement from the Chief Public Health Officer: Pharmacists Help Address the Opioid Public Health Crisis in Canada



OTTAWA, March 13, 2017 /CNW/ - During **Pharmacist Awareness Month**, I am highlighting the important contribution of pharmacists to addressing the opioid public health crisis. Opioid overdoses are claiming the lives of thousands of Canadians of all ages, and from all walks of life. The impact of the opioid crisis continues to be devastating to individuals, families and communities. Concern is growing about the impact of this crisis on Canadian youth. There has been a significant increase in the number of opioid overdoses and an acute rise in deaths from fentanyl and other synthetic opioids in several provinces in Canada. Both illegally manufactured and prescribed opioids are being sold on the street. Some people have become addicted as a result of over-prescription and have turned to street drugs to manage their addiction. Drug addiction is an illness that requires care and compassion like any other health condition. Unfortunately, drug addiction often carries stigma, which in itself can be a serious barrier to care.

Pharmacists are often the first healthcare providers to notice a prescription drug problem in a patient, or over-prescribing by physicians. Pharmacists are a knowledgeable and accessible resource — they provide information about proper use of prescription opioids, and offer services such as taking back old or unused medications and disposing of them safely. Their work helps to prevent opioid misuse, overdoses and deaths from overdose.

I encourage all Canadians to learn about the health risks associated with the use of opioids, the signs and symptoms of a possible overdose, and how to help themselves and those around them who may be using these drugs. Knowing more means you can help prevent opioid misuse and addiction, and potentially save a life.

Use medication properly

- Your pharmacist can answer your questions about the risks of drugs, their proper use and alternatives.
- Use prescribed opioids exactly as directed. Prescribed painkillers can be dangerous if they are taken incorrectly or misused. Taking opioid medication also comes with a risk of developing an addiction.
- Use painkillers only if you absolutely need to.

Keep prescription medication out of the wrong hands

- Pharmacies will take back your old and unused medications and dispose of them safely.
- Keep your prescription medication safe and secure to prevent medication such as opioids from ending up on the street.
- Keep your medication out of the reach of children to avoid serious harm or death.
- Don't throw medication in the garbage or flush it down the toilet.

Learn how to administer naloxone

- Naloxone is a drug that temporarily reverses the effects of opioid medications. If you or someone you know is at risk for possible overdose, get a naloxone kit. Naloxone kits are available without a prescription at pharmacies, certain walk-in clinics, community health units and some local non-governmental organizations.
- Your pharmacist can provide guidance on the appropriate and safe use and administration of naloxone. The Canadian Pharmacists Association has developed a [short video](#) that demonstrates how to administer naloxone.

Learn about drug use

- Youth need accurate information to understand the harms and consequences of drug use. Knowing how to address stress and troubled relationships can also help.
- Parents may be interested in the guide [Talking with teenagers about drugs](#).
- Physicians are encouraged to not over-prescribe opioids as pain medication.

Recognize the symptoms of an overdose

- An opioid overdose can be identified by a combination of:
 - slow or weak breathing;
 - dizziness, confusion, drowsiness;
 - cold and clammy skin;
 - pinpoint (very small) pupils; and
 - collapse and coma.

Know what to do if you witness someone experiencing an overdose

If you think you are witnessing someone experiencing an overdose:

- Call 911 and follow their directions.
- If you have a naloxone kit, use it.
- Stay with the person until help arrives.

For more information, visit Canada.ca/opioids.

SOURCE Public Health Agency of Canada

For further information: Contacts: Media Relations, Public Health Agency of Canada, 613-957-2983

Organization Profile

Public Health Agency of Canada

[Public Health Notice - Ongoing outbreak of norovirus and gastrointestinal illnesses linked to raw and undercooked oysters from British Columbia](#)

[Public Health Notice - Outbreak of gastrointestinal illnesses linked to raw and undercooked oysters](#)

[Government of Canada invests in program to promote healthy eating](#)

[More on this organization](#)

Government of Canada

The logo for the Government of Canada, featuring the word "Canada" in a serif font with a stylized Canadian flag above the letter "a".

[The Government of Canada Invests in Infrastructure Projects in Lennox Island First Nation](#)

[Lake St. Martin First Nation Rebuilding its Flooded Community with More Housing and a New School](#)

[/R E P E A T -- Media Advisory - Government of Canada/](#)

[More on this organization](#)



Health
Canada

Santé
Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

250 Lanark Avenue
Graham Spry Building
A.L. 2007A
Ottawa, Ontario
K1A 0K9

JAN 11 2017

16-114838-597

Dear Dr. Gerace and Ms. Resnick,

Thank you for your letter of December 15, 2016 seeking clarity on Health Canada's position regarding the conditions of use for Mifegymiso. I've also taken the liberty to cc Nancy Lum-Wilson on this response. Nancy, congratulations on the new appointment, and I look forward to working with you again.

With respect to the issues raised in your letter, we understand from the company that Mifegymiso is expected to be available on the Canadian Market by the end of January 2017. The company has also indicated that the English educational program is currently available (<https://sogc.org/online-courses/courses.html>), with the French version to be available shortly.

The product monograph (PM), including Mifegymiso's conditions of use, are based on the data package provided by the sponsor to Health Canada. Please note that after the original approved product monograph was made available, professional organisations raised the issue that there was a potential for confusion as the wording regarding administration in Parts I and III was not fully consistent. To address this, the product monograph was revised in October 2016.

Specifically, Part I of the PM was revised to read: "*Mifepristone should be administered under the supervision of the prescriber. In the clinical trials supporting Mifegymiso efficacy and safety, mifepristone was administered under the supervision of a physician in a clinical setting*". To better align with Part I, Part III was also revised and now states: "*As directed by your doctor or as given to you by medical staff*".

The wording in the product monograph was deliberately chosen such that physicians could use their discretion for each individual patient. It does not mandate that the medication be taken in front of the physician. Such decisions are best made by the physician and are considered the practice of medicine.

.../2

-2-

Pharmacists will be involved in the dispensing of Mifegymiso, however their role may be different than the traditional one of dispensing directly to the patient. For example, doctors may write a prescription, which is filled by a pharmacist, whereby the drug is then returned to the doctor who provides it to the patient.

The wording in the product monograph is based on the data provided to support the authorization of Mifegymiso. The product monograph is not a legally binding document. If, under the practice of medicine or pharmacy, the administration or distribution of the drug is outside of what is in the approved product monograph, the health care professional would assume any liability associated with the product being used off-label.

Revisions to the indication or conditions of use of the product will be considered if the company submits evidence supporting these changes. As with all submissions, Health Canada would apply the same rigorous scientific review to the new information.

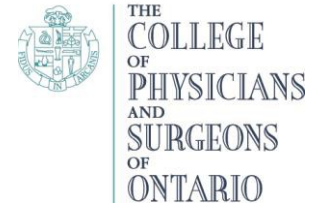
I appreciate your organisations taking the time to write to us seeking clarity regarding the conditions of use for Mifegymiso and I hope that the above information is helpful. If you have any other questions or concerns, please don't hesitate to contact me directly.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Supriya Sharma', written over a horizontal line.

Dr. Supriya Sharma
Chief Medical Advisor to the Deputy Minister

cc: Nancy Lum-Wilson, Registrar Ontario College of Pharmacists



VIA EMAIL

December 15, 2016

Dr. Supriya Sharma
Chief Medical Advisor
Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9

Dear Dr. Sharma,

Re: Mifegymiso

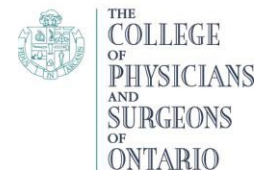
The College of Physicians and Surgeons of Ontario (CPSO) and the Ontario College of Pharmacists (OCP) write in relation to Mifegymiso. We understand that the drug will become available to the Canadian public in January 2017 and wish to clarify details regarding requirements contained in the product monograph which may impact patient access to this drug.

We are aware that the product monograph submitted by Celopharma Inc. and approved by Health Canada states:

1. Mifegymiso will be prescribed and dispensed by physicians;
2. Physicians will undergo training and be registered prior to dispensing Mifegymiso;
3. The physician shall confirm gestational age by ultrasound and exclude ectopic pregnancy; and,
4. The registered physician will supervise the administration of mifepristone by the patient.

We understand that the College of Physicians and Surgeons of British Columbia and the College of Pharmacists of British Columbia have received confirmation from Health Canada that despite the product monograph, it is permissible for Mifegymiso to be dispensed by a pharmacist to the patient and delivered to the prescribing physician or dispensed directly to the patient with a prescription. Similar to our counterparts in British Columbia, we wish to confirm that Ontario physicians and pharmacists who have completed training regarding the safe use of Mifegymiso can proceed in this manner, and that this will be considered acceptable by Health Canada .

We also wish to confirm that consistent with Health Canada's 'Myths and Facts' document published online, that the product monograph requirement for 'supervision of the administration of mifepristone' does not require patients to consume the medication in front of the physician,



Page 2

Dr. Supriya Sharma, Chief Medical Advisor
December 15, 2016

but rather determining how and where the medication is to be ingested would be a treatment decision between the physician and the patient.

As professional regulatory authorities, the CPSO and the OCP have mandates to act first and foremost in the public interest. Ensuring Ontarians have access to approved medical treatments supports this mandate. Upon receiving a response from Health Canada providing confirmation on the two elements raised above, we intend to communicate with our respective members informing them of the need to complete training regarding Mifegymiso, as well as the options for dispensing this medication.

We appreciate Health Canada's assistance in clarifying these matters. As there may be others across the country who will seek similar clarification, Health Canada may wish to consider updating the current product monograph to provide more clarity around this medication's dispensing and administering procedures.

Yours very truly,

Handwritten signature of Rocco Gerace.

Rocco Gerace MD
Registrar
College of Physicians and Surgeons of Ontario

Handwritten signature of Anne Resnick.

Anne Resnick, R.Ph., B.Sc.Ph., CAE
Interim Acting Registrar
Ontario College of Pharmacists

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TRUDEAU IN WASHINGTON

How the arrival of the abortion pill reveals a double standard

As reproductive rights come under assault in the U.S., the story of new pregnancy-termination medication reveals continuing barriers to reproductive health for Canadian women

Anne Kingston

February 5, 2017





(Jim Rankin/Toronto Star/Getty Images)

Few drugs have arrived in Canada accompanied by more fanfare, delays, hope, controversy and politicking than Mifegymiso, the pregnancy-termination medication approved by Health Canada in 2015 after a two-and-a-half-year process. The drug began shipping to a handful of hospitals and health centres only last month.

At the very moment reproductive rights in the U.S. are coming under assault—with Canada upheld as a progressive bastion of abortion access—the Mifegymiso story reveals continuing barriers to reproductive health for Canadian women, as well as “abortion exceptionalism,” a double standard surrounding the procedure, even in a country where provincial insurance plans have covered surgical abortion for decades. In one grim detail, Health Canada took the rare step of removing the names of reviewers who approved the drug from its website due to threats against them.

Canada lags more than 60 countries in providing mifepristone, a drug that ends a pregnancy; France has offered it since 1988, the U.S. since 2000. It’s also on the World Health Organization’s essential medicines list. The reason was simple: no manufacturer had submitted an application until France-based Linepharma Inc. commenced talks with Health Canada in 2008. “It wasn’t seen as cost-efficient,” says Dawn Fowler, Canadian director of the National Abortion Federation. Others say the omission is telling of a

historical lack of leadership on women's health care, particularly abortion access.

"Health Canada isn't proactive," says Sandeep Prasad, executive director of the Ottawa-based Action Canada for Sexual Health & Rights. "It doesn't seek out needed drugs, which is why we don't have access to contraceptive implants," as are available in other developed countries.

RELATED: After 35 years, abortions are finally available in P.E.I.

Mifegymiso is a two-drug regimen: mifepristone and misoprostol, taken 24 to 48 hours later. Mifepristone blocks the effects of progesterone, a hormone needed for a pregnancy to continue; misoprostol causes contractions of the uterus and relaxation of the cervix, which leads to miscarriage.

The drug's initial labelling in Canada signalled the sort of danger one associates with, say, handing asbestos to children. To be certified to prescribe it, doctors have to complete a six-hour online course; such certification has been limited in the past to select cancer drugs and methadone. Pharmacists were shut out: only certified doctors with access to ultrasound could prescribe and dispense to women up to 49 days of pregnancy; this included supervising the swallowing of the first pill, like overseeing a sick child. Dustin Costescu Green, a Hamilton, Ont.-based OB/GYN who co-chairs the training program run by the Society of Obstetricians and Gynaecologists of Canada (SOGC) says that's unique, "the first time in women's health we've had a product that required such rigorous training."

Keeping the process in the hands of doctors can seem paternalistic but is crucial, says Costescu Green, "to prevent the potential for abuse, to ensure the patient receives the correct product and the product dispensed is given to the right patient." Yet international examples of abuse of mifepristone are rare, he says: "I don't know if there are any in public literature."

The response to these regulations, combined with outrage over the uninsured drug's \$300 price tag being just one barrier to access, revealed medical activism was alive and well. B.C. pharmacists successfully lobbied to dispense the drug, as is the case in Australia, under certain conditions. Other provinces are expected to follow suit.

Labelling has been modified; the drug can be taken at the discretion of a health-care professional, which means women could take it at home. Distributor Celopharma Inc.

has applied to Health Canada for permission for pharmacists to dispense directly to the patient if indicated by the prescriber, and to increase gestational limit to 63 days (the FDA extended the limit to 70 days in 2016). The company expects a response by the fall.

Women's-health advocates express concern that the rules mean Mifegymiso won't help expand access to abortion; instead, existing surgical abortion providers will just add it as a service. The first shipments have been sent to hospitals and health centres in B.C., Alberta and Ontario. And this is a problem in a country where abortion is centralized in the largest cities within 100 km of the U.S. border, with a dearth of providers in rural areas, says family physician Wendy Norman, an associate professor at UBC's School of Population and Public Health. Yet the need exists. A 2012 study Norman authored found 31 per cent of Canadian woman have had at least one abortion.

The drug's arrival will not transform physicians into abortion providers, says Costescu Green, citing international data: "Abortion rates don't go up, but medical abortion rates go up." It's a choice many women make. Planned Parenthood in the U.S. reports that half of women seeking an abortion request medical abortions. In Europe, 80 per cent of abortions are medical. In Canada, some 300 doctors and pharmacists have enrolled in or taken the course, which began in January, the SOGC reports. Celopharma reports that 70 doctors, and "very few" pharmacists have completed it.

Expecting doctors to be drug dispensers is a disincentive for family doctors to prescribe, says Lianne Yoshida, the medical director of the abortion clinic at Halifax's Victoria General Hospital: "They don't have the same options as free-standing clinics to stock, nor are they set up to receive payment." There is also the inconvenience for the patient. "I can see a patient, do evaluation and counselling. I can write her prescription, which she takes to the pharmacy, where the pharmacist has done the training; they accept the prescription, accept the payment, order the medication and have it delivered to my office. It's silly." Such hoops signal discomfort with abortion, says Prasad: "Those needing access have to work harder, and we don't trust those seeking abortion care to responsibly take medication that will safeguard their health." Others see a risk of restigmatizing abortion: "You're defeating the access benefit by insisting on physician dispensation and observation," says Jocelyn Downie, a Dalhousie University law professor specializing in health law. "You're also making this seem like an exceptional intervention. And it's not."

RELATED: Why the anti-abortion movement is embracing gender equality

Supriya Sharma, chief medical advisor with Health Canada, calls Mifegymiso a unique product. "It's not used in a standard way; it's replacing a surgical procedure," she says in an interview with *Maclean's*. "Significant politics" exist around the drug, she says: "We got letters that were critical. We had marches focused on the product." The agency ignored the fray, she says: "We made sure we were treating it as any other drug, and [the review] was based on science, evidence and law."

Yet the Mifegymiso "facts vs. myths" page on Health Canada's website isn't standard practice (the other example offered by the department is a page discussing naturopathic remedies). These "myths" include, "The medication has lower risks than surgical abortion" and, "Requiring the medication to be taken under supervision is unnecessarily restrictive."

Yoshida questions posting such information, noting all drugs have potentially scary side effects. "It's bizarre, considering how safe this medication is," she says. (Repeated studies show medical abortion to be only slightly less safe and effective than surgical abortion, which has a better than 98 per cent success rate.) The messaging concerns her: "The delays, the training, the physician dispensing sends the clear message: 'This is dangerous to women.' "

Research to discern how to make the drug more accessible is in the works. Norman's UBC team received a Canadian Institutes of Health Research grant to investigate barriers faced by physicians and pharmacists, particularly in rural areas. Breaking through is key to access, says Downie. "If doctors can offer it in the privacy of their offices, they won't feel vulnerable to stigmatization and ostracization that can be associated with a clinic."

Adding nurse practitioners or midwives as providers, as is the case in the U.S., is seen as another strategy. Costescu Green says it's up to nurses and midwives to express interest: "We depend on those organizations to come forward and be involved in the discussion and process." Josette Roussel, senior nurse adviser with the Canadian Nurses Association, says they weren't contacted by Health Canada about Mifegymiso until last year. Nurses serve as primary care providers for more than three million Canadians, she says. Members in New Brunswick have already expressed interest in providing the drug

and have asked the association to advocate. (Celopharma also cites telemedicine as an option for medical supervision in remote areas.)

Insurance coverage is the next battle. The Canadian Agency for Drugs and Technologies in Health, which advises all the provinces except Quebec on drugs to cover, will review Mifegymiso in March (Quebec is reviewing coverage separately). Norman wants provincial governments to subsidize all women, as with surgical abortion, “not only those on social assistance.” Certainly the system is structured for surgical abortion, which can cost up to \$1,500. “But medical abortion can help reduce demand for surgical time—and women get their care faster,” Fowler notes.

Speaking to doctors and activists, it’s clear that despite the frictions, Mifegymiso has forged new alliances. One upside, says Norman, is that medical groups, not industry, coordinated the training. Downie speaks of a more responsive Health Canada. After she was publicly critical of pharmacists not dispensing, a Health Canada official called her to discuss the issue: “I’m hopeful this is a sign of a new era of listening,” she says.

