Ontario College of Pharmacists
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Agenda

ONTARIO COLLEGE OF PHARMACISTS

COUNCIL MEETING AGENDA

MONDAY, DECEMBER 11, 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 December 2017 Council ..... Appendix 1
4.2 Briefing Note - September 2017 Council Meeting Evaluation ..... Appendix 2

5. Approval of Minutes of Previous Meeting
5.1 Minutes of September 2017 Council Meeting ..... Appendix 3

6. Notice of Motions Intended to be Introduced

7. Motions, Notice of Which Had Previously Been Given

8. Inquiries

9. Matters Arising from Previous Meetings
9.1 Briefing Note – Proposed Changes to the *Pharmacy Act* (Registration and Quality Assurance Regulation) .....Appendix 4

10. For Decision
10.1 Briefing Note – Finance and Audit Committee (Appointment of Auditor) .....Appendix 5
10.2 Briefing Note – Executive Committee (NAPRA Compounding Standards) ..Appendix 6
10.3 Briefing Note – President (Governance – Election of Council Members) .....Appendix 7

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11. For Information

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

11.2 Memorandum re: 2018 Strategic Planning Session .....Appendix 9

12. Other Matters

12.1 Presentation by College of Nurses of Ontario – Vision 2020
(Time: 11:00 a.m. to noon)

13. Unfinished Business

14. Motion of Adjournment

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

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

Thank you.

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COUNCIL BRIEFING NOTE
MEETING DATE: DECEMBER 2017

FOR DECISION	FOR INFORMATION	X

INITIATED BY: Régis Vaillancourt, President

TOPIC: President's Report to December 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 September 2017 Council Meeting. In addition to regular meetings and phone calls with the Registrar and the Vice President, listed below are the meetings, conferences or presentations I attended on behalf of the College during the reporting period. Where applicable, meetings have been categorized into general topics or groups.

College Meetings:
October 12th - OCP Regional Meeting in Ottawa
October 17th – Meeting with Ms. Rocha re discussion on Governance and College processes.
October 25th – Teleconference – Cannabis Task Force
November 16th - Patient Relations Committee Meeting
November 23rd - OCP/Ontario Pharmacists Association Conjoint Meeting; Executive Committee Meeting
December 12th - Cannabis Task Force Meeting

Other Stakeholder Meetings:
October 26th - Ottawa Carleton Pharmacists Association - AGM
November 15th – Canadian Foundation for Pharmacy event honoring Marshall Moleschi
November 17th – Royal Ottawa Health Group Pharmacy Retreat
November 18th – Ontario Branch, Canadian Society of Hospital Pharmacists - AGM and Award Ceremony

Ontario College of Pharmacists
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COUNCIL BRIEFING NOTE
MEETING DATE: DECEMBER 2017

FOR DECISION	FOR INFORMATION	X

INITIATED BY: Régis Vaillancourt, President

TOPIC: Evaluation Report of September 2017 Council Meeting

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 September 2017 Council meeting, we provided Council members with the opportunity to provide their feedback. 26 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	18	8	0	0	0	26
2. Members were well prepared to participate effectively in discussion and decision making	8	17	1	0	0	26
3. In accordance with the governance philosophy, Council worked interdependently with staff	16	8	0	1	0	25
4. There was effective use of time	17	8	1	0	0	26
5. There was an appropriate level of discussion of issues	11	14	1	0	0	26
6. The discussion was focused, clear, concise, and on topic	11	13	2	0	0	26

2. Did the meeting further the public interest?

YES = 25 = 96%
NO = 1 = 4%

There was no media presence. Twitter posts appeared to be not engaging enough for members of the general public.

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

- The discussions of cannabis and the opioid strategies. Informative, open to input.
- Medical marijuana: pleased with the depth of the discussion and believe that it is important that Council's decision-making maintain validity by ensuring that those members with actual/perceived conflicts declare such conflicts and exclude themselves.
- Case studies presented by Richard Steinecke and dividing members to groups of 3 to tackle each case were excellent means for learning!

- Finance clear presentation of budget... unfortunately it appeared that many Council members have insufficient financial acumen to ask deeper questions
- Regis kept everyone focused and on point.
- All questions were dealt with, and when not exactly on side, the issues dealt with respectfully and brought on track. I feel comfortable asking questions.
- Opioid strategy and task force. Dr Juurlink was very informative and knowledgeable. I believe this is a very important issue and the OCP: Strategy to Address Opioid Misuse and Abuse in Ontario, having the education part as one of the pillars was well discussed and many points and concerns raised.
- Most of the agenda items were information only. Good discussion around 2018 budget and CEO performance review. I felt we didn't have an open discussion about narcotic strategy and hurried up to move as planned.
- This is my first council meeting at the college which I greatly enjoyed, despite I was a NCCM for number of years, but I observed the dynamic, the energy and the level of discussion is quite different from the special committee level I sat on which is expected ... so in general I felt that the decision -making process worked well in my opinion as my first meeting. As an example I found the discussion around the budget, pharmacy technician fee and the decision -making process around were handled effectively and the issue raised from council members were heard and addressed.
- The opiate strategy. Regis was able to redirect discussions that were related to the how versus the what.
- 2018 proposed budget, the speaker justified the spending and the council members discussed the importance of maintaining a non-for-profit organization.
- The budget presentation was well done and very informative.
- Opioid Strategy and Cannabis discussions were productive, as we had very good background materials that facilitated informed discussions.
- Opioid strategy matter was presented in a concise and succinct manner which was easily appreciated. I especially respected Dr. Juurlink's presentation. It relayed and underlined issues that were most pressing. The discussion that followed was on point with the public's interest being paramount.
- Good orientation for new members and 'reminder' for existing. Excellent presentation and discussion related the opioid crisis. Process for budget approval and format of slides from staff was well done and helped to identify and answer the various potential questions and concerns from council members.
- Opioid strategy; members provided with good information, the process that the task force took and the result was excellent.
- As new joining council member, I found the presentation by Mr. Steinecke that pertained to the College's Governance Model and the role expected of Council members, conflict of interest and the examples discussed in term of governance scenarios was helpful and addressed general behaviours and draw some lines on the role expected from council members.

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

- The evaluation of the Registrar/CEO was too open-ended, and therefore not as effective as it could have been. I think the evaluation should have been conducted by a much smaller evaluation committee or the Executive, not the whole Council. However, input from everyone was good to have.
- N/A

- It was my first time in this Council to see the Finance Committee financial reports and I have expected that the Chair would give us the rundown (at least the highlights) in verbiage format which was the practice in the Council that I used to serve (which also provides opportunity for Council members to ask questions/clarifications). Could it be that this was already presented and discussed in the previous Council meeting I was unable to attend? Or, was this so since it was considered more operational than a governance matter?
- All were effective to varying degrees.
- The medical cannabis question-all the "experts" were technically conflicted out-who is going to partake in the discussion to protect the public? All pharmacists are inherently conflicted out as we can all stand to gain financially from this. But we stand to gain financially from the expanded scope - but does this conflict us out as well? I feel that there is no reasonable balance around COI.
- It would be ideal if we could figure out how to keep the pharmacists in the room for the discussions around medical marijuana.
- Cannabis for medicinal purpose, due to conflict of interest, was not able to be part of discussion.
- We have to be clear on what happens when we will have a discussion around an information only agenda item. What happens to that feedback and does anyone really care about that?
- My only comment and thought will be around the cannabis matter (access to cannabis for medical purpose use) the fact that too many members (over 2/3 of council) had COI, in my opinion, the decision that might have been taken might lack the views of the majority of council opinions around that matter given that large number of members left the room while that discussion took place.
- None
- The opioid strategy. The education part only addresses the education to pharmacists and not the education by pharmacists to the general public. I feel this could have been discussed further and the strategy could have been modified to include education of the general public.
- Cannabis -- I am concerned that we are interpreting the conflict of interest guidelines too strictly and thus losing a lot valuable front line knowledge. I think striking a working group is a great idea that will move the discussion forward in a meaningful way.
- All discussions were effective and productive.
- I appreciate that the registrar is present to assist the council and works closely with the president, however there were a couple of times that the agenda was perhaps controlled by the registrar. It may have just been my perception and it was not really an issue.
- The cannabis issue and discussion continues to be somewhat odd and awkward with so many council members out of the room. We discuss various drugs and pharmacy services at times - so not sure it's valid to single out a specific drug in such a way. There are many who could contribute to the knowledge, experience, and background related to the cannabis discussion. There were are few situations, I believe, new members, who's questions were somewhat operational, however, the chair did a good job in managing.
- The cannabis issue will always be difficult because of the numbers of people in conflict; those remaining must think clearly and make decisions only in the interest of the public.
- In general I found the discussion for most of the topics was effective including the decision process , But I felt in my opinion the discussion related he role of pharmacy related to cannabis for medical purposes was not that effective given the facts that close to half or more of the council members conflicted in that meeting. We all learned after that a task force will be composed and established and will report to council through executive but no further discussion regarding that task force took place.