Anusa Sivalingam, board chair of Yellowknife Women’s Society, is also hopeful, noting women in the north don’t receive “the full suite of reproductive services.” It’s not clear yet how the drug will be distributed to more remote regions, “but we’re optimistic and think it was a good step it was approved.” Costescu Green expects to see disparities across the country: “In different provinces, there will be different practices.” And that means the fight for equitable reproductive health in Canada must rage on.



Filed under:

Abortion Editor's Picks Mifegymiso Reproductive Health



- College of Nurses of Ontario
- College of Physicians and Surgeons of Ontario
- College of Physiotherapists of Ontario
- College of Optometrists of Ontario
- Ontario College of Pharmacists
- Royal College of Dental Surgeons of Ontario

February 15, 2017

Private and Confidential
Via Courier &
Via Email: Robert.Bell@ontario.ca

Dr. Bob Bell, Deputy Minister
Ministry of Health and Long-Term Care
Hepburn Block – 10th Flr
80 Grosvenor St
Toronto ON M7A 1R3

Dear Deputy Minister Bell: *bab*

On behalf of the Advisory Group for Regulatory Excellence (AGRE) Registrars Group, I am offering the support of our members as Bill 87, *Protecting Patients Act, 2016*, proceeds through the legislative processes. AGRE members have the expertise in operationalizing legislation and would support the Ministry to ensure the goals of Bill 87 are achieved as intended.

While individual College Councils are considering submissions on Bill 87, and the Federation of Health Regulatory Colleges of Ontario (FHRCO) is also discussing a response to Bill 87 on areas of agreement of FHRCO members, AGRE is also offering to begin to work collaboratively now with the Ministry, similar to AGRE's work on transparency.

I welcome a contact from the Ministry to explore the opportunity for collaboration and support.

Yours truly,

A handwritten signature in blue ink, appearing to read 'Irwin Fefergrad', is written over a horizontal line.

Irwin Fefergrad, Chair
AGRE Registrars Group

cc: Denise Cole, Assistant Deputy Minister
MOHLTC, Health Workforce Planning and Regulatory Affairs Division

Allison Henry, Director
MOHLTC, Health System Labour Relations and Regulatory Policy Branch

AGRE Registrars Group



Governance Discussion Paper

February 14, 2017

Prepared for AGRE by:

Paulette Blais, BA, MIR
www.blaisconsulting.com



Introduction

The purpose of this discussion paper is to provide background and context for the Advisory Group for Regulatory Excellence (AGRE) roundtable discussion regarding governance.

Since AGRE was formed in 2012 the group has had considerable success in collaborating together to develop the AGRE Transparency Principles, engaging with the provincial government regarding these principles and having them adopted in bylaw by the AGRE regulators. As will be seen from the Bill 87 Protecting Patients Act summary provided in the Background section, this forward-thinking work on transparency both anticipated and was able to shape to some extent the Ontario government's policy direction. Regulators who have adopted the AGRE Principles and amended their bylaws accordingly are therefore well-prepared for transparency amendments to the Regulated Health Professions Act (RHPA) that may become effective through Bill 87.

The current focus of AGRE regulators on governance is similarly intended to position regulators to get "ahead of the curve" on regulatory governance. This is in response to apparent trends in the regulatory landscape, anticipation that the Ontario government is looking to impose changes to the governance sample framework of all regulated health professions and the College of Nurses of Ontario's (CNO's) December 2016 Council decision to pursue a new "Vision 2020" for its governance structure.

While the governance conversation so far has been a high-level discussion among the AGRE Group, this paper is intended to share information and context in order broaden the discussion to AGRE College Executive Committees and eventually Councils.

Background

Trends in Regulatory Governance

There are important external influences and trends that provide both impetus and context for AGRE to look at regulatory governance at this time. These are international (particularly related to regulatory developments in the UK, Australia and New Zealand), national and provincial.

Richard Steinecke, Robert Lapper and others who provide guidance to regulated professions on these issues have highlighted that these trends in regulatory governance have and are anticipated to continue to influence Ontario government policy in the near future.

Robert Lapper, CEO of the Law Society of Upper Canada has spoken about changing trends in regulatory governance, including in a presentation to CPSO Council in February 2016. He was a member of CNO's Governance Task Force and in his address to CNO Council in December 2016 stated that "At very least every professional regulator will have to consider...and be able to justify, in the public interest, its own sample framework of professional regulation, against the benchmarks that these trends arguably establish." External trends that he pointed out are included in the summary here¹:

- "There is a growing tendency in the western democratic world to question whether self-regulating professions truly live up to their mandate to protect the public interest."

¹ Direct quotes are from Robert Lapper's CNO presentation.

- "Regulatory governance is in the spotlight. Regulatory outcomes that are perceived to favour the professional over the public interest are often the subject of intense media scrutiny. Governments are called to account and address the public outcry that ensues."
- Governments have diminished self-regulation in many countries. This has included, in the UK the "co-regulation" of health and legal professions under standards authorities governed by public and not professional members. Similar reforms are being active considered or implemented in Ireland, Australia and New Zealand.
- In Canada, governments are increasingly inclined to oversee the regulation of professions. For example fairness legislation in a number of jurisdictions scrutinizes the registration practices of regulators and imposes significant reporting requirements.
- In recent years governments have become more likely to intervene in professional regulation. In BC both teachers (2012) and the real estate profession (2016) have lost the right to self-regulate. The 2012 appointment of a supervisor for the College of Denturists of Ontario (CDO) also signalled willingness by the government to use a power it had not exercised previously².
- Reviews of professional regulation worldwide have led to trends such as:
 - Moving to more balanced professional/public representatives in governance (UK health and legal professions).
 - Selection of members from specific practice sectors rather than regions (Nursing and Midwifery Board – Ireland).
 - Moving from election of professional members to competency or criteria based appointment of professional members or to a mix of election and appointment of professional members (Federation of Law Societies, Canada / UK Health and Legal Professions).
 - Reducing Board/Council sizes (UK health professions³, *Barreau du Québec*, other Canadian Law Societies).
 - "Professionalizing" or specializing some regulatory functions (Professional discipline tribunals – Law Society of Upper Canada, New Zealand Health Practitioners Disciplinary Tribunal).

² The power to appoint a College supervisor is outlined in the RHPA as "**College supervisor** s. 5.0.1 (1) The Lieutenant Governor in Council may appoint a person as a College supervisor, on the recommendation of the Minister, where the Minister considers it appropriate or necessary. 2014, c. 14, Sched. 2, s. 9." Evidence that this is the first exercise of this power can be read in the CDO Council Highlights of September 12, 2013: <https://cdo.in1touch.org/document/1160/73rd%20Council%20Highlights.pdf%20>.

³ The General Medical Council (GMC) was reduced from 104 members to 35 in 2003 (source: *Dyer, Clare (10 May 2003). "New slimmed down GMC takes shape". BMJ. 326: 1002.*). The Professional Standards Authority report (September 2011) *Board size and effectiveness: advice to the Department of Health regarding health professional regulators*, advised that "boards with a range of 8-12 members are associated with greater effectiveness". Subsequently consultations were undertaken and the boards of health councils were reduced - the GMC and the General Dental Council each now have 12 members, the Nursing and Midwifery Council went from 14 to 12 members, the General Osteopathic Council went from 14 to 10 members.

The UK's Professional Standards Authority (PSA)

- A very significant and influential international development has been the move away from the self-regulation of professions in the UK. As indicated in Grey Areas⁴ "With the publication of its paper on Right Touch Regulation in 2010, the United Kingdom's Professional Standards Authority (PSA) leapt to the forefront of international thinking on professional regulation." The subsequent updating of that paper in 2015 as well as publishing another paper entitled Rethinking Regulation "called for a radical overhaul of the regulation of the health and social service professions in the UK".
- Richard Steinecke reported⁵ that "The PSA is being considered by the Ministry of Health and Long-Term Care of Ontario (Ministry) as a possible sample framework for oversight of the RHPA Colleges."
- The PSA⁶ was established in 2012. It was previously known as the Council for Healthcare Regulatory Excellence (CHRE)⁷. The PSA oversees statutory bodies that regulate health professionals in the UK and social care in England. Where occupations are not subject to statutory regulation, it sets standards for those organisations that hold voluntary registers and accredits those that meet them.
- The PSA is a publicly appointed body. None of the members of the Board of Directors of the PSA can have been practitioners of a profession overseen by the PSA. The PSA is funded by fees and levies charged to the bodies it oversees or, in the case of advice to government agencies or international bodies, fees charged to the recipients of the advice.
- The March 2013 PSA report *Fit and Proper? Governance in the public interest*⁸ indicates that:

"Over the past decade the governance of the health and care professional regulators in the UK has been transformed. The UK approach is no longer self regulation but shared regulation; regulation shared by professions and the public in the interests of society as a whole. The councils or boards of the professional regulators are now much smaller, and have a balanced number of appointed professional and public members, rather than the large, elected, representative bodies of old. Presidents have become chairs and many are public rather than professional members. The focus of regulation on serving the public rather than the professions

⁴ Steinecke Maciura LeBlanc. Grey Areas (October 2016 - No. 210), retrieved January 25, 2016 from: <http://www.sml-law.com/wp-content/uploads/2016/10/Greyar210.pdf>.

⁵ Richard Steinecke provided a 10-page analysis of the legal authority of the PSA and implications for the RHPA to AGRE in July 2016. The points included in this paper are a very brief synopsis of his much more detailed review.

⁶ The full name of this body is the Professional Standards Authority for Health and Social Care.

⁷ The CHRE was established in 2002 as a body to oversee the regulation of healthcare professionals in the UK following the 2001 Kennedy "Bristol heart scandal" report which looked at the causes of high rates of paediatric cardiac deaths at the Bristol Royal Infirmary. "[National body to oversee healthcare professionals](#)". The Guardian. Retrieved February 7, 2017.

⁸ Professional Standards Authority (March 2013) *Fit and Proper? Governance in the public interest*. Retrieved February 7, 2017: <http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/fit-and-proper-2013.pdf?sfvrsn=2>.

is manifest in these reforms, and is mirrored in similar developments in professional regulation in other sectors, such as the regulation of legal professionals."

- The functions of the PSA fall into four broad categories:
 1. Provide oversight of health and social work regulators, which includes:
 - a) reviewing all disciplinary decisions of regulators;
 - b) conducting an annual performance review of each regulator;
 - c) mentoring and providing advice to regulators (e.g. how to handle dishonest behaviour of members, Rethinking Regulation paper);
 - d) directing regulators to make rules; and
 - e) (in future) considering complaints against regulators.
 2. Accredit unregulated professions: Unregulated professions may apply for may apply to have their "voluntary" register accredited by the PSA. There are currently 50 registers accredited by the PSA - ranging from Acupuncture to Yoga therapy.
 3. Advise government: The PSA provides policy advice and develops discussion papers for government⁹. For example, the PSA undertook research and provided specific advice to government on board size and effectiveness that resulted in the reduction of the size of health councils. The PSA also advises the Privy Council about the quality of the processes eight of the regulators use to recommend candidates for appointment and re-appointment as chairs and members of their councils. The PSA "check(s) the process the regulator has used, and assess(es) whether it is fair, transparent and open, whether it inspires confidence, and whether it ensures all selection decisions are based on evidence of merit."¹⁰ The PSA advises the Privy Council whether each process meets the standard, but does not assess the suitability of individual candidates or have any say in who is appointed.
 4. Other activities: The PSA is sometimes retained to conduct reviews and publish reports internationally, and has done so for the Royal College of Dental Surgeons of Ontario (2013) and the College of Registered Nurses of BC (2015).
- As outlined by Robert Lapper during his December 2016 address to CNO Council:

"In its original report and subsequent updates the PSA has set out governance strategies that it recommends toward the objective of rebuilding trust between professionals, the public and regulators".¹¹ These include:

 - Smaller sized Councils/Boards;
 - Equal numbers of professionals on Councils/Boards; and

⁹ PSA policy advice to government can be found at: <http://www.professionalstandards.org.uk/publications/policy-advice>.

¹⁰ The PSA's role in advising the government on appointments can be found at: <http://www.professionalstandards.org.uk/what-we-do/our-work-with-regulators/appointments-to-councils>.

¹¹ Governance recommendations were originally described in the September 2011 CHRE report *Board size and effectiveness: advice to the Department of Health regarding health professional regulators*. Retrieved February 7, 2017: <http://www.professionalstandards.org.uk/docs/default-source/publications/advice-to-ministers/board-size-and-effectiveness-2011.pdf?sfvrsn=12>.

- Transparency of appointment processes (which assumes that Boards/Councils are not elected by members of the profession.)"

The establishment of the PSA and effective removal of the right of self-regulation from health professions is significant and was anticipated to influence Ontario government policy, particularly in response to the recommendations of the Sexual Abuse Task Force Report. While Bill 87 does not create a new oversight body or a separate adjudicative tribunal to handle complaints of sexual abuse, it does create new powers of oversight by the Minister, including direction regarding the structure of and appointments to statutory committees and investigatory activities related to sexual abuse.

Bill 87, Protecting Patients Act, 2016

On December 8, 2016 the Ontario Minister of Health and Long-term Care (MOHLTC) introduced for first reading Bill 87, which includes significant changes to the RHPA and Code in the following areas:

1. Increased powers of the Minister of MOHLTC;
2. Investigations, prosecution of and mandatory revocations related to sexual misconduct and funding for victims of sexual abuse, etc.; and
3. Transparency, including expansion of the public register and new self-reporting obligations.

Richard Steinecke provided an analysis of Bill 87 in a December 22, 2016 memo to the Federation of Health Regulatory Colleges of Ontario (FHRCO). In his introduction he states:

"Bill 87 will make significant changes to the *RHPA*. The changes go well beyond reforming the sexual abuse provisions. For example, enormous powers will be transferred to the Minister including the power to restructure the statutory committees of the College, such as by reducing or even removing professional members from their composition. The Minister will also have the authority to require Colleges to provide information to the Minister about the Colleges' handling of individual cases."

There are several amendments that are specifically relevant to discussions about governance and are anticipated to have a high impact on Colleges. These include the increased power of the Minister of MOHLTC to oversee and direct College functions by controlling the composition and actions of statutory committees. These are highlighted in Steinecke's analysis as follows:

- Committee Structure: RHPA s. 43(1)(p) to (s), Code s. 10(3), 17(2) and (3), 25(2) and (3), 38(2), (3) and (5), 64(2) and (3), 73(3).3, 94(1)(h.1) to (h.4). The Minister will have the power to make regulations controlling all aspects of the structure of the statutory committees (committees established by by-law are not affected). The regulations can establish their composition, panel quorum, eligibility requirements and disqualification grounds. For example, the Minister could require a majority of public members (or even all public members) on committees or panels. *This provision has the potential to compromise a fundamental principle of self-regulation, namely that the profession is governed by its own members* [emphasis added]. However, it should be noted that these regulations would not alter the composition of the Councils of the Colleges in either size or composition
- Sexual abuse: Minister Prescribed Functions: RHPA s. 43(1)(w). The Minister can make regulations specifying how Colleges are to investigate and prosecute sexual misconduct cases (e.g., requiring the use of investigators with particular credentials, mandating the videotaping of witness interviews, making rules of procedure allowing for the videotape to be received as the evidence in-chief of a

witness). In addition, the Minister can make regulations providing for further “functions and duties” for Colleges (e.g., requiring Colleges to provide legal counsel paid for by the College for individuals alleging sexual abuse; requiring Colleges to conduct research on sexual abuse by their members).

- Bill 87 also includes changes to the public register and self-reporting obligations (RHPA s. 43(1)(t) and the Code s. 23, 94(1)(l.2)). These proposed amendments are largely consistent with AGRE's Transparency Principles and include those related to expansion of information provided on the public register, new mandatory self-reporting obligations and the posting of Council meeting information on College websites.¹²

Regulatory Governance in Ontario

AGRE Discussions

- Following the success of the Transparency Project AGRE identified at their January 14, 2016 meeting a second identified task: the need to focus on governance. This was inspired by comments made by Deputy Minister of MOHTC Bob Bell¹³ and Assistant Deputy Minister Denise Cole at public meetings. Their remarks included:
 - How can College Councils function in the public interest when Council members are elected by peers/College members? Will Council members be considering the interests of those who elected them to Council? Are professional members really needed on College Councils?
 - Councils are too large.
 - There are too many Colleges.
 - Should College Presidents be elected from amongst the full profession, i.e., not by the College Council?
- AGRE recognized an opportunity to proactively and positively influence system change for *RHPA* Colleges, in a manner similar to the successful transparency initiative. There was agreement to hold a retreat to dedicate time to this issue, and the Policy Working Group (WG) developed an initial list of governance issues to be discussed at a retreat.
- The half-day retreat was held April 6, 2016 and was attended by the AGRE representatives. The focus of the governance discussion was on "how anticipated amendments to the RHPA could be influenced at early stages of decision-makers' thoughts and conversations".
- The retreat consisted of brain-storming sessions regarding Councils, committees and next steps. Questions included what Councils could look like, who the members would be, how they would become members, what their roles would be etc., with similar questions being considered for the structure and composition of committees. This discussion yielded good discussion and some general themes emerged, which are briefly summarized here:

¹² These points were excerpted from Richard Steinecke's December 22, 2016 Analysis of Bill 87 prepared for the Federation of Health Regulatory Colleges of Ontario (FHRCO).

¹³ Similar comments were subsequently made at a February 2016 meeting of FHRCO and during a presentation that Mr. Bell gave at a spring 2016 CPSO Council meeting.

- Councils:
 - All Council members (professional and public) should have similar competencies - this is difficult to ensure given the current sample framework of elections and appointments.
 - Possible that appointing rather than electing could enhance recruitment of effective members.
 - Consistent governance training and evaluation is needed to enhance performance and effectiveness of Councils.
 - Theoretically electing members brings geographic representation and connection to the profession, but some professional members may feel that they represent a constituency.
 - Important that public appointments are not political.
 - All Council members have same role so should be remunerated the same.
 - Currently there may be a disproportionate representation of certain demographics (e.g. those who practice in settings that allow paid time away) - how can greater participation be enabled?
 - Principles: Have competent Council members, selected through an application process, reflective of society (gender-balanced, representative of the profession).

The brainstorming also generated the following specific ideas:

- All Council members should have similar competencies: intelligent/knowledgeable; prepared; open-minded/willing to learn; up-to-date with current standards of practice, boundaries, trends, etc.; understanding of the public interest; independent (i.e., not an advocate); available; possessing integrity and transparency.
- Council member skill sets: Should include financial background; critical reasoning skills (actuary or lawyer); similar qualities as those required for members of for-profit Boards; previous regulatory experience (e.g., served on Committees); and perspectives (not representation); from different types of practice.
- Competencies/skill sets should be measured in a transparent, objective way: e.g. formal application; interview; references; recruitment; similar to robust screening processes used when hiring staff.
- Three types of recruitment:
 - Council (Board) members (by External Governance Committee)
 - Committee members (by Internal Governance Committee)
 - Discipline committee members (by Internal Governance Committee)
- Two Governance Committees to be formed:
 1. External Governance Committee: External body to appoint Board members
 2. Internal Governance Committee: to appoint Committee membersBoth committees to be comprised of representatives from the College, other Colleges and government.
- Colleges to become Boards:
 - Board activities to be reduced to focus on governance/policy
 - Full Board to serve as Executive - no separate Executive Committee
 - Board members would not sit on Committees.
 - Size of Boards to be same for all health Colleges (e.g., between 8-12 members)

- 50/50 balance of professional and public members
- College Committees to include:

Board-Related (comprised of members with Board experience):

- Governance Committee
- Finance/Audit Committee
- Other College-specific committees

Member-Related (comprised of members with clinical expertise, appointed by the Board):

- Registration Committee
- Quality Assurance Committee
- Patient Relations Committee
- Fitness to Practice Committee
- Inquiries, Complaints, and Reports Committee
- Discipline Committee

- All committee members to require same competencies plus additional clinical/profession-specific knowledge as needed. Discipline Committee to be created as a pool of panel members, perhaps with a system similar to jury selection process.

- As an initial follow-up to this retreat in June 2016 the Policy WG provided an update at a subsequent meeting which included the status of governance discussions at AGRE Colleges. The purpose of this review was to evaluate the state of organizational or Council readiness, along a continuum from unaware of governance issues to making a decision to change their governance structure, as follows:

Unaware -> Aware - No discussion -> Aware - Discussion -> Ready -> On board-> Decision

- Generally speaking, most of the Colleges were considered to be at the 'aware' stage. The CNO was at that time characterized, after two years of governance work, to be at the 'ready' stage.
- It was agreed that as a next step a discussion paper should be developed and a "governance roundtable" held to further develop AGRE's governance initiative.
- Subsequent to these discussions, in December 2016 CNO's Leading in Regulatory Governance Task Force Final Report was submitted to Council and all recommendations were approved. In terms of the continuum above CNO can now be considered to be at the "On board" stage of governance transformation and working towards implementation planning and decisions.
- The following section provides an overview of CNO's "Vision 2020" as background and a sample framework for discussion at the AGRE governance roundtable.

CNO's Leading in Regulatory Governance Task Force Report

- The College of Nurses of Ontario's (CNO's) Leading in Regulatory Governance Task Force was formed in December 2014, with the purpose of the work being:
 - To conduct a proactive, objective, expert, best-practice and evidence-based review of all aspects of College governance.
 - To seek new governance perspectives and approaches to enhance Council's excellence in governance.
 - To engage Council in an informed conversation to determine what, if any, changes are needed to governance principles and processes, so that the College is recognized as a leader in regulatory governance.
- As stated in its Final Report "The Task Force believes that Council needs to consider what is fundamental to self-regulation and what needs to change to maintain public trust in nursing regulation in Ontario."¹⁴ The theme was that regulators need to be proactive in order to strengthen public trust.
- Activities undertaken by the Task Force to develop its recommendations included:
 - a Spring 2015 evaluation of CNO Council governance by an external governance expert;
 - an extensive literature review of academic studies about governance sample frameworks and group dynamics including which included looking at: governance sample frameworks and policies; regulatory board and committee structures; election/appointment/recruitment processes; leadership etc.
 - a review of trends and best practices in the governance of regulators around the world;
 - a report of a survey of regulators about governance; and
 - Council's input and insights provided at governance workshops.
- The Governance review milestones included in the attached final report attest to the significant consultation with and involvement of CNO Council in the Task Force's work. Some of the significant issues Council wrestled with regarding the draft framework when it was initially presented were:
 - ensuring that a diversity of views would continue to inform Council decision-making;
 - concerns, including about engagement of members, inherent in moving from an election to appointment process; and
 - concern regarding the power of the Governance Committee.The Task Force used this feedback to modify the vision presented in the final report.
- At its December 6 - 7, 2016 Council meeting, CNO Council devoted a half-day discussion to the Task Force's final report, reviewing the proposed vision (sample framework) and the recommendations.
- The governance vision recommended by the Task Force is very different from the current RHPA model. Some of the most significant elements are:
 - Move from a council to board of directors governance structure.
 - Replace the current CNO Council (35 - 39 members) with a 12-member board.
 - Have an equal number of nurse and public directors (6 nurses, with at least one registered and one registered practical nurse member) rather than a majority of professional members.
 - Eliminate Executive Committee - the Board will act as the Executive Committee.

¹⁴ The Final Report, literature review and all other Task force materials are posted on CNO's website at: <http://www.cno.org/en/what-is-cno/councils-and-committees/council/Governance-Review/>.

- Establish and make attendance at a governance "boot camp" mandatory for those interested in participating on the board or committee, to ensure that they understand the roles and expectations.
 - Directors (board members) will not serve on statutory committees.
 - Make selection of all directors and committee members based on a competency-based application and appointment process (no elections). Ensure that the board is intentionally structured to bring different perspectives.
 - Committee members to be appointed to represent a diversity of nursing and other backgrounds and bring specific, relevant knowledge and skills required for committee work.
 - Advisory Groups to be established as a new mechanism to ensure continued engagement with the profession, provide knowledge and input to Council on nursing issues specific to sectors, regions, practice areas etc.
 - Two standing committees (Governance and Nominating) be established to handle all processes related to appointments to the board and committees.
 - All directors will receive the same honorarium, as will all committee members.
- **CNO's Governance vision:**

With a commitment to the public, the College of Nurses of Ontario's board of directors (the board) will govern the regulation of the nursing profession in accordance with:

- the College's regulatory mandate as set out in Ontario's health regulatory legislation; and
- the governance principles approved by the board.

A small governing board made up of an equal number of public and nurse members - with all members having the needed governance competencies, appropriate conflict of interest provisions and ongoing education and evaluation - will be able to meet the governance principles and the changing expectations of society. It will be, and will be seen to be, a proud protector of the public.

Components¹⁵ of Recommendations for CNO Governance Vision 2020

1. Size

- The board will have 12 members, with no Executive Committee
- The addition of advisory groups (e.g. consumer, educator, clinician) and a stakeholder engagement approach will ensure diverse input on issues the board will consider.

2. Composition

- The board will have equal numbers: 6 public and 6 nurse members (at least 1 RN, 1 RPN, and 1 NP).

3. Competency based

- Directors to be selected based on competencies (knowledge, skills, attitude) needed for the role.

4. Competency-based application and appointments process

- Board, statutory and standing committee members, board and committee leadership will all be appointed by the board based on competencies and a transparent, open appointments process.
- A Nominating Committee will recommend appointments of board and committee members.
- Governance Committee will recommend the competencies and board and committee leadership.
- Attendance at a “boot camp” to be required for individuals interested in applying for appointment.

5. Chair and Vice-Chair

- Effective leadership will be characterized by:
 - The Chair and Vice-Chair having the leadership competencies identified by the board.
 - Appointment/succession recommended by Governance Committee, approved by the board.

6. Director and board development

- Each director will be supported in understanding and meeting their role expectations and accountabilities through: participation in a “boot camp” during the appointment process, orientation and ongoing development/continuous learning, support for informed decision-making, staff support.
- Advisory Groups will be constituted by the board to help inform the board on views across the profession and the public.

7. Evaluation of Board and Directors

- Good governance as journey; with performance bar on the board and individual directors rising.
- The board will constantly improve through: a Governance Committee, ongoing meetings, self-evaluation, peer feedback and board evaluation to support continuous improvement; and an evaluation of governance effectiveness by an external expert every 3 years, with the results being publicly available.

8. Role clarity of board and statutory committees

- The roles, responsibilities, expectations and accountabilities of the board and statutory committees will be clearly stated and differentiated.

9. Statutory committees

- Statutory committee members will be appointed by the board on the recommendation of the Nominating Committee.
- Statutory Committee chairs will be appointed by the board on the recommendation of the

¹⁵ Please note that this table is an excerpt of the 2020 Vision Components from pp. 12 - 20 of the Task Force's Final Report. In the Final Report these components are more fully described, with Evidence/Rationale and Principles. A

Governance Committee.

- The board will appoint all statutory committee members and Chairs based on competencies and on the background needed for the specific committee.
- Statutory committees will be composed of non-directors.
- Statutory committees will report to the board on their legislated mandates.

10. Standing Committees

- There will be two new standing committees: Governance and Nominating

11. Terms of office

- Directors: 3-year term; 2-term maximum
- Leadership roles (Chair, Vice- Chair, Committee Chairs): 1-year term; one possible reappointment. Possible one-year term extension on the board if the Chair has reached the maximum 6 years of service term on the board.
- Committee members: 3-year term; 2-term maximum. Reappointments will be made within term limits and based on meeting role expectations

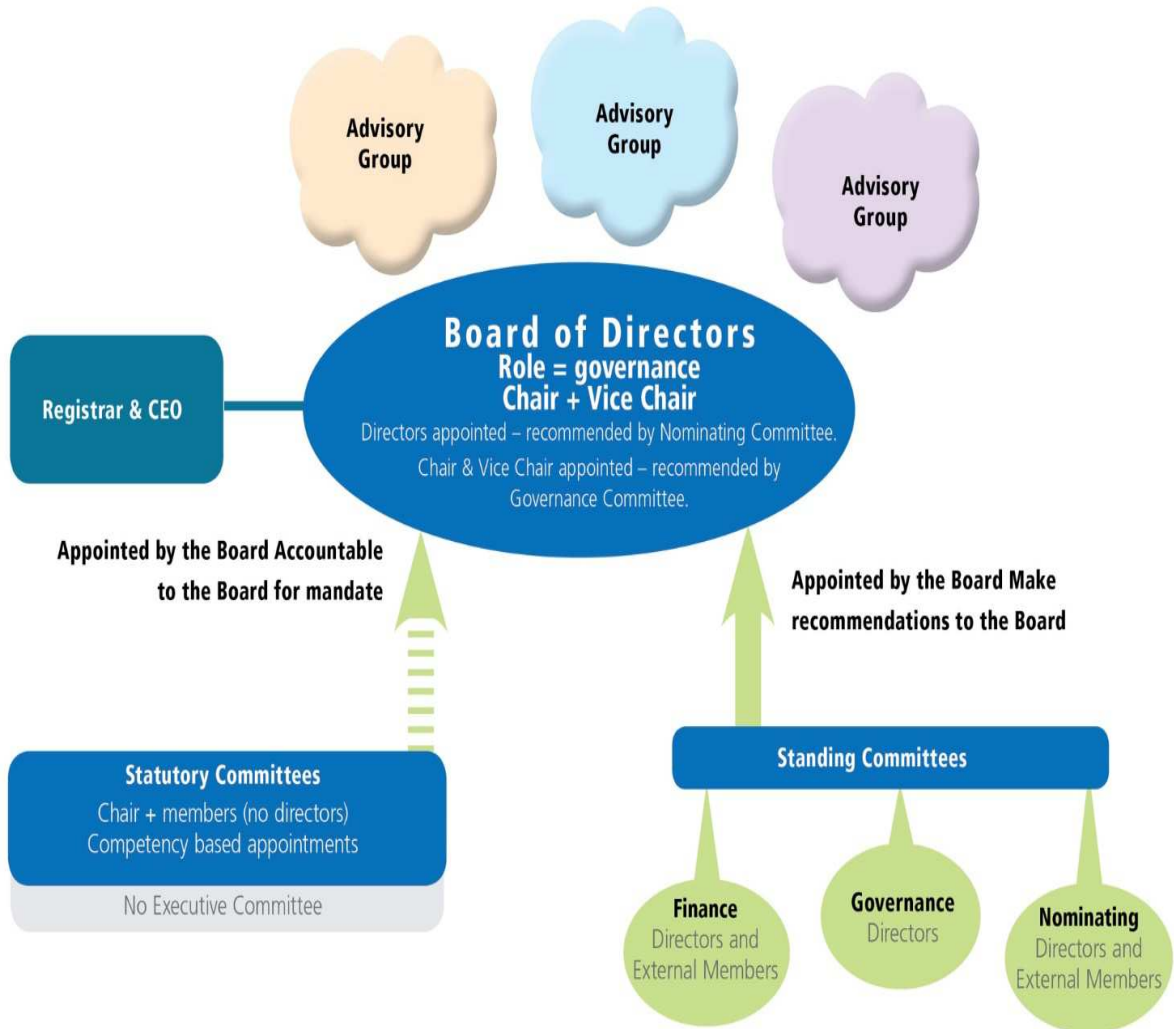
12. Funding governance processes

- The College will be accountable for funding the governance and statutory processes.
- all directors will receive the same honorarium; and
- all committee members will receive the same honorarium.

CNO's Governance Model is provided on the next page as background and a sample framework for discussion.

College of Nurses of Ontario's Governance Model
as illustrated on page 21 of the Leading in Regulatory Excellence Task Force Report

Governance Model



FOUNDATION



CNO Council approved the following motions:

- 1. That Council adopt the recommended vision: “Vision: The College of Nurses of Ontario’s Board of Directors for 2020” as it appears at attachment to the Leading in Regulatory Governance Task Force’s Final Report: A vision for the future.**
- 2. That, in June 2017, Council establish a working group of five Council members to work with Council to develop a plan for implementing the governance vision. The plan will include the communications and stakeholder engagement needed to build understanding of and support for the vision to enhance the likelihood that the needed legislative change will happen in 2020.**
- 3. That the working group’s terms of reference include working with Council to identify changes to advance the governance vision and that can take place before legislative change, and developing an action plan to support implementing those changes.**

Summary

- Trends in regulatory governance internationally, nationally and provincially point to significant changes: more scrutiny of the role of regulators; a greater propensity of governments to oversee and intervene in professional regulation; the creation of bodies that oversee the activities of regulators; and in some cases, the effective removal of the privilege of self-regulation. This has included an overhaul of the structures of governing councils to smaller board structures with equal (to professional) or sometimes complete public membership.
- The Ontario government has been increasingly critical of regulators and has shown a growing interest and has taken actions to "pull back the reins" on self-regulation. In recent years this was evidenced by the oversight function created by the Office of the Fairness Commissioner and the unprecedented exercise of the government's power to appoint a supervisor for a regulatory body. Recent comments by the Deputy Minister and Assistant Deputy Minister of MOHLTC and the proposed increased powers of the Minister to restructure statutory committees, as outlined in Bill 87, point to the Ontario government's intention to increasingly oversee and intervene in the functioning of health Colleges.
- Common themes about the thinking and future of regulatory governance in Ontario are emerging, at least among the AGRE regulators. This can be seen from the notes of the AGRE 2016 governance retreat and CNO's Leading in Regulatory Governance Task Force report, which is provided as background and a sample framework for discussion. These themes include:
 - A smaller Council or board structure may be more effective in discussion and decision-making. ➤ A small board should focus on governance/policy only - no participation in committees.
 - Full Board to serve as Executive - no separate Executive Committee
 - Having an equal number of professional and public members reflects international trends and may foster greater public trust.
 - The competencies required of directors and committee members should be identified and members selected/appointed based on competency and skills suited to the role, not elections.
 - Potential participants in regulatory governance should have access and potentially be required to complete training in governance and the role of regulatory bodies.

- All Council members/directors should be compensated equally as should all committee members - there should be no distinction between the roles and competencies of professional and public members - they are all there to serve the public interest.

Information Gaps & Additional Considerations

Proposed changes to governance represent significant modification of the current RHPA model. The CNO 2020 Vision was informed by broad and deep research into how governance can be made more effective and best serve the public interest. To develop and implement such a framework in Ontario would require additional research and information to fully understand the implications and determine next steps for AGRE regulators.

1. How can a new sample framework for governance as proposed by CNO be implemented in Ontario, and how long may it take? While AGRE transparency initiatives required that individual Colleges gain approval from their Council to make by-law changes, changes to governance as outlined in CNO's Vision 2020 will require amendments to the RHPA and Code, all profession-specific acts and College by-laws.
2. What specific sections of the RHPA and Code, profession-specific acts and bylaws would require amendment? What other legislation would be affected? How will the details such as Committee composition, quorum, performance evaluation and the role of advisory committees be established?
3. In other jurisdictions new governance models have been introduced and implemented by governments, not the governing bodies themselves. What are the challenges of having the governing body (i.e. Council) initiate develop and oversee the changes to its own structure? Will there be concerns regarding conflicts of interest, public perceptions of the College's motivation etc.?
4. How will members and professional associations react to moving from an election to appointment and Council to board structure? Will there be concern that members' perspectives will be less well represented? Will they perceive a new board governance structure as better serving the public interest?
5. The magnitude of the change in number and the new role of board directors outlined in the CNO sample framework is significant - to go from a Council of 36 members to a board of 12 directors. Other AGRE Councils currently have between 17 - 34 members. Does the magnitude of proposed change present different challenges? Would all AGRE Colleges choose to move to a governance structure of 12 members/directors? Alternatively, would the size of boards be determined by other factors, such as being reduced proportional to the current Council or total number of members of a profession?
6. Will the public perceive a new governance framework, such as that proposed in CNO's Vision 2020, as better serving the public interest?
7. What kind of communications will be needed to explain a change of governance structure, given that even the current RHPA model may not be well understood by stakeholders, including the public?

8. What will be the implications of CNO's initiative for other health Colleges (can one College alone change its governance structure)? Could the six AGRE Colleges pursue this collectively, or must the governance framework for all health Colleges be affected?
9. While the Ontario government has signalled through Bill 87 and other initiatives a growing willingness to oversee and intervene in College governance, is it truly willing to "rethink regulation"? How can AGRE best influence the provincial government?
10. How "ready" and what resources/capacity for change has each of the AGRE regulators? Does the proposed sample framework developed by CNO "fit" with the culture, issues, governance experience of each AGRE College?
11. What would be the effect of governance changes on non-health regulatory bodies? As these changes are intended to strengthen governance and better serve the public interest in the health sector, what about non-health professions (engineering, architecture, social work etc.)?