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	14
Mostly Satisfied	12
Neither Satisfied Nor Dissatisfied	0
Mostly Dissatisfied	0
Completely Dissatisfied	0
Total Responses	26

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

- Meeting was run efficiently and effectively. Well done.
- General comment: it is important that the President continue, as is his custom, to identify members who have indicated a desire to comment and rank their speaking order. It may also be helpful to indicate, on the Agenda, where it is possible to do so, the designated time for the presentation of an item, and in particular, the maximum time available for the discussion of an item.
- Excellent meeting!
- It is great that the College seeks ongoing and frequent feedback (e.g. this survey/CEO performance etc.)... however, might I suggest that it is time to review the surveys... some of the questions are difficult to answer and may not be getting the info needed. Joan
- Ensure transparency and that council is directing the college not the opposite.
- Suggestion: consider using Canadian alternative with data servers hosted in Canada instead of survey monkey; has creator of surveys disabled automatic capture of IP address?
- I will be able to comment on that more effectively after the second council meeting, generally, I felt that meeting agenda were all met on time, I praise the punctuality on the time which is positive.
- None
- Juurlink’s presentation was very interesting
- The two-day meeting was productive and well managed. Sylvia Moustacalis
- We must maintain a high level of professionalism, even when topics are difficult to discuss.
- Generally as a first meeting on council and as previous NCCM for number of years, I am satisfied with the number of topics and management of time allocated to address those matters. I have no further comments in regard of that council meeting.

Respectfully submitted,

Régis Vaillancourt, President

Ontario College of Pharmacists

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MINUTES OF MEETING

OF COUNCIL

SEPTEMBER 18 AND 19, 2017

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MONDAY, SEPTEMBER 18, 2017 – 9:00 A.M.

COUNCIL CHAMBERS, ONTARIO COLLEGE OF PHARMACISTS

Elected Members

District H	Dr. Régis Vaillancourt, Ottawa
District H	Ms. Christine Donaldson, Mississauga
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. Mike Hannalah, Toronto
District M	Mr. Kyro Maseh, Toronto
District M	Ms. Laura Weyland, Toronto
District N	Mr. Gerry Cook, London
District N	Ms. Leigh Smith, Cambridge
District N	Dr. Karen Riley, Sarnia
District P	Ms. Rachelle Rocha, Sudbury
District P	Mr. Douglas Stewart, Sudbury
District T	Ms. Ruth-Ann Plaxton, Owen Sound
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. Christine Henderson, Toronto
Mr. Robert Hindman, Shuniah
Mr. Javaid Khan, Markham
Mr. James MacLaggan, Bowmanville - **Regrets**
Ms. Elnora Magboo, Brampton
Ms. Sylvia Moustacalis, Toronto
Ms. Joan A. Pajunen, Kilworthy
Mr. Shahid Rashdi, Mississauga
Ms. Joy Sommerfreund, London - **Regrets**
Mr. Dan Stapleton, Toronto
Mr. Ravil Veli, North Bay
Mr. Wes Vickers, LaSalle - **Regrets**

Staff present

Ms. Connie Campbell, Director, Corporate Services
Ms. Susan James, Director, Quality
Ms. Nancy Lum-Wilson, CEO and Registrar
Ms. Ushma Rajdev, Council and Executive Liaison
Ms. Anne Resnick, Deputy Registrar/Director, Conduct

Invited Guests

Dr. David Juurlink, Sunnybrook Health Sciences Centre
Mr. Richard Steniecke, Partner, Steinecke Maciura LeBlanc

1. Noting Members Present

Member attendance was noted.

2 Declaration of Conflict

Dr. Vaillancourt advised Council that there were some members who had declared a conflict at the June Council meeting during the discussion on Cannabis. Consistent with the instructions given at that time, he advised that these members would need to declare a similar conflict when discussing this matter later in the agenda.

He then asked members if there were any other conflicts that needed to be declared at this time. There were no conflicts declared.

3. Approval of Agenda

Council was referred to supplemental material to the Registrar's Report (National Association of Pharmacy Regulatory Authorities – NAPRA – Board material) distributed earlier that morning. **It was moved and seconded that the Agenda be approved. CARRIED.**

Prior to moving to the next agenda item, President Vaillancourt invited all members around the table to briefly introduce themselves.

4. President's Opening Remarks

For the benefit of Council members not in attendance at the previous evening's Council Reception, the President provided a brief summary of the event. He then welcomed the new members to Council - Mr. Mike Hannalah and Mr. Kyro Maseh (District M), Ms. Leigh Smith (District N), Ms. Rachelle Rocha (District P) and Ms. Ruth-Ann Plaxton (District T). Newly appointed public members, Mr. Robert Hindman (Shuniah) and Mr. Dan Stapleton (Toronto)

were also welcomed. Council noted returning members - Ms. Laura Weyland (District M) and Mr. Doug Stewart (District P). President Vaillancourt advised that as is customary, all new members have been paired with a more senior Council member for informal mentoring.

4.1 Briefing Note - President's Report to September 2017 Council

Dr. Vaillancourt referred to his report which summarized his activities since the previous Council meeting. These included attending various committee meetings at the College and various phone calls and meetings with the Registrar and the Vice President. Referencing the Governance Manual, he advised that meeting attendance was required to be recorded and reported annually and that this information was attached to his report.

Dr. Vaillancourt reminded Council that at the June Council meeting, the Council and Council member evaluation was introduced and advised that a summary of the feedback from this evaluation was also attached to this Report. Council noted for information that in general, the evaluation was very positive and showed a very high degree of goals being met or partially met. He pointed out that the form mirrors the responsibilities of Council as set out in the Governance Manual, which was approved in 2014. Council further noted that following the governance review (planned for 2018) and in light of changes introduced in the *Protecting Patients Act*, the form will be reviewed and amended to more accurately reflect the current activities and responsibilities of Council.

4.2 Briefing Note - June 2017 Council Meeting Evaluation

The President referred Council members to the June 2017 Council meeting evaluation and added that it was very important for Council to continue to provide feedback which will serve to ensure efficiency and enhance Council members' participation at these meetings.

Noting a suggestion that issues be identified for Council as being strategic or operational prior to discussion, Council was reminded that operational issues need not be considered by Council given its governance and oversight role.

5. Annual Council Member Orientation and Committee Chair Training

Registrar Lum-Wilson introduced Mr. Richard Steinecke and invited him to conduct this annual quarter day education session. Mr. Steinecke presented an overview of the College's Governance Model and Council members participated in several governance scenarios.

6. Approval of Minutes of Previous Meeting

6.1 Minutes of June 2017 Council Meeting

It was moved and seconded that the Minutes of the June 2017 meeting be approved. CARRIED.

7. Notice of Motions Intended to be Introduced

There were none.

8. Motions, Notice of Which Had Previously Been Given

There were none.

9. Inquiries

There were none.

10. Briefing Note - Registrar's Report on Election of Members to Council

Ms. Lum-Wilson advised that this Briefing Note was for information only and that all members who were recently elected to Council had been introduced earlier this morning. The Briefing Note was received for information by Council.

12. Appointment of Tellers

Ms. Campbell advised that in order to expedite the election process for members of the Executive Committee and Committee Chairs, members would be casting their votes by electronic means and she explained that since the by-law reflects the expectation that the vote count not be disclosed, tellers could still be appointed to view the results and announce them to Council.