Appendices:

*Appendix 1: College of Nurses of Ontario Leading in Regulatory Governance Task Force. (December 2016)
"Final Report: A vision for the future"*

Appendix 2: AGRE Member Regulators - Council Composition

Final Report:



A vision for the future

Leading in
Regulatory
Governance
Task Force



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Introduction

Council's Leading in Regulatory Governance Task Force is pleased to present its final report and recommendations to the College of Nurses of Ontario's Council.

When Council established the Task Force in December of 2014, it set out the following goal and purpose. These guided the Task Force throughout its work:

Overall Goal:

The College is recognized as a leader in regulatory governance.

Purpose:

- To conduct a proactive, objective, expert, best-practice and evidence-based review of all aspects of College governance.
- To seek new governance perspectives and approaches to enhance Council's excellence in governance.
- To engage Council in an informed conversation to determine what, if any, changes are needed to governance principles and processes, so that the College is recognized as a leader in regulatory governance.

The following informed the recommendations:

- a report of a point-in-time (Spring 2015) evaluation of Council governance by external governance expert, Cathy Trower;
- a review of academic studies about relevant aspects of governance and group dynamics;
- an review of trends and best practices in the governance of regulators around the world;
- a report of a survey of regulators about governance; and
- Council's input and insights provided at governance workshops.

The Task Force also learned about the unique nature of regulatory governance and about self-regulation. The regulatory literature that the Task Force reviewed reflected the changing nature of regulatory governance and of regulatory models. The underlying theme in all of these was that regulators must be proactive in order to strengthen public trust.

The participation of the profession in regulation is the core of self-regulation. The Task Force believes that Council needs to consider what is fundamental to self-regulation and what needs to change to maintain public trust in nursing regulation in Ontario.

Attachment 4 is a summary of the project timelines, reflecting Council's commitment to, and engagement in, this work.

When developing its recommendations, the Task Force did not limit its thinking to the project goal of "leading in regulatory governance." It was informed by the College's Strategic Plan, particularly the goal to build public trust, as well as the commitment to innovation and evidence-based approaches, which are integrated in the recommended governance vision.



Recommendation:

1. That Council adopt the recommended vision: “Vision: The College of Nurses of Ontario’s Board of Directors for 2020” (attachment 1).

Implementation recommendations:

1. That Council share the governance principles, vision, Task Force reports and supporting documents with government, the public, other regulators, nurses and other stakeholders to broaden the dialogue about the future governance of regulators of professions;
2. That, in June 2017, Council establish a working group of five Council members to work with Council to develop a plan for implementing the governance vision. The plan will include the communications and stakeholder engagement needed to build understanding of and support for the vision to enhance the likelihood that the needed legislative change will happen in 2020; and
3. That the working group’s terms of reference include working with Council to identify changes to advance the governance vision that can take place before legislative change, and developing an action plan to support implementing those changes.

Recommendation 1: That Council adopt the recommended vision: “Vision: The College of Nurses of Ontario’s Board of Directors for 2020” (attachment 1).

Implementing this vision for governance will equip the board to support the College in meeting its strategic vision of leading in regulatory excellence and further the College’s public interest mandate.

The Task Force has identified an integrated vision rooted in the evidence, best practice in regulatory governance and input from Council. The Task Force considered presenting Council with options, but agreed unanimously that its task was to prepare a vision recommendation that was informed by evidence and best practice. Attachment 2 is a model illustrating this vision.

In a June 2016 workshop, Council discussed the building blocks of the vision. The Task Force presented each vision element along a continuum within which Council identified the optimal position. To support its discussions, Council was provided with evidence and information on trends in regulation. At this discussion, Council supported having a small Council, equal public and nurse members, and directors (board members) and committee members having the competencies needed to fulfil their roles. The Task Force developed a model as a result of evidence, best practices and Council’s feedback from this meeting, and presented it to Council in September 2016.

In September 2016, when exploring the model Council flagged some issues. Every member of the Task Force participated in that workshop and listened carefully to the issues raised. The Task Force reviewed the evidence and best practice, explored emerging practices and requested additional information before defining the recommended vision. The vision includes many aspects of the model discussed by Council in September. It also includes changes made as a result of Council’s feedback.



Diversity

An issue raised by Council was whether a board of 12 members — 6 public and 6 nurses — would have the needed diversity. With this integrated model, the Task Force believes that diversity will be strengthened in several ways:

- An emerging practice in governance is advisory groups that are established by the board to bring different perspectives. They report directly to the board. For the College, these groups can be made up of consumers, nurses from different practice sectors (e.g. remote/ marginalized, community, long-term care), different aspects of practice (e.g. clinical, education), members of other professions, or a combination. It would be up to the board at any time to consider the gaps in its perspectives based on the issues under consideration. The board would identify the needed advisory groups and what it needed from a specific group.
- Appointment rather than election of board members supports diversity. For example, our current electoral system is based on regions, and while there are two northern regions, they do not guarantee that the unique needs of remote and rural patients are considered. Usually, candidates from the large teaching hospitals in the north are elected. In an appointments process, the board can identify and seek nurses who work with specific types of patients, such as a nurse who works with high risk communities
- A small board intentionally structured to bring different perspectives, composed of members possessing governance competencies, and provided with additional perspectives through feedback from Advisory Groups and stakeholder engagement, will be able to raise and discuss these diverse perspectives more effectively.

Appointment of Board members

At the September 2016 governance workshop, divergent views were expressed about moving from election to appointment of board members. In particular, some Council members stated that the election is an opportunity for nurse engagement and that nurses and the public could perceive appointments as less transparent.

The Task Force weighed this input, including data on member engagement in the election and the committee appointments process. The data shows that fewer than 15% of members vote in the Council election. While 10 to 20 candidates stand for election each year, over 100 usually volunteer to serve on a statutory committee.

The Task Force believes better, more appropriate mechanisms exist for member engagement, such as advisory groups, consultations and a more engaging quality assurance program.

A theme in the literature about regulatory governance is that electing professional members to regulatory boards sets up a conflict of expectations. This was clearly identified in the Trends in Regulatory Governance document and was flagged by Richard Steinecke in *Will the Real Public Interest Please Stand Up*. Regulatory board members serve the public, not the profession. An election process sets up an expectation of, and perception of, a representational role.

In addition to the concern about the misperceptions created by an election, the following informed the Task Force as it weighed whether to recommend continuing with electing members of the board following a competency screen or moving to an appointment process:



- In September, Council expressed concerns regarding ensuring diversity of perspectives on the board. While the election process can be enhanced through a competency screen, once the candidate passes that bar, there is no ability to screen for a needed perspective or area of practice. This was highlighted in more detail earlier.
- Council has identified the importance of succession planning to effective governance. An appointments process supports succession planning; an election process does not.
- Public members currently are appointed. The Task Force is recommending that in the future they be appointed based on competencies.

The Task Force believes that all members should come onto the board in the same way. Doing so builds mutual respect as each member has met the same expectations and gone through the same process to join the board.

- As part of the implementation process, a robust, objective and transparent recruitment and appointments process would be developed by Council. This process could be piloted for the appointment of committee members, evaluated and further refined. A competency screen could be developed for people seeking to serve on the board. It could be tested as a pre-screen for the election and further refined in anticipation of legislative change and a move to the appointment process.
- To further strengthen the outcome of an appointments process, the Task Force is also recommending having a “boot camp” for people interested in participating on the board or committees. This idea was raised in the October 2016 issue of Grey Areas, “Screening Committee Members,” where it was suggested that the appointment of committee members should be competency based. The boot camp would support potential board and committee members understanding the voluntary roles they are considering and the requirements needed to serve. It would mean that once appointed, they would begin the orientation process with a basic understanding of the roles and expectations.

Role of the Governance Committee

The last issue raised at the workshop that the Task Force will address is the view that the Governance Committee, as envisioned in the model presented in September, was too powerful. The perspective was that another Executive Committee was being created. That input gave the Task Force an opportunity to rethink the role of the Governance Committee. In the proposed vision, the functions initially proposed for the Governance Committee are split as follows:

- A Nominating Committee will recommend appointments for directors and committee members who are not directors, and address succession planning for those roles. To bring broad perspectives, the committee will include directors and individuals who are not directors.
- The Governance Committee — made up of directors — will support the board in remaining attentive to changes in governance, steer evaluation processes, support the board in identifying the competencies, and recommend the appointments of board and committee leadership.

The Task Force also recommends that the terms of reference for both of these committees — which will be determined by Council — include requirements for ongoing engagement of the full board in their work.



Implementation Recommendation 1: That Council share the governance principles, vision, Task Force reports and supporting documents with government, the public, other regulators, nurses and other stakeholders to broaden the dialogue about the future governance of regulators of professions.

Government and other regulators have expressed considerable interest in the work being done by Council on governance. The Task Force is recommending releasing all the information generated by the review in order to support the ongoing dialogue about regulatory governance in Ontario and elsewhere.

The Task Force believes that releasing its reports, the literature review, trends in regulatory governance and report of the survey of regulators will support achieving two of the objectives from the Strategic Plan:

▪ **Advancing the use of CNO knowledge:**

The significant resources the College developed to support the Task Force and Council in working through the governance issues are relevant to government and other regulators. Sharing this information will provide all stakeholders with evidence that supports the governance dialogue.

▪ **Leading in regulatory innovation:**

Sharing the supporting materials will provide leadership to others exploring governance issues and will lead transformative change. For example, The Advisory Group for Regulatory Excellence has already made a commitment to reviewing governance, and the Ministry of Health and Long-Term Care has identified governance as part of its project to modernize the health professions. By sharing this information, the Council will provide leadership to the exploration of new regulatory governance approaches in Ontario.

In addition, releasing the Task Force's reports as well as the briefing materials supports transparency, which is one of Council's governance principles.

Implementation Recommendation 2: That, in June 2017, Council establish a working group of five Council members to work with Council to develop a plan for implementing the governance vision. The plan will include the communications and stakeholder engagement needed to build understanding of and support for the vision to enhance the likelihood that the needed legislative change will happen in 2020.

The Task Force recognizes that governance change will not happen immediately. Many of the proposed changes require legislative change. Some are a change from the current regulatory paradigm. For example, the proposal in the vision that the board be half public and half nurses is different from the current constitution of the councils of Ontario health regulators, where there is a small majority of nurses on all councils.

The Task Force recommends that Council establish a working group of Council members to develop a plan to be ready to implement the vision in 2020. This would mean proposing legislative change to government in 2019.

The Working Group's terms of reference will be determined by Council and explicitly include the requirement that it does its work in collaboration with the full Council.



Governance is the board's business and the board needs to be engaged in, and directing, the process at all times.

The suggested timing of appointing the working group in June of 2017 is to give time for Council to review and provide input into terms of reference and decide how members will be selected in March of 2017, and to appoint the members in June of 2017.

The Task Force believes it is important to engage stakeholders, including other health regulators and government, in order to achieve the vision. In addition to releasing the Task Force materials, the Task Force suggests developing a communications and engagement plan that includes the President and Executive Director sharing Council's work with other health regulatory Councils, nursing stakeholders and government.

Implementation Recommendation 3: That the working group's terms of reference include working with Council to identify changes to advance the governance vision that can take place before legislative change, and developing an action plan to support implementing those changes.

The Task Force believes that several aspects of the vision can be implemented before legislative change and have a positive impact on governance. The Task Force notes that Council has already implemented a number of changes in how it works and believes this should continue.

The following might be considered for implementation before legislative change:

- Establish one or more Advisory Groups: perhaps starting with a pilot of a consumer advisory group in late 2017/early 2018;
- Pilot test competency-based appointments using committee member appointments:
 - identify competencies needed for statutory committees and add collection of information needed to assess competencies in a computer app to be used in the fall of 2017 for the 2018–2019 appointments;
 - establish a rigorous, fair and objective appointments process to be pilot tested with the committee member appointments in late 2018 for the 2019–2020 appointments.
- To ensure the public's confidence that the College's Council and committees are focused solely on the public interest, conflict-of-interest provisions for Council and committee members need to be reviewed to ensure they remain appropriate and consistent for today's high scrutiny environment.
- Develop "boot camp" programs for those seeking election to Council and those seeking appointment to statutory committees so they understand the College's mandate and the expectations for the role.
- Develop and implement an evaluation framework that includes evaluation of Council meetings, self and peer evaluation of Council members and an evaluation of Council effectiveness carried out by an external expert every three years.



Conclusion

In 2014, Council began a journey to advance regulatory governance. It was done with foresight and to support the College’s vision of being a leader in regulatory excellence. This report is not the end of that journey — it is a fork in the road. As Cathy Trower said in her assessment report: “Good governance is a journey”. The Task Force proposes that good governance is a journey without end.

Adopting the recommended vision of the Task Force means that Council and future College of Nurses boards will always be attentive to governance.

The Task Force appreciates the opportunity to have participated in your journey.

It took courage to bring outside eyes and outside perspectives to examine your processes. It took courage and foresight to empower the Task Force with such a broad mandate.

Council and staff have already changed how governance at the College works. We have seen this at the governance workshops that we attended where there was so much engagement and thoughtful dialogue.

The Task Force recognizes that it is recommending transformative change and it will take time to fully implement. It will be dependent on the government making changes to the paradigm for regulatory governance in the province. We have heard that the government has an appetite for that change. While the major changes being recommended in the vision will take time to be implemented, many other measures can be taken in the interim to continue Council’s never-ending governance journey.

Attachments:

1. Vision: The College of Nurses of Ontario’s Board of Directors for 2020
2. A governance model based on the vision
3. Council’s Governance Principles
4. A timeline of the governance review
5. A literature review on governance (on the portal for Council members)
6. A review of trends in regulatory governance (on the portal for Council members)
7. A survey of regulators regarding governance (on the portal for Council members)



Recommended Vision: The College of Nurses of Ontario's Board of Directors in 2020

Introduction

In 2014, Council established the Leading in Regulatory Governance Task Force and charged it with developing recommendations that would position Council as a leader in regulatory governance.

The recommended governance vision is designed to put in place an integrated governance model that will move from a council to a board of directors model. The vision acknowledges the value of the input nurses bring to the board, while building the public's trust that the board is focused on the public's needs and interests by moving to equal public and nurse membership. It is designed to position the board as a leader in regulatory governance and support the College in achieving its strategic vision of leading in regulatory excellence.

The Task Force identified this vision after completing a two-year journey that included:

- ongoing engagement with Council;
- reviewing a point-in-time assessment of Council governance that was conducted by an external governance expert (Cathy Trower);
- considering an extensive examination of peer-reviewed academic literature about governance and group dynamics;
- considering a comprehensive report on trends and best practices in the governance of organizations that regulate professions; and
- reviewing the results of a survey of other regulators about their governance practices.

Governance Vision for 2020:

With a commitment to the public, the College of Nurses of Ontario's board of directors (the board) will govern the regulation of the nursing profession in accordance with:

- the College's regulatory mandate as set out in Ontario's health regulatory legislation; and
- the governance principles approved by the board.

A small governing board made up of an equal number of public and nurse members - with all members having the needed governance competencies, appropriate conflict of interest provisions and ongoing education and evaluation - will be able to meet the governance principles and the changing expectations of society. It will be, and will be seen to be, a proud protector of the public.



The following is the detailed vision for governance of the College of Nurses of Ontario beginning in 2020:

Components of recommendation	Evidence/rationale	Principles
<p>Size</p> <ul style="list-style-type: none"> ▪ The board will have 12 members (see page 13 for composition) ▪ An Executive Committee will no longer be needed. ▪ The board will be small enough to engage in generative discussions with contributions from all members who together provide a balance of the needed competencies and diversity. ▪ The addition of advisory groups (e.g. consumer, educator, clinician) and a stakeholder engagement approach will ensure diverse input on issues the board will consider. 	<ul style="list-style-type: none"> ▪ Evidence about board governance and group dynamics shows that: <ul style="list-style-type: none"> ▸ small boards (e.g. 6 to 9) make more-effective decisions. The proposed size of 12 is a compromise recognizing the need to include both nurse & public on a regulatory board. ▸ a smaller board fosters input from all directors and makes it more comfortable for individual directors to speak up. ▸ “social loafing” occurs with larger boards, meaning not all perspectives are on the table. ▸ regulatory governance is moving away from large, representative elected boards to smaller, competency based appointed boards. ▪ With a small board, an Executive Committee is not needed. Having an Executive Committee is no longer seen as good governance practice ▪ Council members provided feedback, starting with the Cathy Trower review, that <ul style="list-style-type: none"> ▸ size is an issue in relation to effective discussion. ▸ smaller groups work better [the Task Force believes this is valid experiential evidence]. ▸ they would prefer to discuss issues in small groups as they feel more able to participate in those circumstances [this is not congruent with the legislative requirements for open meetings and the principle of transparency]. 	<p>Accountability</p> <ul style="list-style-type: none"> ▪ A small board will not require an Executive Committee. ▪ The board will have full accountability for its agenda and decisions. ▪ Every member will be expected to participate. ▪ Individual directors will carry the expectation for personal accountability. <p>Adaptability</p> <ul style="list-style-type: none"> ▪ A small board will enable the group to come together quickly to respond to emerging issues. <p>Diversity</p> <ul style="list-style-type: none"> ▪ Evidence shows that with a small board all members participate and as a result, diversity of perspectives is more likely to be gained.



Components of recommendation	Evidence/rationale	Principles
<p>Composition</p> <ul style="list-style-type: none"> ▪ The board will have equal numbers of public and nurse members (including at least 1 RN, 1 RPN, 1 NP). 	<ul style="list-style-type: none"> ▪ This composition: <ul style="list-style-type: none"> ▸ is the direction in regulation internationally as it reinforces public confidence that the board is focused on the public and not on professional interests. ▸ reflects the board's commitment to the public interest and confirms the value of nurses' expert input. ▸ is the best compromise between public trust and maintaining professional expertise in regulation (self-regulation). ▪ A board of equal public and nurse members will be seen to be impartial and not controlled by the profession. 	<p>Independence</p> <ul style="list-style-type: none"> ▪ A board made up of equal numbers of nurse and public directors will facilitate both professional and public input into governance decisions. <p>Integrity</p> <ul style="list-style-type: none"> ▪ A board made up of equal numbers of nurse and public directors will maintain, and be seen to maintain, its regulatory integrity through its focus on the public interest.
<p>Competency based</p> <ul style="list-style-type: none"> ▪ Directors will be selected based on having the competencies (knowledge, skills and attitude) needed for the role. ▪ Individual directors will have competencies required: governance, leadership and regulation (protecting the public interest), and analytic, strategic and creative thinking. ▪ Individual directors will have a commitment to the public interest and a passion for nursing regulation. ▪ The board will have the ability to balance innovation and risk. 	<ul style="list-style-type: none"> ▪ Literature supports competency-based boards. ▪ A move to competency-based boards is a trend in regulatory governance, as well as in other sectors. ▪ Roles, responsibilities and expectations for boards and directors are rapidly changing and expanding. Directors will need specific competencies to meet these expectations. ▪ Public confidence will be enhanced if skills and competencies on the board are transparent. 	<p>All</p> <ul style="list-style-type: none"> ▪ Having all directors with the needed competencies and attributes will support the board to meet all of the principles.



Components of recommendation	Evidence/rationale	Principles
<p>Competency-based application and appointments process</p> <ul style="list-style-type: none"> ▪ Board, statutory and standing committee members, and board and committee leadership are all appointed by the board based on competencies ▪ A transparent, open appointments process will be developed by the board, including structure and terms of reference of a Nominating Committee (composed of directors and non-directors) that would recommend appointments of board and committee members and of a Governance Committee to recommend the competencies and board and committee leadership. <ul style="list-style-type: none"> ▸ Attendance at a “boot camp” for individuals interested in applying for appointment will be required. ▸ All applications will be reviewed by the Nominating Committee. ▪ Each year the board will review the criteria for appointment, including addressing any specific needs for the coming years. ▪ The board will identify the needed checks and balances in the process to promote appropriate succession and ensure the needed competencies are in place. ▪ Reappointments to all positions will be based on meeting role expectations as evidenced by director evaluation and peer feedback. 	<ul style="list-style-type: none"> ▪ It is not the role of regulatory directors to represent the electorate. However, there is evidence in the regulatory literature that election of members of a regulatory board sets up an inherent conflict and potential misunderstanding of the role among members of the profession who believe they are being represented. The public may also believe that an election means representation and that the nurse members of Council are there to represent nurses and not serve the public. ▪ Appointment allows the board to consider specific needs for the board at a given time and to identify the competencies and backgrounds needed to meet those needs. ▪ Appointment is a way of ensuring diversity of perspectives. ▪ Council has flagged the importance of succession planning: as confirmed in Cathy Trower’s report. Election does not support succession planning, while appointment does. 	<p>Competence</p> <ul style="list-style-type: none"> ▪ Appointment based on competencies will allow the board to build and maintain a strong, competent group to support evidence-informed, public focused decision-making. <p>Diversity</p> <ul style="list-style-type: none"> ▪ Appointment will allow the board to ensure that it will have the needed diversity of perspectives and skills. <p>Independence</p> <ul style="list-style-type: none"> ▪ An appointed board will be, and be perceived to be, independent of influence by voters, who may be seen to have a professional interest. <p>Transparency</p> <ul style="list-style-type: none"> ▪ Transparency will be supported by <ul style="list-style-type: none"> ▸ clear and public criteria for appointment ▸ an open process to volunteer to serve ▸ an objective and fair process for reviewing candidates, and ▸ a clear rationale for the selection of directors and leadership, including communication with the individuals who were not selected.



Components of recommendation	Evidence/rationale	Principles
<p>Chair and Vice-Chair</p> <ul style="list-style-type: none"> ▪ Effective leadership will be characterized by: <ul style="list-style-type: none"> ▸ The Chair and Vice-Chair having the leadership competencies identified by the board. ▸ Appointment/succession being recommended by the Governance Committee and approved by the board 	<ul style="list-style-type: none"> ▪ Selection of board leadership is consistent with competency-based appointment. ▪ Selection of board leaders based on leadership competencies vs professional designation will support strong leadership. ▪ A succession plan will build and maintain strong leadership. 	<p>Accountability</p> <ul style="list-style-type: none"> ▪ The board will have accountability for setting the leadership competencies and a succession plan. <p>Competence</p> <ul style="list-style-type: none"> ▪ Selecting the best and most competent leaders will support the board in meeting this principle. <p>Transparency</p> <ul style="list-style-type: none"> ▪ How and why members were appointed as chair and vice-chair will be clear to all members of the board.
<p>Director and board development</p> <ul style="list-style-type: none"> ▪ Each director will be supported in understanding and meeting their role expectations and accountabilities. ▪ Participation in a “boot camp” (see page 7) during the appointment process will ensure applicants understand the needed competencies and the regulatory and governance roles and commitments. ▪ Orientation and ongoing development will be expected. ▪ Continuous learning will be part of the board culture. <p>Directors will be well supported in informed decision-making</p> <ul style="list-style-type: none"> ▪ Decision-support materials will be evidence informed. ▪ Staff will provide regulatory expertise, as needed. ▪ Advisory Groups will be constituted by the board to help inform the board on views across the profession and the public. 	<ul style="list-style-type: none"> ▪ In assessing Council governance, Cathy Trower recommended strong orientation and ongoing education. ▪ Orientation and ongoing education: <ul style="list-style-type: none"> ▸ are best practices in governance. ▸ build on the learning from the boot camp prior to appointment to the board. ▪ Ongoing education was identified as a priority in the September 2015 Council workshop on culture. ▪ The board needs knowledge to keep changing and adapting as the expectations and evidence of what is good governance evolves. 	<p>All</p> <ul style="list-style-type: none"> ▪ Having all directors with a sound foundation through orientation and ongoing education and the briefing materials needed to support informed decision-making will support all directors in meeting the governance principles.



Components of recommendation	Evidence/rationale	Principles
<p>Evaluation of Board and Directors</p> <ul style="list-style-type: none"> ▪ Good governance will be recognized as a journey. <ul style="list-style-type: none"> ▸ The performance bar on the board and individual directors will keep rising. ▪ The board will constantly improve through: <ul style="list-style-type: none"> ▸ A Governance Committee that will support the board in meeting its commitments to strong governance. ▸ Ongoing meeting, self-evaluation, peer feedback and board evaluation to support continuous improvement. ▸ An evaluation of governance effectiveness by an external expert every 3 years, with the results being publicly available. This will also support continuous improvement and public accountability. ▪ Terms of reference for the Governance Committee will be developed by Council as part of the implementation plan and will include provisions for ongoing board engagement in its processes. 	<ul style="list-style-type: none"> ▪ A commitment to governance, championed by the Governance Committee together with the board, and supported by strong evaluative and ongoing improvement processes, will ensure that the board maintains its commitment to leading in regulatory governance. <ul style="list-style-type: none"> ▪ The board needs to continually improve to meet changing expectations. ▪ The board will identify competencies. <ul style="list-style-type: none"> ▸ The evaluation processes will measure if specific competencies meet the board's changing needs. ▪ Evaluation will identify gaps, help to identify the Advisory Groups needed, and support succession planning. 	<p>Accountability</p> <ul style="list-style-type: none"> ▪ Evaluation will allow the board to measure whether it is meeting its public interest mandate and will allow directors to determine if they are meeting their duties while identifying opportunities for improvement. ▪ An external evaluation will allow the board to report to stakeholders including the Ministry and the public about how it is meeting its accountability for regulating nursing in the public interest. <p>Competence</p> <ul style="list-style-type: none"> ▪ One indicator of the competence principle is: We evaluate our individual and collective knowledge and skills in order to continuously improve our governance performance. <p>Transparency</p> <ul style="list-style-type: none"> ▪ Conducting oral evaluations of board meetings in the open board supports transparency, as does sharing the results of external evaluations.



Components of recommendation	Evidence/rationale	Principles
<p>Role clarity of board and statutory committees</p> <ul style="list-style-type: none"> ▪ The roles, responsibilities, expectations and accountabilities of the board and statutory committees will be clearly stated and differentiated. 	<ul style="list-style-type: none"> ▪ Mandates are unique and require different competencies for governance and statutory decision-making. ▪ The board sets policies and the statutory committees apply them with respect to individual members and those seeking to become nurses in Ontario. ▪ Separation of board and statutory committee functions is a trend in regulation in other jurisdictions. ▪ Independence: The group that sets policy should not be making statutory decisions. There is a potential to bring bias and perceptions of bias from the board to statutory committees and vice versa. 	<p>Accountability</p> <ul style="list-style-type: none"> ▪ Reporting mechanisms will ensure that statutory committees are accountable to board and public for fulfilling their statutory mandates. <p>Competence</p> <ul style="list-style-type: none"> ▪ Directors and members of statutory committees will be specifically selected through a board-approved process to ensure they have the competencies needed to fulfil their respective roles. <p>Independence</p> <ul style="list-style-type: none"> ▪ Having no directors on statutory committees will enhance the perception of the independence of those committees.



Components of recommendation	Evidence/rationale	Principles
<p>Statutory committees</p> <ul style="list-style-type: none"> ▪ Statutory committee members will be appointed by the board on the recommendation of the Nominating Committee. ▪ Statutory Committee chairs will be appointed by the board on the recommendation of the Governance Committee. ▪ The board will appoint all statutory committee members and Chairs based on competencies required to fulfil the statutory committees' mandates and on the background needed for the specific committee. ▪ Statutory committees will be composed of non-directors. ▪ Statutory committees will report to the board on their legislated mandates. 	<ul style="list-style-type: none"> ▪ The work of statutory committees is different from that of the governing board, and therefore the competencies and attributes needed for these two distinct roles are different. ▪ The board's commitment to excellence in regulation requires having the right person with the right competencies and attributes doing the right work. ▪ With separate board and statutory committee members, individuals can develop expertise in specific roles. ▪ As members will not move back and forth between the detailed statutory committee role and the broad governing board role, there will be no role confusion. ▪ The risk of conflict from being both a board and statutory committee member is eliminated. ▪ Statutory committee members will gain an appreciation for the regulatory mandate, and some may ultimately seek to join the board if they have the needed governance competencies. 	<p>Accountability</p> <ul style="list-style-type: none"> ▪ Reporting mechanisms will ensure that statutory committees are accountable to the board and the public for fulfilling their statutory mandates. <p>Competence</p> <ul style="list-style-type: none"> ▪ Members of statutory committees will be specifically selected to have the competencies needed to fulfil their roles. <p>Independence</p> <ul style="list-style-type: none"> ▪ Having no directors on statutory committees will enhance the perception of the independence of those committees from the College.

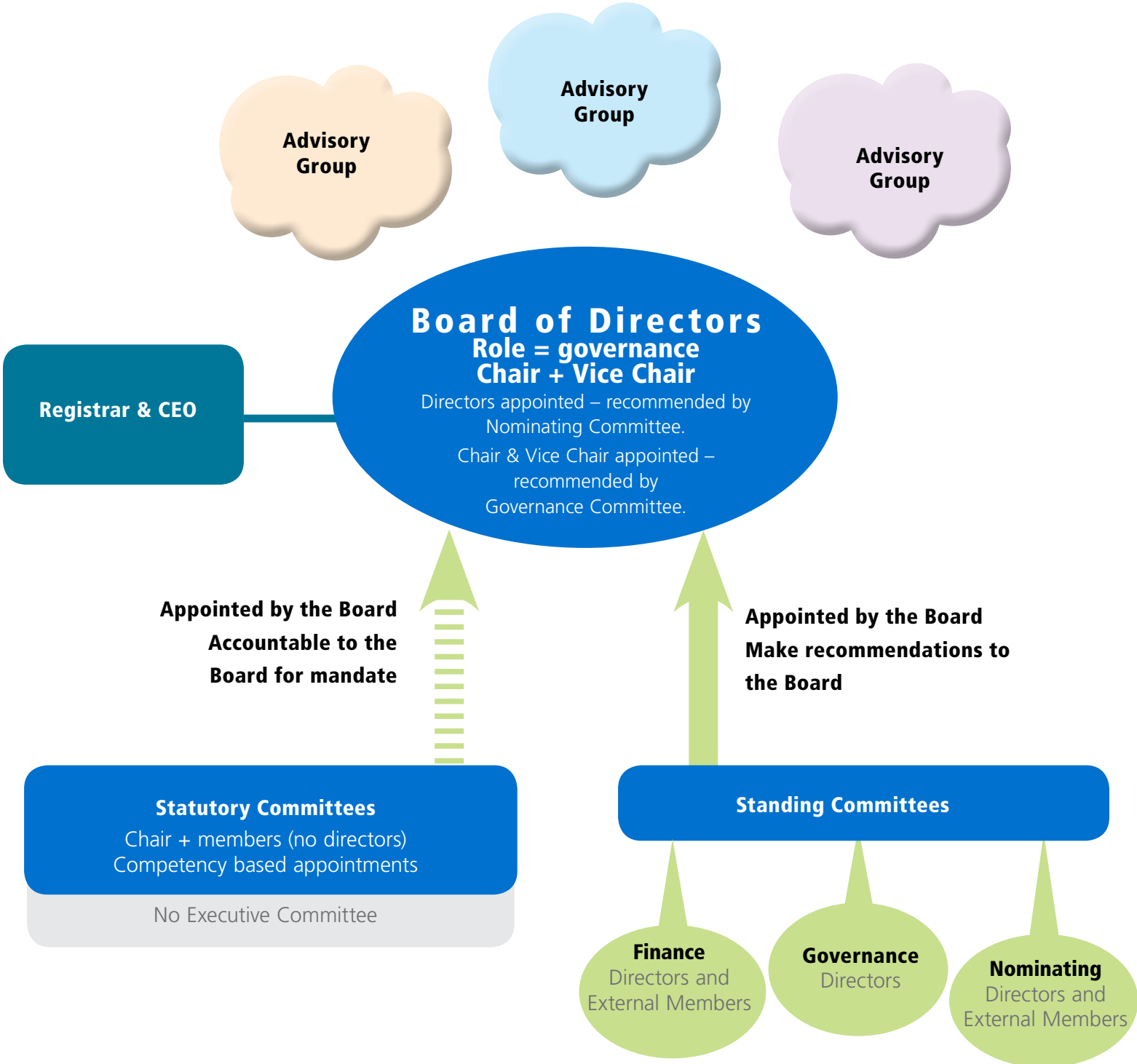


Components of recommendation	Evidence/rationale	Principles
<p>Standing Committees</p> <ul style="list-style-type: none"> ▪ There will be two new standing committees: Governance and Nominating ▪ Terms of reference for those committees will be developed by Council and will include provision for ongoing Council input into the work of the committees ▪ The Governance and Nominating committees will have roles in the appointment of directors, committee members and board and committee leadership 	<ul style="list-style-type: none"> ▪ It is good practice to pay ongoing attention to governance. A Governance Committee, working with the board, will ensure that attention is paid to changing practices and expectations. ▪ The Governance and Nominating committees will ensure effective, competency based appointments (see appointments on page 6) ▪ The Governance Committee will support evaluation processes (see page 7.) 	<p>Accountability</p> <ul style="list-style-type: none"> ▪ Reporting mechanisms will ensure that statutory committees are accountable to the board and the public for fulfilling their statutory mandates. <p>Competence</p> <ul style="list-style-type: none"> ▪ Members of statutory committees will be specifically selected to have the competencies needed to fulfil their roles. <p>Independence</p> <ul style="list-style-type: none"> ▪ Removing directors from statutory committees will enhance the perception of the independence of those committees from the College. <p>All</p> <p>Having committees focusing on governance processes will support the board in meeting all governance principles.</p>



Components of recommendation	Evidence/rationale	Principles
<p>Terms of office</p> <ul style="list-style-type: none"> ▪ Directors: <ul style="list-style-type: none"> ▸ 3-year term ▸ 2-term maximum ▪ Leadership roles (Chair, Vice-Chair, Committee Chairs): <ul style="list-style-type: none"> ▸ 1-year term with one possible reappointment ▸ A 1-year term extension on the board is provided for a Chair to serve a second term if the Chair has reached the maximum 6 years of service term on the board ▪ Committee members: <ul style="list-style-type: none"> ▸ 3-year term ▸ 2-term maximum ▪ Reappointments will be made within term limits and based on meeting role expectations 	<ul style="list-style-type: none"> ▪ Terms of office will ensure appropriate transition and succession. ▪ Appointment rather than election ensures that strong directors are retained and those with new perspectives regularly join the board. ▪ Provisions for a 1-year extension for the Chair will provide for maintenance of effective leadership. ▪ Separating statutory committees and governance allows individuals to serve a maximum of four terms on the board and committees (current limit is three terms). 	<p>Competence</p> <ul style="list-style-type: none"> ▪ Term limits support bringing needed new competencies and backgrounds to the board. <p>Diversity</p> <ul style="list-style-type: none"> ▪ Regular change allows for new perspectives to be brought to the table.
<p>Funding governance processes</p> <ul style="list-style-type: none"> ▪ The College will be accountable for funding the governance and statutory processes. ▪ Since all directors and committee members will be required to meet specific competencies and assessed against those competencies: <ul style="list-style-type: none"> ▸ all directors will receive the same honorarium; and, ▸ all committee members will receive the same honorarium. 	<ul style="list-style-type: none"> ▪ There has been feedback from Council that the unequal remuneration of nurse and public directors is unfair. ▪ Equal pay for equal work is a fundamental societal value. 	<ul style="list-style-type: none"> ▪ All principles will be supported by having a board where directors feel treated as equals. ▪ Equal compensation will allow the College to draw from a broader pool, including individuals in active employment.