President Vaillancourt asked for a show of hands to determine if Council was comfortable with the votes being publicly displayed on the screen upon the close of voting. Council members agreed to the votes being displayed and accordingly, there was no appointment of tellers.

11. Briefing Note - Elections Committee

A motion to receive the Elections Committee Report was moved and seconded. CARRIED.

Ms. Al-Zand, Chair of the Elections Committee, presented the Briefing Note to Council. She advised that the Elections Committee was appointed at the June 2017 Council meeting and the Committee met on August 31, 2017 to put together the slate of members being presented in this Briefing Note. She added that the slate was based on preferences indicated by the Council members and that during the elections process, in addition to the slate being presented, names could be withdrawn or members nominated from the floor.

13. Election of President

Ms. Al-Zand noted that there were two candidates (Dr. Vaillancourt and Ms. Donaldson) nominated for the position of President. After confirming that both candidates wished to let their names stand, she asked for further nominations from the floor. Hearing none, **a motion to close the nominations was moved and seconded. The motion CARRIED.**

Both candidates were invited to briefly address Council after which members were requested to cast their electronic ballots.

Dr. Vaillancourt was re-elected President for the 2017/2018 term after which he briefly addressed Council.

14. Election of Vice President

Council noted that there were two candidates (Ms. Donaldson and Ms. Weyland) nominated for the position of Vice President. After confirming that both candidates wished to let their names stand, Ms. Al-Zand asked for further nominations from the floor. No further nominations were received and **a motion to close the nominations was moved and seconded. The motion CARRIED.**

Both candidates were invited to briefly address Council after which members were requested to cast their electronic ballots.

Ms. Weyland was elected Vice President of the College for the 2017/2018 term.

15. Appointment of Nominating Committee

It was moved and seconded that together with newly elected President, Dr. Vaillancourt and Vice President, Ms. Weyland, Mr. Petrovic and Ms. Al-Zand be appointed to serve on the Nominating Committee. CARRIED.

President Vaillancourt announced that the Nominating Committee and Chairs of the Statutory and Standing Committees would convene after Council adjourned today to discuss the appointments to the various Committees.

16. Election of Executive Committee Members

The President announced that elections would be held for the one remaining elected-member position on the Executive Committee. Council noted that Ms. Rocha and Mr. Stewart had expressed an interest in serving on the Executive Committee. He then asked for nominations from the floor. No further nominations were received and **a motion to close the nominations was moved and seconded. The motion CARRIED.**

Both candidates were invited to briefly address Council after which members were requested to cast their electronic ballots.

Mr. Stewart was elected to serve on the Executive Committee for the 2017/2018 term.

Council next noted that public members Ms. Al-Zand, Ms. Bracken, Ms. Henderson, Mr. Khan, Ms. Magboo, Ms. Moustacalis, Ms. Pajunen, Ms. Sommerfreund and Mr. Vickers had all expressed an interest in serving on the Executive Committee. All members, with the exception of Ms. Sommerfreund and Mr. Vickers who had sent regrets and therefore were not present at the meeting, confirmed their willingness to serve on the Executive Committee. The President then asked for nominations from the floor. No further nominations were received and **a motion to close the nominations was moved and seconded. The motion CARRIED.**

All seven candidates present were invited to provide brief remarks to Council and Council members were asked to cast their votes (i.e. vote for up to three candidates). Council members noted that the provisions in the by-laws state that members vote for up to three candidates. If no candidate receives an overall majority of votes, the candidate who receives the fewest votes will be removed from the ballot and the voting will continue until such time as there are three candidates remaining.

Council members cast and re-cast their votes, each time resulting in the removal of one member's name until it was established that Ms. Al-Zand, Ms. Henderson and Ms. Moustacalis had been elected to serve on the Executive Committee for the 2017/2018 term.

22. Other Matters

22.1 Presentation by Dr. David Juurlink

Given the College's current work on the Opioid Strategy, Council noted that Dr. David Juurlink had been invited to present to Council on his research and work related to opioids. Following introduction by Ms. Lum-Wilson, Dr. Juurlink made his presentation on the opioid crisis in North America to Council. His presentation touched on the role of prescribers and dispensers of opioids, patient safety and the factors that led to the development of the opioid culture and the public health crisis we are faced with today.

17. Election of Committee Chairs

Accreditation and Drug Preparation Premises Committees (DPP)

The President noted that Ms. Donaldson and Dr. Vaillancourt had been nominated for the position of Chair of the Accreditation and DPP Committees. Dr. Vaillancourt withdrew his name and asked for further nominations from the floor. There were no further nominations from the floor and **a motion to close the nominations was moved and seconded. The motion CARRIED.**

Ms. Donaldson was declared Chair of the Accreditation and DPP Committees.

Discipline Committee

The President noted that Mr. Stewart and Mr. Veli had been nominated for the position of Chair of the Discipline Committee. Mr. Veli withdrew his name. The President then asked for further nominations from the floor, and hearing none, **a motion to close the nominations was moved and seconded. The motion CARRIED.**

Mr. Stewart was declared Chair of the Discipline Committee.

Finance and Audit Committee

The President noted that Mr. Cook and Mr. Khan had been nominated for the position of Chair of the Finance and Audit Committee. Mr. Cook withdrew his name. The President then asked for further nominations from the floor, and hearing none, **a motion to close the nominations was moved and seconded. The motion CARRIED.**

Mr. Khan was declared Chair of the Finance and Audit Committee.

Fitness to Practise Committee

The President noted that Ms. Al-Zand had been nominated for the position of Chair of the Fitness to Practise Committee. He then asked for further nominations from the floor. There were no further nominations and **a motion to close the nominations was moved and seconded. The motion CARRIED.**

Ms. Al-Zand was declared Chair of the Fitness to Practise Committee.

Inquiries, Complaints and Reports Committee (ICRC)

The President noted that Ms. Pajunen, Ms. Rocha, Mr. Veli and Ms. Weyland had been nominated to serve as Chair of the ICRC. Mr. Veli withdrew his name and the President asked for further nominations from the floor. There were no further nominations and **a motion to close the nominations was moved and seconded. The motion CARRIED.**

All candidates were invited to provide brief remarks to Council and Council members were asked to cast and re-cast their votes until there was one candidate remaining.

Ms. Weyland was elected Chair of the Inquiries, Complaints and Reports Committee.

Patient Relations Committee

The President noted that Ms. Sommerfreund had been nominated to serve as Chair of the Patient Relations Committee. He then asked for further nominations from the floor, and hearing none, **a motion to close the nominations was moved and seconded. The motion CARRIED.**

Ms. Sommerfreund was declared Chair of the Patient Relations Committee.

Professional Practice Committee

Dr. Vaillancourt advised Council that over the past couple of years, the College has been calling ad-hoc, issue-specific clinical working groups and task forces to give advice and guidance to the College on specific practice issues. This appears to have worked well and is consistent with the proposed governance framework being considered in the regulatory field. He advised that the College would continue this process for the upcoming Council year and that changes to the by-laws to reflect future committee structures will follow after Council discusses this issue in greater detail. Accordingly, he continued, for the upcoming year, Council will not be electing a Chair for the Professional Practice Committee.

Quality Assurance Committee

The President noted that Ms. Phillips had been nominated to serve as Chair of the Quality Assurance Committee. He then asked for further nominations from the floor, and hearing none, **a motion to close the nominations was moved and seconded. The motion CARRIED.**

Ms. Phillips was declared Chair of the Quality Assurance Committee.

Registration Committee

The President noted that Mr. Veli had been nominated to serve as Chair of the Registration Committee. He then asked for further nominations from the floor, and hearing none, **a motion to close the nominations was moved and seconded. The motion CARRIED.**

Mr. Veli was declared Chair of the Registration Committee.

Adjournment

At 3:22 p.m. the President declared the meeting adjourned and advised Council members that the Nominating Committee and the newly elected Chairs would now meet to discuss the appointment of members to the Statutory and Standing Committees.

Council noted for information that given the application of the new competency–based selection process shared with Council in June, the Nominating Committee will be confirming the Non-Council Committee appointments with the newly-elected Chairs over the next week or two.