Governance Model



FOUNDATION



Governance Principles

Council is individually and collectively committed to regulating in the public interest in accordance with the following principles:

Accountability

- We make decisions in the public interest
- We are responsible for our actions and processes
- We meet our legal and fiduciary duties as directors

Adaptability

- We anticipate and respond to changing expectations and emerging trends
- We address emerging risks and opportunities
- We anticipate and embrace opportunities for regulatory and governance innovation

Competence

- We make evidence-informed decisions
- We seek external expertise where needed
- We evaluate our individual and collective knowledge and skills in order to continuously improve our governance performance

Diversity

- Our decisions reflect diverse knowledge, perspectives, experiences and needs
- We seek varied stakeholder input to inform our decisions

Independence

- Our decisions address public interest as our paramount responsibility
- Our decisions are free of bias and special interest perspectives

Integrity

- We participate actively and honestly in decision making through respectful dialogue
- We foster a culture in which we say and do the right thing
- We build trust by acting ethically and following our governance principles

Transparency

- Our processes, decisions and the rationale for our decisions are accessible to the public
- We communicate in a way that allows the public to evaluate the effectiveness of our governance



Governance review milestones

What's been done?	
September 2014	Governance review approved in principle by Council
December 2014	Scope and terms of reference for an evidence and expert informed governance review set by Council.
February 2015	Cathy Trower of Trower and Trower commissioned to undertake a review of current governance and identify opportunities for improvement.
March 2015	Expert Leading in Regulatory Governance Task Force appointed by Council. Council members participate in a survey on the strengths and weaknesses of College governance. Council and staff leaders participate in interviews.
May 2015	Task Force on Leading in Regulatory Governance holds its first meeting. Report on assessment of Council governance provided to the Task Force.
June 2015	Cathy Trower joins Council for its first governance workshop, discussing key findings of her review.
September 2015	Council workshop on culture, possible immediate changes to governance processes – quick wins – identified.
December 2015	Council adopts quick wins recommended by the Task Force
January to April 2016	College staff undertake research to support the review, and prepare : <ul style="list-style-type: none"> • Literature review • Report on trends in regulatory governance • Survey of regulators re. governance processes
June 2016	Council governance workshop provides input on governance principles and key components of a new governance model: <ul style="list-style-type: none"> • Council size and composition • How members join Council • Leadership and • Statutory committees
September 2016	Council approved the Governance Principles (attached) Council provided feedback on governance model recommendations
What's next	
December 2016	Final report and recommendations of the Leading in Regulatory Governance Task Force

² Cathy Trower's summary of the Council survey and final report are in the Governance folder on the Council portal.

³ These reference documents and all Task Force reports are in the Governance folder on the Council portal.



COLLEGE OF NURSES
OF ONTARIO
ORDRE DES INFIRMIÈRES
ET INFIRMIERS DE L'ONTARIO

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Appendix 2: AGRE Member Regulators - Council Composition

Councils: AGRE Member Regulators - Council Composition					
Ontario College (s. re. Council)	Required in legislation		Additional requirements	Current - January 2017	
	Professional	Public		Professional	Public
<i>College of Nurses</i> (s. 9(1) of the Nursing Act)	21*	14-18	*14 RNs and 7 RPNs	21	15
	Total: 35 - 39			Total: 36	
<i>College of Optometrists</i> (s. 6.(1) of the Optometry Act).	10 (9 + 1*)	7	*selected from faculty of School of Optometry	10	7 (1 resigning)
	Total: 17			Total: 17	
<i>College of Physicians and Surgeons</i> (s.6(1) of the Medicine Act)	19 (16 + 3*)	13 - 15	*16 elected and 6 appointed from faculties of medicine *3 appointed from faculties of medicine are voting members	22	12 (3 vacancies)
	Total: 32 - 34			Total: 34	
<i>College of Physiotherapists</i> (s. 6(1) of the Physiotherapy Act).	8 - 10 (7-8 + 1-2*)	5 - 7	7-8 elected members + 1-2 selected from physiotherapy faculty members	8 elected + 2 faculty members	7
	Total: 13 - 17			Total: 17	
<i>College of Pharmacists</i> (s.7(1) of the Pharmacy Act)	11 - 19*	9 - 16	*9 - 17 elected members, of which 2-4 must be pharmacy techs; Deans of 2 ON Schools of Pharmacy	16	12
	Total: 20 - 35			Total: 28	
<i>Royal College of Dental Surgeons</i> (s. 6. (1) of the Dentistry Act)	12 - 14* (10 - 12 + 2)	9 - 11	*10 - 12 elected members + 2 selected from dentistry faculty	14	10
	Total: 21 - 25			24	



- College of Nurses of Ontario
- College of Physicians and Surgeons of Ontario
- College of Physiotherapists of Ontario
- College of Optometrists of Ontario
- Ontario College of Pharmacists
- Royal College of Dental Surgeons of Ontario

February 15, 2017

Megan Sloan, President
College of Nurses of Ontario
101 Davenport Rd
Toronto ON M5R 3P1

Dear Ms. Sloan: *Megan*

On behalf of the Advisory Group for Regulatory Excellence (AGRE), I am writing to you to share with the College of Nurses of Ontario (CNO) the support of AGRE for CNO's "Vision: The College of Nurses of Ontario's Board of Directors for 2020" as part of your "Leading in Regulatory Governance Task Force's Final Report: A vision for the future". CNO is to be congratulated for taking the lead on this very important area.

AGRE has been discussing governance-related issues and will be using your document to inform further considerations. International trends and government initiatives, including the introduction of Bill 87, are affecting how Colleges are looking at governance as a whole. AGRE members will be working to ensure enhancements to governance models best serve their ability to work in the public interest.

Thank you for providing an excellent model for health professional regulators to use now and in the future.

Yours truly,

A handwritten signature in blue ink, appearing to read 'Irwin Fefergrad', is written over a large, light blue circular scribble.

Irwin Fefergrad, Chair
AGRE Registrars Group

cc: AGRE Registrars Group

Ms. Anne L. Coghlan, RN, MScN
Executive Director & CEO
College of Nurses of Ontario

Date: February 21, 2017
To: Nancy Lum –Wilson, Registrar
From: Judy Chong, Manager, Hospital Practice
RE: Implementation of Sterile Compounding Standards - Beyond Use Dates

Background

The Ontario College of Pharmacists will require facilities to be in compliance with the National Association of Provincial Regulatory Authorities (NAPRA) Model Standards for Pharmacy Compounding of Non-Hazardous and Hazardous Sterile Preparations by January 1, 2019. As part of these new standards, there are specific requirements related to the Beyond Use Date (BUD). The standards state that the BUD must not exceed the earliest of the dates established by the following two criteria:

- Expiration date based on chemical and physical stability
- Storage time related to risk of microbial contamination.

The NAPRA model standards provide beyond use dates based on contamination risk levels for sterile preparations.

Implementation

Currently in practice, only chemical and physical stability is used to determine the BUD. This change in practice may have an impact on workflow as well as costs. In assessing adherence to the standards, OCP has indicated that an organization choosing to extend the BUD will be expected to provide the rationale and process followed to do so appropriately, including some assurance that they have established evidence to support their extension.. In order to assess the management of BUDs, the College will need to determine what it would deem as acceptable practice and provide related guidance to practitioners choosing to extend BUDs. .

Activities to Date

1. Discussion at the Healthcare Facilities Oversight Advisory meeting in September 2016: It was noted that a group could explore how best to address BUDs. With outcome based standards the College does not intend to provide specific instructions/details for extending BUDs. Agreed an environmental scan on approaches to extending BUD would be helpful.
2. Environmental Scan re– Management of BUD
 - Reviewed current literature regarding extending BUD
 - Other Regulatory Colleges - BC and AB: high level statement only (if evidence provided for extending BUD but not specific guidance provided by AB. BC has not made a decision at this time on how it will handle BUDs.
 - CSHP (National office) – following established standards for BUD – significant risk to extending
 - Cancer Care Ontario - Established Beyond Use Date (BUD) Mitigation Strategy Working Group) to identify alternatives to extend BUDs for single dose vials

- HealthPRO - working with vendors to obtain information for sterility and stability as well as product availability to assist with determining BUDs
 - Hospital Pharmacy Directors
 - Edith Rolko (North York Hospital) – re-evaluating her processes; questions need to extend
 - Discussion with Ming Lee (The Scarborough Hospital) and Mario Bedard (The Ottawa Hospital) advised that a sub group of HealthPRO pharmacy directors may be working to address BUD
3. Discussion with OCP Compounding Standards Working Group Chair (Chris Leung)
- Plan to have the working group develop a principles based document to provide guidance for members considering extending BUDs
 - Terms of Reference for Working Group revised to include guidance document
 - Additional working group members have been recruited to increase hospital representation

Next Steps

- Working group to meet every two weeks in person or via teleconference,
- First meeting by week of March 6, 2017
- Guidance document to be completed by mid- May, in preparation for submission to June Council

This report is based on data from initial beta testing of Pharmacy5in5. Note that the majority of users to date are pharmacy students, although practicing pharmacists and pharmacy technicians have also been engaged in testing. The data represents a sample of the analytics that are readily accessible, further analysis will be available in the future.

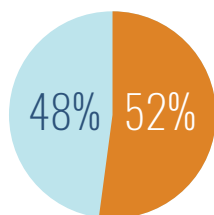
March 2017 Council Appendix 7

OCP Report

March 1, 2017

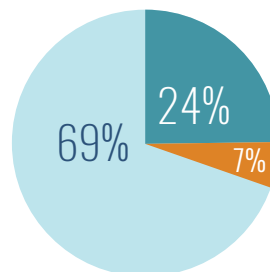
507 users

How many users get 5/5 on a quiz initially?



● Didn't get 5/5 initially
● Did get 5/5 initially

How many users are improving on a single topic?



● Didn't retake any tests
● Retook but didn't improve
● Retook and did improve

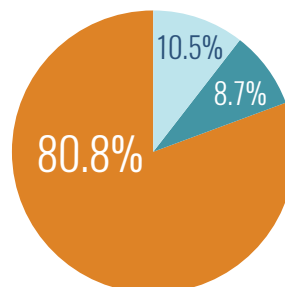
Which topics are users most interested in?



1. Cold Chain (Vaccines)
21 clicks

2. QT Prolongation
15 clicks
3. Renewals
12 clicks
4. Adaptations
10 clicks
5. Point of Care (beta)
9 clicks

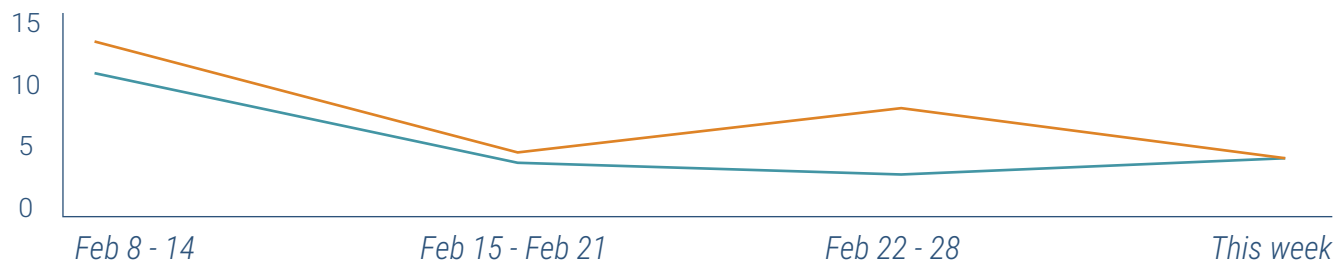
How do users compare to each other on quizzes?



● Users that scored between 0-50%
● Users that scored between 50-80%
● Users that scored between 80-100%

Demographics February 2017

of logins



of pharmacists (based on where they're educated)
ON 501 AB 6

Workload (avg) 133 scripts/shift

Years since graduation (avg) 11 years



Health Minister announces plans to change laws to allow RN prescribing

On Feb. 23, 2017, the Minister of Health and Long-Term Care, Eric Hoskins, announced that he will introduce changes to the *Nursing Act* this spring. If passed, these changes would expand Registered Nurses' (RNs) scope of practice to include communicating diagnoses and prescribing medication for their clients.

When the *Nursing Act* is changed, the College will work closely with government to create regulations for this change to nursing scope of practice.

Prescribing medications is a high risk activity and it is the College's role to ensure RNs have the knowledge, skill and judgment to practice this activity safely. In addition to consulting with nurses, employers, the public and other stakeholders, work to prepare for this may include:

- identifying the competencies and education RNs will need to safely communicate diagnoses and prescribe medication
- setting practice standards for safe RN practice
- determining the requirements for maintaining ongoing competence through the College's Quality Assurance program

It is important to note that Ontario RNs do not currently have the authority to communicate diagnoses or prescribe medication. Only after the College's regulations are approved by the Ontario government will it become legal for RNs to independently perform these activities.

We look forward to working with the Ministry, nurses, employers, the public and other stakeholders on this anticipated change to scope of practice for RNs.

Watch [our website](#), [Facebook page](#) and [The Standard](#) for regular updates as this work develops.

Page last reviewed February 24, 2017

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Standardized Assessment of Pharmacists' Patient Care Competencies: A Model for Maintenance of Licensure (MOL) in the Health Professions

Zubin Austin, BScPhm, PhD; Deanna Williams, BScPhm; Anthony Marini, PhD

ABSTRACT: Assessing the ongoing competence of practicing health care professionals requires regulators to balance complex demands of governments and the public, as well as interests and concerns of practitioners. A proliferation of models has evolved across professions and jurisdictions. In this article, we report on a model utilizing standardized assessment using best-practice measurement techniques and methods for evaluation of ongoing (i.e. post-registration) clinical competencies in the profession of pharmacy in Ontario, Canada. This model involves categorization of the profession into an active patient-facing and non patient-facing register, implementation of a learning portfolio requirement to replace mandatory continuing education credit accumulation, and the use of standardized assessment techniques, such as a multiple-choice test of clinical knowledge and an objective structured clinical examination (OSCE) of clinical reasoning and interpersonal skills. Lessons learned from the development, implementation and retrospective analysis of almost two decades of data from this program can provide regulators in diverse professions and different jurisdictions with tools for standardized assessment of patient care competencies.

Keywords: Maintenance of Competency, Competency Assessment, Standardized Assessment, Clinical Competency, Maintenance of Licensure

Background

The profession of pharmacy in Ontario, Canada, is regulated by the Ontario College of Pharmacists (OCP). Pharmacists in Ontario are the third largest group of regulated health professionals in the province (after nurses and physicians); as outlined in Table 1, in 2015, there were approximately 15,000 registered pharmacists serving a population of approximately 12 million people¹. In the mid-1990s, in accordance with sweeping regulatory changes affecting all regulated health professions in the province, OCP introduced a novel model for assessing ongoing competency of practicing pharmacists. Though the context of this model is specific to one profession in one jurisdiction, the findings and lessons learned through the development and implementation process are of general relevance to many health professions in different jurisdictions. A unique feature of this model was its application to all pharmacists in the province, regardless of specialization, practice setting or professional context.

Historically, pharmacy (like many other professions) had relied upon a self-directed and self-reported continuing competency system focused on collection of mandatory continuing education (CE) hours. As increasing evidence pointed to a negligible

association between compulsory CE hours and practice improvement or change,^{2,3} the regulator considered this historical model unsustainable, particularly in the context of the new legislative framework within the province, requiring regulators to implement and publicly report on quality assurance programs specifically designed to measure and ensure ongoing competency of practitioners.⁴

Table 1
Demographic Profile of the Pharmacy Profession in Ontario, Canada (2015)

Total number of practicing pharmacists	15 113 (58% female = 8 766)
Patient-care vs. non patient-care pharmacists	Part A (providing direct patient care): 14 255 Part B (not providing direct patient care): 888
Regulated pharmacy technicians	3 835 (6% male = 230)
Percentage pharmacists in Part A or Part B register educated internationally	37%
Percentage registered pharmacists in 2015 who were educated internationally	52%
Percentage registered pharmacists who graduated more than 25 years ago	36%
Percentage of pharmacies in Ontario that are independently owned by a pharmacist	49%

For all regulators, the challenge lay in implementing a quality assurance (QA) program that met legislative expectations for a fair, transparent, and robust mechanism for assessing practitioners' competencies that would also be supported by practitioners themselves.⁵ OCP anticipated that a summative assessment process could give rise to resistance from the profession, most of whom had not undergone any type of formal practice-based assessment since they had graduated from university programs and had passed initial entry-

FROM THE OUTSET, PHARMACISTS INVOLVED IN CONSULTATION REVEALED CONCERNS ABOUT AN 'IVORY TOWER' ACADEMIC COMPETENCY ASSESSMENT EXERCISE DEvised BY EXPERTS THAT WOULD NOT BE ALIGNED WITH THEIR DAY-TO-DAY CLINICAL REALITIES IN PRACTICE.

to-practice licensing examinations. As a regulator, this presented both a challenge and an opportunity to innovate in the area of regulator-led competency assessment, providing opportunities to share experiences and practices with other professions and regulators.

The Peer Review Model of Quality Assurance

OCP undertook an extensive consultation process with the profession in the mid-1990s to try to identify and address concerns, and to determine optimal ways of balancing these with the legislative requirements. This consultative process took various formats, including province-wide meetings with pharmacists, consultations with psychometricians and other experts, and reviews of best and promising practices from other professions nationally and internationally. Several key program design principles were identified as being crucial for successful implementation:

1. Gaining buy-in from the profession. Regardless of legislative mandates and requirements, it was clear from the outset that the profession itself would need to accept any changes to the existing processes. To achieve this buy-in, it would be necessary to address both the rational and emotional concerns of pharmacists, and to ensure that the profession itself was involved in every step of program development.

2. Grounding the consultation and program development process in "real-world" professional practice. From the outset, pharmacists involved in consultation revealed concerns about an "ivory-tower" academic competency assessment exercise devised by experts that would not be aligned with their day-to-day clinical realities in practice.

3. Using an evolutionary, not revolutionary, approach. Using an existing system of targeted pilot-testing—with abundant opportunities for pharmacists to provide input—was advantageous. As part of this evolutionary process, it became clear that one of the OCP's greatest assets was its structure as a self-regulating professional body, in which practitioners themselves could fully participate in discussion and program development.

4. Embracing and communicating a message emphasizing the professional value of the formative (rather than the personal impact of the summative) assessment received during the process. Focusing on the theme that quality assurance is educational and not punitive helped to address the concerns of many pharmacists that they could potentially lose their registration or their ability to operate a pharmacy due to an unsuccessful assessment. Framing the competency assessment process as a win-win for pharmacists individually and for the profession collectively, rather than as a simple pass-fail evaluation, was essential.