TUESDAY, SEPTEMBER 19, 2017 – 9:07 A.M.

COUNCIL CHAMBERS, ONTARIO COLLEGE OF PHARMACISTS

Elected Members

District H	Dr. Regis Vaillancourt, Ottawa
District H	Ms. Christine Donaldson, Mississauga - **Regrets**
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. Mike Hannalah, Toronto
District M	Mr. Kyro Maseh, Toronto
District M	Ms. Laura Weyland, Toronto
District N	Mr. Gerry Cook, London
District N	Ms. Leigh Smith, Cambridge
District N	Dr. Karen Riley, Sarnia
District P	Ms. Rachelle Rocha, Sudbury
District P	Mr. Douglas Stewart, Sudbury
District T	Ms. Ruth-Ann Plaxton, Owen Sound
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. Christine Henderson, Toronto
Mr. Robert Hindman, Shuniah
Mr. Javaid Khan, Markham
Mr. James MacLaggan, Bowmanville – **Regrets**
Ms. Elnora Magboo, Brampton
Ms. Sylvia Moustacalis, Toronto
Ms. Joan A. Pajunen, Kilworthy
Mr. Shahid Rashdi, Mississauga
Ms. Joy Sommerfreund, London – **Regrets**
Mr. Dan Stapleton, Toronto
Mr. Ravil Veli, North Bay
Mr. Wes Vickers, LaSalle - **Regrets**

Staff present

Ms. Connie Campbell, Director, Corporate Services
Ms. Susan James, Director, Quality
Ms. Nancy Lum-Wilson, CEO and Registrar
Ms. Ushma Rajdev, Council and Executive Liaison
Ms. Anne Resnick, Deputy Registrar/Director, Conduct

President Vaillancourt welcomed members to the second day of the Council meeting.

18. Matters Arising from Previous Meetings

18.1 Briefing Note – Cannabis for Medical Purposes

The President reminded Council members that Mr. Cheung, Dr. Merani, Ms. Phillips, Mr. Poulose, Mr. Stewart, Mr. Veli and Ms. Weyland had all declared a conflict during the Cannabis discussion at the June Council meeting. Consistent with the instructions given at that meeting, Dr. Vaillancourt asked these members, as well as any new members who have a conflict, to leave the room. Mr. Stewart advised that since he had changed employment, he was no longer conflicted. Ms. Smith, Mr. Cook, Ms. Plaxton, Mr. Hannalah and Mr. Maseh declared a conflict and left the meeting room.

Dr. Vaillancourt advised Council that at the Executive Committee meeting in late August, there was discussion that given the number of people who were conflicted during the Cannabis discussion at the June Council meeting, the Committee recommended that the College not move forward with the issuance of a statement, but that a task force be established to address the development of a cannabis strategy that is consistent with the national position that Council has endorsed.

Following discussion regarding membership of the Task Force and the President's explanation that it would comprise members of Council as well as subject matter experts and that the task force would report through the Executive Committee to Council, **it was moved and seconded that a task force be established to review and make recommendations on the role of pharmacy related to cannabis for medical purposes.** Council members present in the meeting room voted unanimously in favour of the motion. **CARRIED**. It was noted that task force will report back to Council at a future meeting.

Council members who had declared a conflict were invited back to the meeting room and provided with a summary of the outcome of the discussion.

18.2 Briefing Note – Opioid Task Force – Opioid Strategy

Dr. Vaillancourt next presented the Briefing Note on the Opioid Strategy to Council. He advised that the College is committed to supporting and complementing action undertaken by provincial and federal governments and other health system stakeholders to reduce the abuse and misuse of opioids and prevent overdose and addiction. An Opioid Task Force was created to

support the development of a College Opioid Strategy and Council was referred to the logic model distributed earlier in the meeting. He added that this was a draft workplan for some of the Task Force's early thinking of what may be possible and that there was still a lot of work that needed to be done before it could be determined if some of the ideas could be considered feasible from the government's perspective.

Dr. Vaillancourt then made a brief presentation to Council on the proposed Strategy, which focuses on four key priorities – education for pharmacy professionals regarding opioid issues, opioid dependence treatment and harm reduction, prevention of overdose and addiction and quality assurance of practice. He added that he was seeking Council's endorsement for the Strategy itself, and as is consistent with the role of Council, the College staff will be tasked with operationalization of the Strategy. In terms of next steps, it was noted that College staff will prioritize and implement the key initiatives identified by the Task Force with the support of an external working group, where required. Progress on opioid-related initiatives will be reported to Council quarterly through the Registrar's Report.

Following a brief discussion on some of the proposed steps, **it was moved and seconded that Council endorse the Opioid Strategy as presented.** Council members voted unanimously in favour of the motion. **CARRIED.**

19. For Decision

19.1 Briefing Note – Finance and Audit Committee

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

Following introductory remarks by Mr. Khan, Chair of the Finance and Audit Committee, Ms. Campbell was invited to make a brief presentation to Council on the proposed operating and capital budget for 2018.

Council heard that the budget supports the fulfillment of key initiatives set out in the third and final year of the current strategic plan and the ongoing activities associated with the College's regulatory responsibilities. The budget includes a plan to draw down on reserves as necessary to cover a shortfall of revenue against expenses. As a result, no fee increases are recommended for 2018.

She added that Council will undertake a strategic planning process in the spring of 2018 to set the direction and priorities for a new strategic plan commencing in 2019. This planning exercise will seek to further align College strategy with health-system priorities and government initiatives such as those stemming from the *Protecting Patients Act, 2017* including the development of regulations that will advance the College's public-protection mandate and strengthen public confidence in the work of Ontario's health regulatory colleges.

Together with the Registrar and the Chair of Finance and Audit Committee, Ms. Campbell responded to questions from the floor regarding specific line items in the budget.

Following discussion, **a motion to approve the 2018 Operating and Capital Budget was moved and seconded. CARRIED.**

19.2 Briefing Note – Finance and Audit Committee (Appointment of Auditor)

Deferred to next meeting.

19.3 Briefing Note – Registration Committee

A motion to receive the Briefing Note from the Registration Committee was moved and seconded. CARRIED. Mr. Veli, Chair of the Registration Committee presented the Briefing Note to Council.

In June 2016, Council was advised of the necessity for updating the registration regulations in order to implement a mechanism for pharmacy technician graduates to register and practice to scope post-graduation, while completing the remaining registration requirements for full registration. In September 2016, Council approved frameworks for updating quality assurance and registration regulations that would allow the College to proceed with drafting amendments that are outcomes-based and that are supported by standards, policies and guidelines which can change over time to enable the evolution of pharmacy practice.

Mr. Veli invited Ms. James to present the proposed changes to Council. Referring to the high-level framework and rationale for the proposed changes which will assure greater transparency to the public, streamline the registration process and improve accountability, Ms. James explained that for the amendments pertaining to registration, the proposal was to implement an intern pharmacy technician class of registration, to be consistent with the existing intern pharmacists class and to eliminate the registered pharmacy student class of registration which results in unnecessary steps in registration.

Council noted that in accordance with the *Regulated Health Professions Act*, once approved, the proposed changes would be circulated for 60 days to members and stakeholders for comment. A consultation report, including a summary of feedback, will then be presented to Council for consideration in December 2017. Discussion then ensued and Ms. James responded to questions from the floor and provided clarification on the proposed amendments.

Dr. Vaillancourt suggested that since the next briefing note also dealt with proposed amendments to the quality assurance section of the same regulation under the *Pharmacy Act*, that Council consider those changes first prior to voting on the common recommendation which is that the proposed regulation changes be circulated for open consultation.

19.4 Briefing Note – Quality Assurance Committee

A motion to receive the Briefing Note from the Quality Assurance Committee was moved and seconded. CARRIED. Ms. Phillips, Chair of the Quality Assurance Committee, was invited to present the Briefing Note. Council noted that the proposed amendments seek to incorporate pharmacy technicians into the quality assurance regulations, including shifting from an hourly

reporting of practice to a self-declaration of competency in conjunction with practice assessments.

Following a brief discussion, **it was moved and seconded that the proposed regulation changes be circulated for open consultation.** A consultation report, including a summary of feedback, will be presented to Council for consideration in December 2017. Council voted unanimously in favour of the motion. **CARRIED.**

20. For Information

20.1 Briefing Note - Registrar's Report to Council

President Vaillancourt requested the Registrar, Ms. Lum-Wilson, to address Council. Referring to the Strategic Priorities document, the Registrar presented to Council a status report on the achievement of goals and advised Council that everything was on target to meet the commitments for this year. Noteworthy accomplishments were highlighted for Council's information.

She then went on to highlight the salient points in her report, which included an update on some of the noteworthy meetings held with various branches of the Ministry of Health and Long-Term Care, all of which served to bring the College's work and current initiatives (e.g. cannabis, opioid strategy, scope changes, etc.) to the their attention as well as to have meaningful dialogue on these issues.

Work at the College also continues on proposed amendments to the *Regulated Health Professions Act, 1991* (RHPA), a result of the proclamation of the *Protecting Patients Act*.

Ms. Lum-Wilson went on to advise that the College will be hosting a serious of regional meetings during the fall - in Toronto (October 10), Ottawa (October 12), London (October 26) and Sudbury (November 1). Council members were invited to attend these meetings as schedules permitted.

Another significant issue that was brought to Council's attention was the advance notice provided by the National Association of Pharmacy Regulatory Authorities (NAPRA) regarding changes to NAPRA's new governance which will be effective November 2017. Each regulatory body has been requested to formally submit the name of their Registrar to be appointed to the Board. **Accordingly it was moved and seconded that Council put forward Ms. Lum-Wilson's name as the representative for the Ontario College of Pharmacists on the NAPRA Board.** Council members voted unanimously in favour of the motion. **CARRIED**.

20.2 Briefing Note – Statutory and Standing Committee Reports

President Vaillancourt next advised Council that as required in the *Regulated Health Professions Act* and the College by-laws, all statutory committees are required to submit an annual report to Council. He added that the reports were provided for information only and that none of the material in the reports was new but essentially a re-cap of what had occurred and

reported during the previous Council year. He acknowledged the work done by all the Committees over the past year.

21. Other Matters *(continued)*

21.2 Presentation: *The Protecting Patients Act* - Status Update

Deputy Registrar, Ms. Resnick, was invited to make a presentation to Council.

Council received an update on the *Protecting Patients Act, 2017* (PPA) including a summary of changes made to the *Regulated Health Professions Act*, 1991 and the *Drug and Pharmacies Regulation Act,* 1990. The PPA was introduced to strengthen Ontario's zero-tolerance policy on sexual abuse by regulated health professionals and support greater accountability and transparency in the healthcare system.

Ongoing dialogue is anticipated with the Ministry of Health and Long-Term Care as the government moves forward with developing draft regulations over the coming months. Council noted that member and public communication and education as regulations come into effect will be a top priority.

21.3 Approval of Appointments to Statutory and Standing Committees

The President referred Council to the Committee appointments list distributed earlier in the day and thanked the Nominating Committee and the newly-elected Chairs of the statutory and standing committees, who had met the previous afternoon, for their work in this appointment process. He added that once the non-council committee appointments had been made, the information would be made available on the website. **A motion to approve the appointments to the Statutory and Standing Committees was moved and seconded. CARRIED.**

22. Unfinished Business

None.

23. Registrar's Annual Performance Appraisal

President Vaillancourt advised that the Governance Manual sets out the role of the Registrar as well as how the Registrar's performance is to be evaluated by Council as a whole.

Over the summer, Council members were invited to provide feedback on the Registrar's performance over the past year. This feedback has now been collated for final approval by Council. Since this issue pertained to a personnel matter, and accordingly met the requirements for having an in-camera session under section 7 of the Health Professions Procedural Code**, it was moved and seconded that Council do now, at 1:14 p.m., move *in-camera* in order to discuss the Registrar's annual performance appraisal. CARRIED.**

All staff members and observers were requested to leave the Council Chamber during the discussion of this agenda item.

It was moved and seconded that at 1:52 p.m., Council end the closed meeting discussion and return to the public meeting. CARRIED.

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. The motion CARRIED.

24. Motion of Adjournment

It was moved and seconded that the Council meeting be adjourned at 1:53 p.m. and to reconvene on Monday December 11, 2017, or at the call of the President. The motion CARRIED.

Ushma Rajdev
Council and Executive Liaison

Régis Vaillancourt
President

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COUNCIL BRIEFING NOTE
MEETING DATE: DECEMBER, 2017

FOR DECISION	X	FOR INFORMATION

INITIATED BY: Susan James, Director, Quality

TOPIC: Approval of the proposed amendments to General Regulation 202/94 under the *Pharmacy Act* (Registration and Quality Assurance)

ISSUE: Consideration of consultation feedback to proposed amendments to the QA and Registration components of General Regulation 202/94

BACKGROUND:

- In June 2016, Council approved proposed amendments to the registration regulation to permit pharmacy technician graduates to register and practice to scope post-graduation. Council also approved a regulation drafting approach that emphasizes outcomes in order to allow flexibility in application of the regulation and thereby support practice change and evolution.

- At the same time, Council approved proposed changes to the quality assurance (QA) regulation to extend the QA program to pharmacy technicians and incorporate them into the two-part register. Council also approved changes to the current QA process of annual declaration of practice hours, to a declaration of competence, supported by a yearly member self-assessment and evaluation of practice at the member's practice site approximately every 5 years.

- In September 2016, Council accepted the recommendation of the Registration Committee to eliminate the student class of registration and implement a single provisional class of registration for pharmacists and pharmacy technicians. Of note, the university faculties were consulted and were supportive of this change.

- On September 18, 2017 Council reviewed and approved the draft amendments to both the registration and quality assurance regulations, and directed that they be available for public consultation for 60 days. The proposed regulations were posted on the College website, and on October 6, were also posted on the government's Regulatory Registry. The consultation closed on November 20, 2017 and all comments were reviewed.

- There were 41 individual submissions representing 22 Pharmacists, 16 Pharmacy Technicians, and 3 members of the public as well as one organization submission, namely the Ontario Pharmacists Association (OPA).

ANALYSIS:

Overall the feedback was favourable, indicating no need for revisions to the draft. A summary follows:

Feedback from individuals:

- Of the 41 individual submissions, 80% are supportive of the proposed amendments.

- All the pharmacy technicians who submitted a response are in agreement with the proposal to create an intern pharmacy technician class of registration and to extend the two part register to include them.

- Pharmacists are generally supportive of the changes, particularly with respect to improvements to the language proficiency requirements that must be met at initial application and maintained on a continuing basis.

- Of the 22 pharmacist and 3 public submissions, the main concern raised was with the proposed changes from a self-declaration of practice hours to declaration of maintained competence. There were suggestions that practice hour reporting could be incorporated into the on-site practice assessment and there was also concern about whether the College would be able to assess all members as part of the quality assurance process.

- One of the public submissions expressly complemented the College on making positive changes in the name of patient safety, and added that the proposal was a much needed update of the regulation.

- Of note, a previous registrar submitted feedback with respect to the regulations and the revised approach to the on-site quality assurance assessment.
  1. Concern was raised regarding the lack of detail in the regulation, including member/peer interactions. While Ministry feedback to date did not indicate the need for any changes at this time, this will be considered in the next stage of the regulation review process.

  2. Concern was raised regarding the distinction between the site inspection and quality assurance processes, and whether an appropriate firewall exists to properly distinguish these two processes. Although outside the scope of the regulations, this is an issue the College is managing and will continue to consider as the QA processes evolve.

Ontario Pharmacists Association

- The OPA was generally supportive of the draft regulatory amendments; however, the submission raised questions related to the removal of the student class of registration and the result that undergraduates would not be mandated to carry personal professional liability insurance. While this is true, students will be covered by the professional liability insurance contracts in place through their educational institution and employer(s).

Office of the Fairness Commissioner

- The Office of the Fairness Commissioner has been kept apprised of the proposed changes to the Registration Regulation throughout the process. They reported having reviewed the current draft and confirmed they have no concerns with the amendments as they relate to fair registration practices and requirements under the *Fair Access to Regulated Professions and Compulsory Trades Act, 2006.*

RECOMMENDATION: That Council approve the proposed amendments to General Regulation 202/94 for submission to the Ministry of Health and Long-term Care.