Ultimately, a quality assurance model evolved, with the following core components:⁶

1. Use of a two-part register. A two-part register was developed in which pharmacists would self-declare annually whether they were in Part A ("active patient-focused practice") or Part B ("non patient-focused practice"). The nature of pharmacy practice itself means that some pharmacists are simply not involved in direct provision of care and services to patients: Some pharmacists run complex businesses, or manage diverse organizations, or work in research or drug information centers. For these individuals without a patient-facing practice, "competency" may have a very different meaning than for pharmacists who actually work on a daily basis with real patients. The two-part register meant that only pharmacists who were providing direct patient care for a minimum of 600 hours over a 3-year period were required to participate in the quality assurance program; the resources of the regulatory body would not be used to assess pharmacists in Part B, who were by definition not in patient-facing practice.

2. No specific quality assurance assessments for pharmacists practicing in different specialties or sub-specialties. Within this model, and after considerable discussion and debate, the decision was made to not implement specific quality assurance assessments for pharmacists practicing in different specialities or sub-specialities (such as hospital practice or primary care) within the Part A register. This was based on the fact that in Ontario all pharmacists are registered in one “broad-based” class — there are no sub-specialty or setting-specific classes of registration. While pharmacists may be practicing in one setting today (e.g., a community-based drug store), their license permits free movement with no restrictions to any other setting (e.g., tertiary care hospital).

3. Introduction of a continuous professional development (CPD) framework to replace the historical mandatory continuing education credit requirement. The consultation process with pharmacists highlighted the ambivalence within the profession towards compulsory CE credits: While pharmacists appreciated the simplicity and clarity of this requirement, they concurred with the available evidence that the impact of such a requirement on practice change was negligible. Shifting towards a CPD approach, in which pharmacists self-assessed their learning needs and gaps, identified appropriate resources to address these gaps, undertook and self-assessed their learning and development, then implemented change in practice — all through a reflective process — was challenging. The CPD model was built upon a learning portfolio, in which all pharmacists (Part A or Part B) are required to document their learning activities in a retrievable format, and to submit this record to the regulator upon request. Maintenance of such a learning portfolio is a condition for annual renewal of a license to practice.

4. Development of a peer-review competency assessment process. Perhaps the most innovative — and controversial — part of this evolution was the decision to include, as part of the competency assessment process, standardized practice-based assessments that were grounded in day-to-day practice that focused on published standards of practice. During the consultative process, consideration was given to assessing individual pharmacist’s performance (rather than competence) through practice-site visits and on-site clinical audits, where pharmacists would demonstrate their competency (i.e., perform) in their own pharmacy with their own patients. While the contextual richness of this

approach was positive, there were concerns about the significant random variations in pharmacy practice that could never be controlled or accounted for when in-practice evaluations were used as a foundation for competency assessment. Further, the significant variations between individual pharmacist’s practices (such as prescription volumes and complexity of cases seen in a given day) were

A CASE-BASED, OPEN-BOOK, MULTIPLE CHOICE TEST OF CLINICAL KNOWLEDGE WAS USED, IN WHICH THE CORE FUND OF KNOWLEDGE FOR A PRACTICING PHARMACIST WOULD BE ASSESSED USING CLINICAL CASES.

so large that any attempt to actually benchmark or compare pharmacists to each other or to a defined standard of practice would be very difficult. As a result, OCP adopted a model in which a common, single assessment for all candidates on a given day would be utilized in order to facilitate intra-professional comparisons and to ensure each individual practitioner had an opportunity to demonstrate competency as defined by the standards of practice. This standardized assessment consisted of two components:⁷

- **Open-book test.** A case-based, open-book, multiple-choice test of clinical knowledge was used, in which the core fund of knowledge for a practicing pharmacist would be assessed using clinical cases to provide context. Since, in the real world, pharmacists always have recourse to drug information and other resources, the decision was made to allow pharmacists to use any resources they wished to complete this 54-question test. The test itself consisted of 18 cases, each of which lead to three multiple choice questions, each of which contained four options. To emphasize the peer-review nature of this test, practicing pharmacists — not academics or specialists — participate in the writing, reviewing, validation, and psychometric standard-setting of all cases and questions used in this process.
- **Multi-station clinical examination.** A multi-station, objective, structured clinical-examination (OSCE) was used, in which the problem-solving, interpersonal, communication, and clinical decision making skills of pharmacists are evaluated using standardized patients and trained peer assessors applying both analytical checklists and global/

holistic assessment. A total of six stations were used for this portion of the peer review. Similar to the open-book test, individual stations and analytical checklists were written, reviewed, and validated by practicing pharmacists, not by academics or experts. Cut scores for analytical checklists were established by panels of practicing pharmacists using a modified Angoff method.

Importantly, this regulator-led model focused on competence rather than performance, and emphasized use of standardized assessments using best-practice evaluation methods rather than non-standardized in-service/in-practice site visits or practice audits. The decision to utilize standardized assessments benchmarked to core competencies (rather than site- or context-specific assessments) was made in recognition of the generalist nature of the pharmacy license. Pharmacists can move between different practice-contexts (e.g., a community pharmacy/drug store to an ambulatory care clinic to a family-practice site to a tertiary-care hospital) without any regulatory limitations or requirements. Consequently, a standardized assessment of core practice competencies central to safe and effective

dollars). Individual pharmacists randomly selected to participate in this program do not pay any additional fees or charges as this is considered part of the regulator's mandate, and costs are covered by the annual registration fees paid by all members of the profession.

Taken together, the multi-station clinical examination and open-book test provided the most robust, objective, and defensible form of clinical skills assessment for pharmacists available.⁸ Recognizing the concerns previously expressed by pharmacists that a standardized competency assessment, administered by a regulator, could give rise to disciplinary, fitness-to-practice, or other proceedings, considerable efforts were taken to provide reassurance to participants.⁵ In particular, a key provision of the legislative framework ensured confidentiality of all information gathered under the auspices of the quality assurance program. Strict rules were embedded within the regulations to prevent disclosure of information gathered through the QA process with any other areas within the regulatory body.⁹ This message was communicated frequently—the program was educational, not punitive.

TAKEN TOGETHER, THE MULTI-STATION CLINICAL EXAMINATION AND OPEN-BOOK TEST PROVIDED THE MOST ROBUST, OBJECTIVE, AND DEFENSIBLE FORM OF CLINICAL SKILLS ASSESSMENT FOR PHARMACISTS AVAILABLE.

practice in any type of practice was deemed essential for this process. The decision to focus on “competence” (i.e., measurement of core pharmacy practice knowledge and skills within a standardized and objective context) rather than “performance” (i.e., real-world demonstration of practice knowledge and skills in unique subjective contexts that are non-standardized and highly situational) was made to emphasize both the fairness and transparency of the process to both pharmacists and members of the public.⁸ As this quality assurance function was considered integral to OCP's role of public protection, no separate cost accounting was undertaken regarding direct program costs to implement and maintain this program (i.e., costs were allocated across the entire regulatory body rather than to this specific activity). All pharmacists, as part of their annual renewal of registration with the regulatory body, pay an annual fee of ~\$750CDN (Canadian

Framing the overall competency assessment process — referred to as Practice Review — as educational and developmental was reinforced through inclusion of an additional component: a facilitated learning portfolio and sharing session in which pharmacists discussed and shared their continuous professional development needs, challenges, and successes with one another.¹⁰ The learning portfolio was initially introduced as a tool to support CPD — and in particular, self-reflection, self-assessment, identification of learning gaps and documentation of learning outcomes. Within the competency assessment process, however, the opportunity to use the learning portfolio as a tool for peer benchmarking and sharing of experiences through a facilitated discussion format became both apparent and uniquely valuable in situating the assessment in a constructive, educational context rather than a summative, evaluative one.¹⁰

It also prompted the regulatory body to engage in education/remediation for those practitioners who were not able to meet competency standards through the assessment process.¹¹ Meeting or exceeding standards in the peer review process was viewed as demonstration of the success of the pharmacist's continuing professional development activities and approaches. Those pharmacists who successfully completed the assessments were

listed as being in the “self-directed” continuing professional development group. Those pharmacists who did not meet expectations required additional support and education, and were identified to participate in “peer-directed” continuing education. Specifically, these pharmacists worked with peer practitioners and regulatory-body staff to develop a structured learning plan to address knowledge and skills deficits identified through the assessment process. To this end, OCP partnered with educational institutions and other providers to develop a menu of remedial and skills-development supports. Once the plan was successfully implemented and pre-defined milestones were achieved, the pharmacist

OF THOSE WHO WERE INITIALLY IDENTIFIED AS REQUIRING PEER-GUIDED CONTINUING EDUCATION, 73% WERE ABLE TO SUCCESSFULLY RE-CHALLENGE THE COMPETENCY ASSESSMENT A SECOND TIME AND MEET OR EXCEED EXPECTATIONS.

was eligible to re-challenge the assessment, in whole or in part as directed by the individual’s results from the standardized assessment and if successful, to be listed in the self-directed continuing professional development group. This support, provided by the regulatory body to actually work with its members to address knowledge and skills deficits in a collegial manner, rather than simply punishing the individual, was crucial to building acceptance from the profession.¹¹

Results

The Quality Assurance program was launched by the College in 1996, after more than three years of consultations and pilot testing. A significant profession-wide education and consultation process was also introduced to inform pharmacists of the process and the safeguards in place to balance public protection with member interests. For logistical reasons, approximately 260 Part A pharmacists (representing approximately 5% of the practitioners in the province), initially and each year thereafter, were randomly selected to participate in the peer-review process. In addition, those pharmacists who elected to transfer from Part B to Part A of the register were also required to successfully complete the peer review. The process itself required

between five and six hours to complete, and consisted of three major components: first, the case-based multiple choice test of clinical knowledge; second, the objective structured clinical examination (focusing on clinical reasoning and communication/interpersonal skills); and third, the facilitated learning portfolio sharing session, in which practitioners discussed and shared relevant practice-focused continuing professional development issues and activities.

Table 2 outlines overall performance in the peer review program: Between 1997 and 2012, close to 90% of pharmacists in Ontario met or exceeded competency expectations established by the profession and measured through the process by OCP and were deemed to be part of the self-directed continuing professional development group.

Of those who were initially identified as requiring peer-guided continuing education, 73% were able to successfully re-challenge the competency assessment a second time and meet or exceed expectations, resulting in a shift to the self-directed continuing professional development group. A number of resources had been put into place to assist pharmacists requiring reassessment. First, a peer support group provided the reassessment-pharmacists an opportunity to meet with a small group of peers to discuss the nature of their practice and the challenges they were encountering with the Practice Review. In addition, OCP developed a Professional Development Workshop focusing on problem solving skills related to the clinical knowledge assessment and communication skills related to the Standardized Patient scenarios. Based on the results of the Practice Review, common knowledge and skills deficits identified included: 1) difficulty in conducting a structured interview to gather information in an efficient and comprehensive manner; 2) lack of appropriate monitoring parameters or discussion of follow-up plan with patient/caregiver/prescriber; 3) difficulties using standardized pharmacy reference texts and

Table 2
Overall Performance for Peer Review
(Period Covering 1997–2012)

	Total Number	Percentage
Self-directed	2651	89.4
Peer-guided	331	10.6
Total	2964	100

electronic resources to answer drug information or clinical questions; and 4) difficulty in effectively applying a clinical reasoning process to identify, resolve, or prevent drug therapy problems. These identified deficits were used to provide a curricular

...A PEER SUPPORT GROUP PROVIDED THE REASSESSMENT PHARMACISTS AN OPPORTUNITY TO MEET WITH A SMALL GROUP OF PEERS TO DISCUSS THE NATURE OF THEIR PRACTICE AND THE CHALLENGES THEY WERE ENCOUNTERING WITH THE PRACTICE REVIEW.

structure for the remediation process. Overall, the impact of attending the workshop was positive (particularly with respect to participants' confidence in structuring a comprehensive patient interview and in using drug information resources) but notably, pharmacists in practice less than 25 years demonstrated a greater benefit compared to pharmacists in practice for more than 25 years.¹¹

Since inception, the program has been tracking performance of pharmacists based on years since

graduation from their professional degree program. As seen in Figure 1, there is a clear increase in the number of individuals who do not meet competency expectations and therefore require peer-guided continuing education the further away in time they are from original graduation with a pharmacy degree. A total of 207 individuals were identified as requiring peer support through this program (based on years in practice: 0-5 years = 0; 6-15 years =24; 16-24 years =58; 35-44 years = 96; and 45 years or more in practice = 29)

Within the profession of pharmacy in Ontario, only one type of license/registration is provided; there are no provisions for specialty licenses or for different registrations based on site of primary practice (e.g., community vs. hospital). Since only 12% of registrants in the province self-identify as primarily hospital pharmacists,¹ there were some initial concerns that the competency assessment (and in particular, the OSCE component) would be biased towards community practitioners or primary care. Cumulative data, however, suggests that hospital pharmacists perform significantly better across the competency domains than their community-based colleagues (Figure 2).