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COUNCIL BRIEFING NOTE
MEETING DATE: DECEMBER 2017

FOR DECISION	X	FOR INFORMATION

INITIATED BY: Finance and Audit Committee

TOPIC: Appointment of Auditors

ISSUE: The Finance and Audit Committee is required to make recommendations to Council on the appointment or reappointment of the auditors annually

BACKGROUND:

OCP received notice in September, 2017 that Clarke Henning, the college auditor for several years, had recently merged with another firm. The committee convened to consider options for appointment given the timing of the notification in relation to year end activity. The services were last taken to market in 2014 at which time the Finance and Audit Committee identified two audit firms they believed to be suitable; they opted to retain Clarke Henning at that time. Given this background, the following options were considered:

a) Appointing the newly merged firm as auditor
b) Taking the services to market to select a new auditor
c) Appointing the second audit firm identified through the 2014 market review (Tinkham & Associates LLP)

ANALYSIS:

To undertake a full market review was not feasible given the time needed to solicit proposals and assess vendor suitability in time for associated audit activity that would deliver audited financial statements prior to the March Council meeting. Moving the audit services to the newly merged firm was also ruled out as an option due to differing opinions on accounting approach.

After reviewing the Finance and Audit committee minutes surrounding the previous market review, the Committee was satisfied that, provided there were no material changes to the structure of Tinkham & Associates LLP, their proposed fees or to their accounting approach, they continued to meet the criteria for appointment as OCP Auditor. Upon confirmation of this criteria and reference checking, the recommendation for appointment was confirmed along with a commitment to take the services to market again no later than 2019.

RECOMMENDATION: **That Tinkham & Associates LLP Chartered Accountants be appointed as Auditor for the College for the fiscal year 2017.**

EXECUTIVE COMMITTEE RECOMMENDATION AND COMMENTS (if any):

Ontario College of Pharmacists
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COUNCIL BRIEFING NOTE
MEETING DATE: DECEMBER 2017

FOR DECISION	X	FOR INFORMATION

INITIATED BY: Executive Committee

TOPIC: Model Standards for Pharmacy Compounding of Non-Sterile Preparations

ISSUE: NAPRA has approved Model Standards for Pharmacy Compounding of Non-Sterile Preparations for inclusion in the suite of model standards, currently pertaining to non-hazardous and hazardous sterile preparations

BACKGROUND:

- In September, 2016 Council approved the adoption of Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations and Hazardous Sterile Preparations with an implementation date of January 1, 2019
- The College posted draft Model Standards for Pharmacy Compounding of Non-Sterile Preparations for consultation in fall 2016 and based on responses, provided feedback to NAPRA's National Advisory Committee on Pharmacy Practice
- National consultations elicited over 800 comments, many of which were extremely detailed, leading to a new approach to the standards via the development of an accompanying Guidance document
- The aim of the Guidance document is to support the implementation of the Standards and to provide pharmacists and technicians, who compound non-sterile preparations, with the details necessary to evaluate their practice, develop service-related procedures, and implement appropriate quality controls for both patients and compounding personnel
- The Standards and the Guidance are currently being edited and translated and will be published on the NAPRA website in Q1 2018

ANALYSIS:

- In an outcome-based regulatory environment, detailed standards and supporting guidance are required in order to convey the expectations of pharmacy practice
- Submissions received by the College, which were reviewed with the support of the College's Compounding Working Group, were supportive of the adoption and publication of such standards
- The impact of these Standards will be greater than that of sterile compounding standards due to their likely application to all pharmacy settings
- Informed by the implementation experience over the past year, the Working Group will review these Standards to recommend to Council timelines for implementation in June 2018

RECOMMENDATION: **That Council adopt the Model Standards for Pharmacy Compounding of Non-Sterile Preparations with the implementation date to be recommended to Council in June 2018.**

Model Standards for Pharmacy Compounding of Non-Sterile Preparations

Published with the Guidance Document For Pharmacy Compounding of Non-Sterile Preparations

National Association of Pharmacy Regulatory Authorities

ACKNOWLEDGEMENTS

The National Association of Pharmacy Regulatory Authorities (NAPRA) would like to first thank one of its members, the Ordre des pharmaciens du Québec, for having made possible the adaptation of its document entitled “Préparation magistrales non stériles en pharmacie – Norme 2012.01” to create this national document, “Model Standards for Pharmacy Compounding of Non-Sterile Preparations and the accompanying document “Guidance for the Model Standards for Pharmacy Compounding of Non-Sterile Preparations”

In addition, NAPRA would like to thank the members of the National Advisory Committee on Pharmacy Practice for their continued diligence in the establishment of these documents

Table of Contents

1. INTRODUCTION

The "Guidelines to Pharmacy Compounding" published by the National Association of Pharmacy Regulatory Authorities (NAPRA) in October 2006 have recently been reviewed, resulting in a new set of documents: the NAPRA Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations[1]; the Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations[2]; the Model Standards for Pharmacy Compounding of Non-Sterile Preparations and its accompanying document Guidance for the Model Standards for Pharmacy Compounding of Non-Sterile Preparations (Guidance Document).

The NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations and the accompanying Guidance Document have been adapted from standards originally developed by the Ordre des Pharmaciens du Quebec, which are in turn based on General Chapter <795> of the United States Pharmacopeia – National Formulary (USP–NF) in effect in the United States since 2004. Their preparation was led by the NAPRA National Advisory Committee on Pharmacy Practice (NACPP) and involved extensive consultation with experts and stakeholders. These Model Standards and Guidance Document are put in place to ensure patient safety and the safety of personnel involved in compounding non-sterile drugs.

Each standard has a corresponding section in the Guidance Document with details on how these standards can be achieved. Requirements of the applicable pharmacy regulatory authority should also be consulted.

2. OBJECTIVES

The aim of these Model Standards is to provide pharmacists and pharmacy technicians who compound non-sterile preparations with the standards necessary to evaluate their practice, develop service-related procedures and implement appropriate quality controls for both patients and compounding personnel, with a view to guaranteeing the overall quality and safety of non-sterile preparations. The Model Standards apply to all non-sterile compounding by pharmacy personnel; however, not every standard will apply in all practice settings. These Model Standards will come into effect in each province/territory once they have been adopted by the respective provincial/territorial pharmacy regulatory authorities.

These Model Standards represent the **minimum** requirements to be applied in compounding non-sterile preparations; however, it is always possible to exceed these standards. The use of other technologies, techniques, materials and procedures may be acceptable, if they are proven to be equivalent or superior to those described in the accompanying Guidance Document.

[1] National Association of Pharmacy Regulatory Authorities (NAPRA), Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations, November 2015. Available from: http://napra.ca/Content_Files/Files/Mdl_Stnds_for_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Dec2015_FINAL.pdf

[2] National Association of Pharmacy Regulatory Authorities (NAPRA), Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations, Draft 4, March 2015

These Model Standards support NAPRA's Model Standards of Practice for Canadian Pharmacists and Pharmacy Technicians[3, 4], as well as other policies and guidelines that may be in place in provincial/territorial jurisdictions.

As with all prescriptions, a pharmacist would be expected to review the prescription and use their expertise to determine if the compounded preparation is appropriate for the patient. In addition, the pharmacist and/or pharmacy technician, designated as the compounding supervisor, must determine if they have the appropriate knowledge and resources to develop the formulation and/or the appropriate equipment and competency to compound the preparation. See section G 2.1 in the Guidance Document for a guideline which may help make the determination on whether or not to compound a preparation. Once it has been determined that it is appropriate to compound the preparation, the model standards for pharmacy compounding of non-sterile preparations must be applied.

3. REGULATORY FRAMEWORK

While compounded non-sterile preparations are prepared by other health care professionals, including nurses, physicians and veterinarians, the majority of non-sterile compounding is performed by pharmacy personnel under the supervision or direction of pharmacists. Although these standards could serve as best practices for other health care practitioners, they pertain specifically to compounding by pharmacy personnel for human or animal use[5] in all pharmacy settings where compounded non-sterile preparations are prepared.