Figure 1
Performance by Years Since Graduation

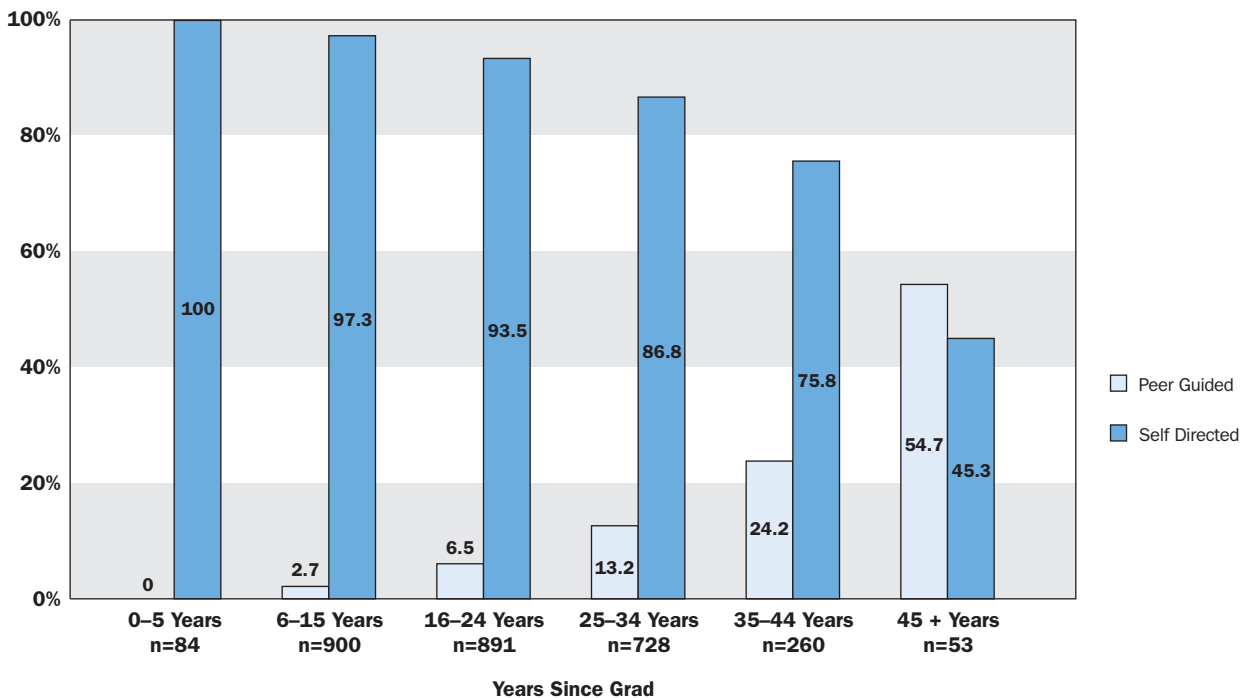


Figure 2
Competency Assessment Results by Practice Site

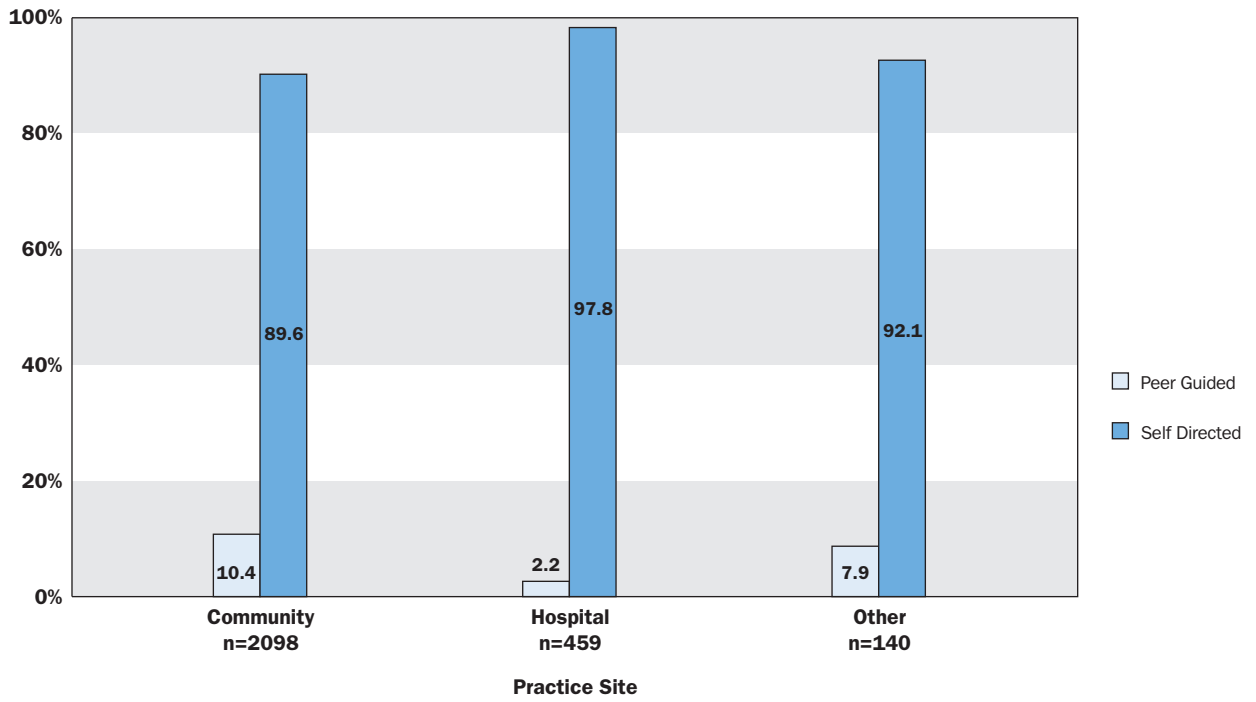
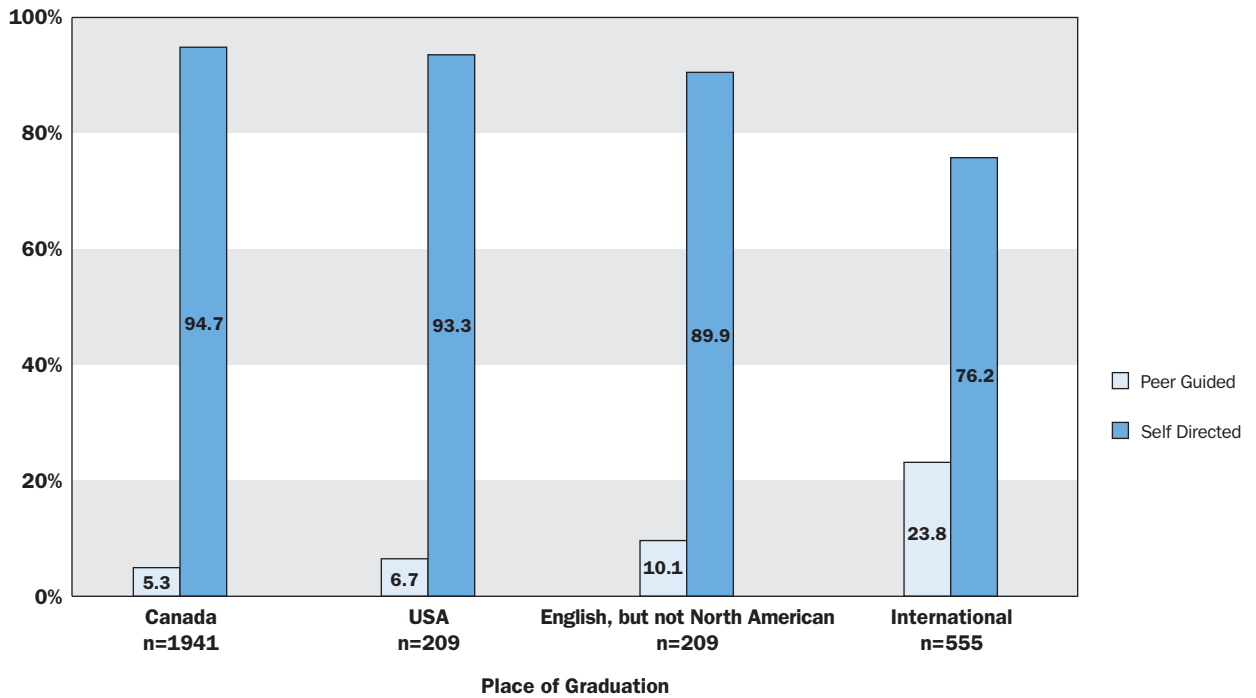


Figure 3
Competency Assessment Results by Place of Graduation



The strong performance of hospital pharmacists did not diminish the fact that the Practice Review, from their perspective, was outside their comfort zone. Nevertheless, their performance does argue for the position that the underlying skills that the Practice Review assesses are common for the pharmacy community as a whole.

Pharmacy in Ontario is notable for having a significant reliance upon internationally educated health professionals (those educated outside Canada or the United States) within the domestic workforce.¹² Since the early 2000s, more than 40% of all newly registered pharmacists in the province have consistently been international pharmacy graduates (IPGs).¹³ In large part, this has been attributed to the fact that there are only two schools of pharmacy in the entire province, and only eight schools of pharmacy across English Canada. As illustrated in Figure 3, the data reveals a differential pattern of performance on competency assessments based on place of graduation.

Factors contributing to these differences could reflect the fact that professional preparation around the world does in fact differ in the profession of pharmacy. Some programs place greater emphasis on the technical or clinical aspects of practice while others emphasize pharmacy patient relationships and the need to exercise professional judgment. The Practice Review was necessarily grounded in the practice of pharmacy in Ontario. Therefore, it would be expected that those trained in Ontario would have both education and experience better aligned to the underlying expectations of the Practice Review than those who were educated elsewhere.¹⁴

These differences continue to exist despite the fact that pharmacists may have registered in Ontario years previously with the expectation that they would eventually adapt to Ontario practice. While the adaption most certainly occurs for the majority of international candidates, the results indicate that a number of international pharmacists experienced greater difficulty in meeting the competency level as determined by their peers for the Practice Review.¹⁵

Discussion

The direct, standardized, and objective assessment of practitioners' clinical competencies by a regulatory body is unique, and has not been attempted in such a systematic and sustainable manner in other health professions or jurisdictions. While the psychometric strength of this approach is both clear and defensible,⁸ it is also important to acknowledge

that such an approach gives rise to levels of concern and anxiety among many registrants. The fear of "being tested" is pervasive and there were added concerns about how results would be used by OCP — both of these were significant challenges that needed to be addressed and overcome in order to allow this model to be successfully implemented. Through the combination of extensive and ongoing consultation with members of the profession, policy

THE FEAR OF 'BEING TESTED' IS PERVASIVE AND THERE WERE ADDED CONCERNS ABOUT HOW RESULTS WOULD BE USED BY OCP — BOTH OF THESE WERE SIGNIFICANT CHALLENGES THAT NEEDED TO BE ADDRESSED AND OVERCOME IN ORDER TO ALLOW THIS MODEL TO BE SUCCESSFULLY IMPLEMENTED.

decisions that reinforced the notion that this was an educational (rather than punitive) intervention, and a structure that ensured confidentiality through clear protocols for sharing of results across the regulatory body, the profession collectively moved from grudging acceptance of this model to actual buy-in. While few pharmacists would say they "liked" this approach, eventually, most pharmacists would agree that it was a fair, transparent, appropriate — and necessary — process to ensure ongoing safe and effective professional practice.¹⁶

A key contributing factor to the success of implementation involved a strong commitment on the part of the regulatory body to data gathering, analysis, and dissemination. Based on this analysis, several important and consistent trends have been identified regarding competency drift within pharmacy in Ontario. Those at highest risk of not meeting competence standards over time include: 1) pharmacists who were 25 years or more away from graduation (accounting for 36% of pharmacists); 2) pharmacists working in sole-practitioner environments with limited opportunities to interact with peers in daily practice (49% of registered practitioners); and 3) international pharmacy graduates (IPGs) who received their initial education and training outside Canada or the United States (approximately 37% of pharmacists in Ontario).^{7,8}

Importantly, almost 90% of practitioners randomly selected for this process were able to meet or exceed competency expectations on their first attempt

and did not need to return for reassessment. For those who were unable to meet expectations, the peer-supported professional development process appeared successful, with 73% of these individuals being able to meet or exceed expectations on their second attempt.

While the data generated and feedback provided by peer review candidates over 20 years are of interest, the development of the program model itself and the experience of a regulator in direct competency assessment of practitioners is perhaps of greater interest outside the profession of pharmacy. In most jurisdictions, regulators are challenged to balance the competing priorities of ensuring public safety and facilitating engagement of members in their CPD processes. Competency assessment—especially for seasoned practitioners who have not been tested in some time—can be daunting and stressful, and navigating the shoals of pharmacists' misconceptions and fears about this process were challenging. Focusing on competency assessment using best-practice evaluation techniques in a standardized and objective manner, rather than situational performance assessment of a more variable nature, supported the regulator's objective of ensuring safe and effective practice of the profession of pharmacy in a fair, transparent, and psychometrically defensible manner.

Practice Review as a Catalyst in Promoting Continuing Professional Development

Two elements were not directly part of the standardized assessment process, but each played an important role in the overall peer review program. The first was the learning portfolio sharing session where practitioners shared with each other the activities they had engaged to promote continuing professional development. The feedback respecting the perceived importance of this component of the Practice Review was overall very positive. Specifically, pharmacists overwhelmingly confirmed that they saw value in learning from their peers about the activities and approaches they were engaging in. The sessions, which were facilitated by a peer practitioner, provided participants with an opportunity to consult each other in terms of best practice and to share, with their peers, changes in approaches to practice that they were considering implementing.¹⁶

Over the years, the learning portfolio sharing session evolved to where the candidates themselves influenced its content and structure. Initially, the session was designed to assist members in understanding

the principles in maintaining a learning portfolio, but in the later years, the session also became an opportunity for pharmacists to talk about important issues such as advanced practice. In fact, specific cases involving challenging issues related to patient care were developed and these simulations formed the basis for group discussion and emergence of examples of best practice. Taken together, this activity served as a catalyst for many members to explore a variety of learning activities that would benefit both their practice and the patients that they would care for on a day-to-day basis.¹⁶

A second, and most surprising, result of the Practice Review, in terms of serving as a catalyst for professional development, was brought to light during the feedback sessions that pharmacists participated in at the end of each review. Facilitated by both College staff and an assessment consultant, the sessions were designed to elicit from pharmacists important feedback respecting the impact experiencing the Practice Review had on them, personally

...PHARMACISTS OVERWHELMINGLY CONFIRMED THAT THEY SAW VALUE IN LEARNING FROM THEIR PEERS ABOUT THE ACTIVITIES AND APPROACHES THEY WERE ENGAGING IN.

and professionally. Interestingly, the candidates commonly described the experience as initially stressful (when first selected to participate), but just as frequently described it as a valuable experience and necessary program. Further, one of the most interesting and prevalent comments commonly identified the very existence of the Practice Review as a key catalyst for motivating members to engage in further learning.¹⁶ The types of learning pharmacists reported engaging in varied, however, what was consistent was the notion that without having been selected for the Practice Review, the learning activity would not have occurred at the level that it did.¹⁶ Most encouraging was the candidates' non-solicited positive feedback statements around the impact of feeling the need to prepare for the Practice Review. In the course of doing so, many pharmacists stated that they rediscovered the confidence to learn and grow professionally and considered this not only beneficial for themselves but also for the patients they served.

Other Impacts

The Practice Assessment and Peer Review process implemented in Ontario for pharmacists has been of interest as a model program for continuing competency assessment by health care regulators in Canada and around the world. Data gathered and analyzed over the years of administration has generated measurable and reportable results and identified consistent trends reported in this paper.

The positive impact of OCP's QA program — with its use of standardized patient scenarios — strongly influenced the College to support the Pharmacy Examining Board of Canada's (PEBC) addition of an OSCE component to its existing written clinical examination. The PEBC examination, with OSCE, was implemented in 2001.¹⁷ In addition, the findings related to particular challenges faced by International Pharmacy Graduates (IPGs) led the regulatory body to partner with a university to develop one of the world's first International Pharmacy Graduate Programs, a 16-week intensive bridging program designed to better support immigrant pharmacists (particularly from non-English speaking jurisdictions) in applying their previous knowledge and skills to the Canadian pharmacy practice context.¹⁵ This program has, as of 2016, graduated more than 1,000 pharmacists. Performance on this Practice Review is comparable between Canadian graduates and IPGs who have completed the program.¹⁵

Ontario's program has also garnered much international attention — and has been the focus of numerous presentations at conferences such as Federation International Pharmaceutique (FIP), Royal College of Physicians and Surgeons of Ireland (RCSI), the Pharmaceutical Society of Ireland (PSI) and the international Council on Licensing, Enforcement and Regulation (CLEAR). In 2010, Ontario's continuing competency assessment process for pharmacists was chosen by the Pharmaceutical Society of Ireland as the model on which the Quality Assurance Program for Pharmacists in Ireland would be built.¹⁸ Ontario's program was selected as the desired model by the PSI after a comprehensive review of international programs in multiple health care professions. Unlike Ontario, where the program is under the direct auspices of the pharmacy regulator, in Ireland, the program is to be administered through the Irish Institute of Pharmacy (IiOP), an independent body accountable to the regulator.

The province of Ontario began examining the potential expansion of scope of practice of pharmacists to

enhance care of patients and to optimize use of health care resources in 2006. Part of this scope of Practice Review involved greater independence for pharmacists in adapting, modifying, renewing, and initiating prescriptions, within a collaborative care framework. In 2012, this scope of practice expansion became a reality, in part due to the recognition that pharmacists were well qualified and that continuing competency assessment/quality assurance/peer review for pharmacists was robust, meaningful and provided the public, physicians, and government with the assurance that they were capable of greater independent responsibilities for direct patient care.^{19, 20}

The long-term impact on patient care of this program on the quality of pharmacists' practice has not been fully established. While general acceptance and satisfaction is strong, and specific learning of new skills has occurred,¹¹ it is less clear whether this has actually translated into behavioral change of pharmacists and whether any behavioral change has actually resulted in improved outcomes for patients (e.g., decrease in drug therapy problems or errors). Anecdotally, pharmacists have reported that the act of preparing for the Practice Review results in new learning that translates into behavioral change;¹¹ whether this learning and change sustain beyond the immediate period of the Review itself is not known.

While the pharmacy profession in Ontario was, as noted above, initially wary of the practice and peer review process, most pharmacists today agree that the program and its accompanying assessments were fair, valid and necessary and that overall the very existence of the Practice Review has had a positive impact on their own professional development and practice.

Conclusion

The peer review model of quality assurance described here has been successfully used by the profession of pharmacy in Ontario for more than two decades. The impact of this program on individual practitioners' professional development has been meaningful. Data from this program has been used provincially to support expansion of scope of practice of pharmacists, and has been used internationally to implement similar programs in other jurisdictions. The use of a standardized assessment model using best-practice measurement techniques and methods for the evaluation of clinical competencies has helped OCP balance its

responsibilities to the public and government, and to the practitioner community.

Chaudry et al (2013) have highlighted the need to “...thoughtfully explore pathways and procedures by which Maintenance of Licensure (MOL) may be implemented for physicians in the years ahead.”²¹ As medicine — and all of the health professions — consider ways of balancing these responsibilities and needs, consideration of the use of standardized assessment as implemented by pharmacy in Ontario may be of value. ■

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COUNCIL BRIEFING NOTE

MEETING DATE: MARCH 2017

FOR DECISION

FOR INFORMATION

X

INITIATED BY: Nancy Lum-Wilson, CEO and Registrar

TOPIC: Pharmacy Technician Strategy

ISSUE: Executive Committee requested development of a strategy to improve pharmacy technician engagement

BACKGROUND:

- The Executive Committee explored the issue of increasing Pharmacy Technician members on Council to more closely reflect the percent representation of membership at their November 2016 meeting.
- During the discussion it was noted that voter participation rate in the most recent election for pharmacy technician positions on Council was very low (about 10%) suggesting low member engagement within the profession. Additional evidence of low engagement was discussed, leading Committee to recommend development of an engagement strategy prior to seeking increased pharmacy technician representation on Council.
- One of the key priorities in the College's strategic plan is defined as "High performing professional health teams in place to achieve coordinated patient care" (Priority #3). The key performance indicator under this objective is pharmacists and pharmacy technicians practicing to their full scope and maximizing their respective roles. In order to achieve this objective, engagement and integration of pharmacy technicians within the practice setting is needed.
- In support of the strategic plan, development of pharmacy technician components of core College programs (registration, quality assurance, and community and hospital site and member assessments) is well underway. Many of these programs will be implemented in the upcoming operational year and will impact the integration of pharmacy technician practice.
- In order to support any further expanded scope for Pharmacists, it is critical that pharmacy technicians work to full scope of practice to support an environment that will be conducive to furthering the clinical role of pharmacists as medication therapy experts.

DEVELOPMENT OF A PHARMACY TECHNICIAN STRATEGY:

- The development of a pharmacy technician strategy will assist the College to achieve the strategic objective of high performing teams providing optimal patient care. A lack of engagement and integration undermines the ability of the profession to provide optimal patient care. As noted on the NAPRA website "*The development of a regulated framework for pharmacy technicians was the logical next step in the evolution of pharmacy practice, in an effort to increase patient safety and improve patient care. It allows the pharmacy technician to better support the pharmacist, allowing the pharmacist to focus more on the clinical aspects of patient care.*"

- Development of an integrated Pharmacy Technician Strategy, focused on engagement and integration in practice, is underway and will be finalized in April as part of the 2017/18 operational plan, with progress reported as part of regular operational plan updates to Council.
- Core to the strategy is the development and implementation of a communication plan that will address all stakeholders, including pharmacy technicians, pharmacists, designated managers, owners, corporations, educators and associations with aligned objectives.
- In addition to internal College activities, the strategy will support the education system in preparing pharmacy technicians to fully engage and work to their full scope; and pharmacists to work collaboratively with pharmacy technicians, utilizing their support to maximize their own clinical role.
- Pharmacy owners, corporations and designated managers are also key stakeholders within the strategy and will be engaged to address business practices and work flow to enable a practice environment to support the strategy.
- Measures of engagement and integration will be used to track progress over time and inform decisions about ongoing activities within the Strategy. Election voting rates serve as a measure of engagement, while member and practice site assessment data provides information about integration in practice (see Appendix 1). Additional measures will be developed in conjunction with implementation of new initiatives, which may require new or revised data collection methods.
- Successful implementation of the Strategy will support an environment that positions the profession to pursue additional scope activities.

Appendix 1 – Sample Pharmacy Technician Data

The following tables provide an example of existing data that can be used to assess degree of integration in practice. Additional sources of data will be established to expand on these measures.

of Technicians working to scope based on community pharmacy assessments between December 5, 2014 and January 24, 2017

On Average How Many Pharmacy Technicians work to scope in a day?	Number of Pharmacies	% of Total
Not Applicable (none)	3020	81
1	530	14
2 to 3	138	4
4 to 5	19	0.5
6 or more	15	0.4
Total	3722	99.9%

Number of Pharmacy Technicians Registered at year end by employment type

Employment Type	2014	2015	2016
Community Pharmacy	926	1181	1403
Hospital and Other Health Care Facilities	1073	2042	2178
Association/Academia/Government	38	56	59
Industry/Other	14	39	44
Pharmacy Corp Office/Professional Practice/Clinic	6	12	14
No Workplace Recorded	870	505	588
Total	2927	3835	4286

This data shows a 100% increase in the hospital sector over three years compared to 50% in community practice.

Note that most hospitals in Ontario have chosen to utilize only pharmacy technicians within their support workforce (i.e. they do not have pharmacy assistant positions). The majority of hospitals set the end of 2015 as the deadline for existing employees to become registered with the College.