In January 2009, Health Canada developed its "Policy on Manufacturing and Compounding Drug Products in Canada"[6]. It is expected that Health Canada policy will be followed along with these Model Standards. Compounding must always be carried out within a patient–healthcare professional relationship, or in the case of a compounded veterinary product, within a veterinarian/client/patient relationship. In the absence of a patient-specific prescription, and with a prescriber's order for office use, compounders may prepare a compounded product in such a scale, time or frequency to ensure it is being used within a patient-health care professional relationship. Compounders may also prepare batches of compounded product in limited quantities in anticipation of prescriptions. Requests to compound preparations outside the patient-healthcare professional relationship in bulk quantities for distribution or sale, generally fall into the realm of manufacturing, and outside the jurisdiction of pharmacies. Section G 3.1 in the Guidance Document provides general guidelines on differentiating between compounding and manufacturing activities.

NAPRA's professional competencies for Canadian pharmacists and pharmacy technicians at entry to practice provide guidance for developing an ethical, legal and professional practice. One of these competencies specifies that a pharmacist or pharmacy technician must seek

[3] National Association of Pharmacy Regulatory Authorities (NAPRA). *Model standards of practice for Canadian pharmacists.* Ottawa, ON: NAPRA; 2009. Available from: http://napra.ca/Content_Files/Files/Model_Standards_of_Prac_for_Cdn_Pharm_March09_Final_b.pdf

[4] National Association of Pharmacy Regulatory Authorities (NAPRA). *Model standards of practice for Canadian pharmacy technicians.* Ottawa, ON: NAPRA; 2011. Available from: http://napra.ca/pages/PharmacyTechnicians/pharmacytechnicianssstandards.aspx

[5] The Canadian Veterinary Medical Association's *Guidelines for the Legitimate Use of Compounded Drugs in Veterinary Practice,* states that the veterinarian is responsible for the safety and efficacy of the prescribed drug and for establishing adequate withdrawal times to avoid residues when it is used in food producing animals.

[6] Health Canada, Health Products and Food Branch Inspectorate. *Policy on manufacturing and compounding drug products in Canada.* POL-0051. Ottawa, ON: Health Canada; 2009. Available from: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol_0051-eng.php

guidance when uncertain about his or her own knowledge, skills, abilities or scope of practice. Given that pharmacists and pharmacy technicians are expected to maintain competency in basic compounding skills, pharmacists and pharmacy technicians are expected to provide compounded preparations within their level of expertise and within the limitations of available and appropriate facilities and equipment. When individuals do not have the knowledge, training, expertise, facilities or equipment required for compounding complicated non-sterile preparations or hazardous non-sterile preparations, they must refer patients to a colleague who does have the competencies and facilities required to do so, or, where permitted by provincial/territorial legislation, ask another pharmacy to compound the preparation. The risk assessment (section G 4) and previously mentioned questions (section G 2.1) in the Guidance Document provide information for pharmacists and pharmacy technicians to consider when making the decision whether or not to compound the preparation.

The Model Standards for Pharmacy Compounding of Non-Sterile Preparations excludes mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on the label of a drug approved by Health Canada within the normal practice of pharmacy, as these minor modifications are not classified as "compounding" by Health Canada.[7] However, the minimum conditions for good pharmacy practice should be maintained when performing these activities, and pharmacies are encouraged to follow basic requirements for non-sterile compounding found in this document.

Pharmacists and pharmacy technicians must also comply with any federal regulations regarding the compounding of a product that is not a drug such as cosmetics or food, and it is recommended that, in the absence of specific legislation, these model standards be considered best practice for those compounded products.

4. ASSESSING RISK FOR COMPOUNDING NON-STERILE PREPARATIONS

A risk assessment must be undertaken to identify the appropriate level of requirements to minimize contamination of each compounded product and to provide adequate protection for personnel. In addition to assessing the compounding of single products for risk, the compounding supervisor must also consider the cumulative risk of all preparations compounded in the pharmacy.

[7] Health Canada, Health Products and Food Branch Inspectorate. *Policy on manufacturing and compounding drug products in Canada.* POL-051. Ottawa, ON: Health Canada; 2009. Available from: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol_0051-eng.php

Steps for Conducting a Risk Assessment

<table>
<tr><td rowspan="2">Conduct a risk assessment for compounding non-sterile preparations including: risk to preparation and risk to person(s). See G4.1 for references and G 4.2 for factors to consider</td><td>Risk to Preparation

The preparation must be compounded in an area free from interruption from other activities in the surrounding space

The area must be large enough for compounding equipment and ingredients

The compounder must ensure that they or anything in the surrounding area do not contaminate the preparation being compounded</td></tr>
<tr><td>Risk to Person(s)

The compounder must be protected from materials which may be hazardous or harmful

The compounding area must be contained so it does not create a hazardous environment for others</td></tr>
<tr><td>Document your risk assessment clearly explaining how you have mitigated the risk to preparation and risk to person(s)

See Decision Algorithm G 4.2.1</td><td>Document rationale on the Master Formulation Record

Document procedures for mitigating risk on the Master Formulation Record

Rationale and procedure must be referenced

Rationale and procedure must be clear to all

Rationale and procedure must be reviewed at least every 12 months</td></tr>
<tr><td rowspan="3">Implement the level of requirements which are commensurate with the risk.

See Section 8 in this document and the Guidance Document</td><td>Level A

Simple and moderate compounds as defined in USP 795[8]</td></tr>
<tr><td>Level B

Complex compounds defined in USP 795

Small quantities of ingredients / preparations which require ventilation</td></tr>
<tr><td>Level C</td></tr>
</table>

[8] Excludes reconstituting and mixing as per Health Canada, Health Products and Food Branch Inspectorate. *Policy on manufacturing and compounding drug products in Canada.*

	Hazardous drugs which are classified by NIOSH[9] as Group 1 Hazardous materials classified by WHMIS[10] as a health hazard, such as those very irritating to the respiratory tract, the skin and the mucous membrane NIOSH group 2 and 3 drugs where large quantities of APIs are used routinely

5 REQUIREMENTS FOR ALL LEVELS[11] OF NON-STERILE COMPOUNDING ACTIVITIES

5.1 Compounding Personnel

All personnel are responsible to know and perform their roles and responsibilities in accordance with these standards and the applicable pharmacy regulatory authority.

Pharmacy Manager Pharmacy Department Head	Responsible for the development, organization and supervision of all activities related to compounding of non-sterile preparations in the pharmacy (see G 5.1.1)
Compounding supervisor Pharmacist Pharmacy Technician	Develops, organizes and oversees all activities related to compounding of non-sterile preparations in the pharmacy (see G 5.1.2)
	Ensures personnel are fully trained and know policies and procedures
	Ensures a risk assessment is performed for each preparation
	Ensures appropriate facilities, equipment and references are available for use
	Ensures Master Formulas and BUDs are developed using scientific references and that these are reviewed appropriately
	Ensures a quality assurance program is in place
	Ensures all records of decisions, activities or specifications are complete and appropriately documented
Regulated pharmacy personnel	Compounds non-sterile preparations in accordance with

[9] National Institute for Occupational Safety and Health (NIOSH), NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2014. Available from : http://www.cdc.gov/niosh/docs/2014-138/
[10] WHMIS at http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/index-eng.php
[11] Additional information on the compounding of hazardous preparations can be found in section 9.

Pharmacist / Pharmacy Technician	approved formula (see G 5.1.3)
	Complies with established policies and procedures
	Clearly documents decisions, completed activities and verifications prior to dispensing (pharmacist) or releasing (pharmacy technician)
	Ensures all compounding standards and standards of practice have been met
Non-regulated pharmacy personnel	Compounds non-sterile preparations under appropriate supervision in compliance with the requirements of the provincial/territorial regulatory authority. (see G 5.1.4)

5.2 Training and Skills Assessment

All compounding personnel must possess an expertise commensurate with their responsibilities	A training program must be in place for all compounding personnel and a record of all training must be kept (see G 5.2.1 for a template elements to cover in training)
	A skills assessment must be established, administered and documented for all personnel involved in non-sterile compounding (see G 5.2.1.1 for an example of a skills assessment)
	A record of the results of skills assessments and any corrective action taken must be maintained
Cleaning Personnel	Those involved in the cleaning of compounding areas must be properly trained and assessed such that they are aware of the importance of cleaning activities required to prevent cross-contamination. (see section G 5.2.2 for template of elements to cover in training)

5.3 Policies and procedures[12, 13]

Policies and Procedures for all activities related to compounding (see G 5.3.1 for a	Must be clear and provide detailed descriptions of all activities, including cleaning
	Must be reviewed at least every 3 years, or more frequently if

[12] United States Pharmacopeial Convention (USP). General chapter <795>: pharmaceutical compounding — non-sterile preparations. USP 39. Rockville, MD: USP; 2016. pp.31,37.
[13] Pharmacy Compounding Accreditation Board (PCAB). Standard 1.40: Standard operating procedures compliance indicators. In: *PCAB accreditation manual.* Washington, DC: PCAB; 2011. p. 7.

table with examples of policies and procedures and 5.3.2 for a template)	there is a change in practice or standards
	Must be promptly updated when there is a change affecting practice
	Additional procedures must be developed if handling hazardous products

5.4 Facilities and equipment

This section applies to all levels of non-sterile compounding. Additional requirements are expected for Level B and Level C as described in section 9.

5.4.1. Facilities for Non-sterile Compounding

All compounding must be performed in a separate space specifically designated for compounding	Compounding areas must be large enough for compounding personnel to be able to work comfortably and safely. There must be room to store equipment and products in an orderly fashion, in clean and secure surroundings (G.5.4.1.1)
	All components, equipment and containers must be stored off the floor in a manner that prevents contamination and allows for appropriate cleaning
	The compounding area must be conducive to necessary cleaning, maintained in sanitary condition, and in good repair. There must be adequate systems in place to ensure safe and appropriate waste disposal
	Lighting fixtures must be located such that they provide sufficient light for all compounding activities (G 5.4.1.2)
	The heating, ventilation and air conditioning systems must be controlled to avoid decomposition and contamination of chemicals, maintain the quality of products and ensure the safety and comfort of compounding personnel. (G 5.4.1.3)
	A clean water supply with hot and cold running water must be available in, or close to, the compounding area. (G 5.4.1.4)
	Work surfaces and furniture, as well as floor and wall surfaces must be designed to facilitate repeated cleaning. (G 5.4.1.5)
	Compounding areas must be maintained with the cleanliness and hygiene needed to ensure the quality and integrity of the final preparations (G 5.4.1.6)

5.4.2. Equipment for Non-sterile Compounding

Equipment, instruments and accessories	Must be appropriate for the type of preparations to be compounded
	Must not negatively impact the purity or quality of the preparation being compounded
	Must be well cleaned after each use
All equipment, instruments and accessories must be maintained to ensure proper performance (G 5.4.2.1)	Must be routinely inspected and calibrated, if applicable, at appropriate intervals as recommended by the manufacturer, and at least once a year if there are no such recommendations
	Equipment (i.e., fridges, balances, etc.) must meet any requirements established by the pharmacy regulatory authority
	Records of calibration dates for equipment and instruments must be maintained
All specialized equipment must be clean	Must be cleaned regularly, as recommended by the manufacturer (G 5.4.2.2)
	A log must be kept to record the cleaning (G 5.4.2.3)

6 PRODUCT AND PREPARATION REQUIREMENTS

Beyond-use date (BUD) and dating methods (see G6.1.1 for guidelines on assigning BUD)	Must be determined by regulated pharmacy personnel with adequate experience and broad scientific knowledge
	Must be assigned after consulting the manufacturer and literature on the stability, compatibility and degradation of ingredients
	Compounded preparations must be monitored for signs of instability and/or degradation
Master Formulation Record (see G 6.2 for requirements and template)	Must be developed for each non-sterile compound by regulated pharmacy personnel with adequate experience and broad scientific knowledge
	Must include all necessary information to prepare a non-sterile compound

	Must contain supporting rationale and references
	Must be kept in a format that is easily accessible to compounding personnel
Ingredients used for compounding (G 6.3)	Must be pure and of good quality(G 6.3.1)
	Purified Water or water of equivalent or superior quality must be used whenever the formula requires water as an ingredient (G 6.3.1)
	Must be sourced from recognized and reliable sources (G 6.3.2)
	The source of ingredients (including lot numbers, expiry dates, and date of receipt in the pharmacy) must be traceable. (G 6.3.3)
	Ingredients for compounding that have been recalled or withdrawn from the market for safety reasons must not be used (G 6.3.3)
	Current Safety Data Sheets must be readily accessible for all ingredients. (G6.3.4)
	Must be stored in conditions that preserve their purity and quality. (G 6.3.5)
Compounding Record (G 6.4)	Must be kept (paper-based or electronically) for each individual prescription, as well as for non-sterile preparations made in batches.
Conduct of Personnel (G 6.5)	Compounding personnel must behave in a professional manner, following all pertinent procedures on the Master Formulation Record
	Must perform good hand hygiene
	Must wear a clean lab coat, reserved for compounding
	Must wear powder free gloves
	Must use any other PPE or equipment indicated on the Master Formulation Record
	Must not store or consume food or drink, or use tobacco in the compounding area.
	Must take any other reasonable measures to prevent cross

	contamination and to protect themselves from chemical exposure
Verification (G 6.6)	Must be performed at each stage of the compounding process
	Final verification must take place prior to dispensing the preparation
Labelling and Packaging (G 6.7)	A policy for labelling and packaging must be established which is consistent with the applicable provincial/territorial regulatory requirements (6.7.1)
	The label and supplementary label must provide all information required for proper use of the compounded preparation by the patient or for safe administration by a third party (G 6.7.2)
	Packaging appropriate to maintain integrity of the compounded preparation must be used (G 6.7.3)
Storage (G 6.8)	A storage procedure must be established which is consistent with any requirements of the pharmacy regulatory authority, as applicable
	Active and inactive ingredients must be stored according to manufacturer's recommendations, and in a manner which prevents cross contamination (See G 6.8.1 for chart on recommended temperatures)
	Finished product must be stored according to the requirements outlined in the Master Formulation Record
Transportation and delivery	Policies for transportation and delivery must meet regulatory requirements and address any special precautions for non-sterile compounded products (G 6.9)
Recalls	Procedures for recall of products must include documentation to ensure traceability of all ingredients included in non-sterile compounded products (G 6.10)
Incidents and accidents	An event report must be completed for any incident or accident involving a compounded non-sterile compound (See G 6.11.1 for an example of an incident/accident reporting and follow up form)

7 QUALITY ASSURANCE

Quality Assurance Program (see G 7.6 for example components of a QA program)	Must be implemented to ensure the clear definition, application and verification of all activities affecting the quality of the final product, and the protection of personnel (G 7.1)
Equipment and Compounding areas (G 7.2)	Equipment must be certified at installation and regular intervals as recommended by the manufacturer (G 7.2.1)
	Temperature readings must be taken at regular intervals to ensure integrity of products stored in refrigerators, freezers or at room temperature (G 7.2.2)
Compounding personnel (G 7.3)	Must be trained, certified, and reassessed at regular intervals to maintain competency
Compounding procedures (G 7.4)	Compliance with compounding procedures must be monitored
Documentation (G 7.5)	Must be verified, signed and retained as per regulatory requirements
	Non-compliance with the QA program and corrective actions must be documented

8 LEVELS OF REQUIREMENTS

The requirements for non-sterile compounding are based on the complexity and risks associated with preparing the compound and handling the substances used to make the compound. The requirements have been categorized into three levels. A summary of requirements chart can be found in G 8.4. See sections 5, 6 and 7 above and G5, G6 and G7 for more detail

8.1 Level A

What is included	Requirements
Simple and moderate compounds as defined in USP 795[14]	Separate space designated for compounding

[14] Excludes reconstituting and mixing as per Health Canada, Health Products and Food Branch Inspectorate. *Policy on manufacturing and compounding drug products in Canada.*

8.2 Level B

What is included	Requirements
Complex compounds defined in USP 795	
	Separate well-ventilated room
	Larger workspace and appropriate equipment
	Environment conducive to little or no interruptions
	Greater protection from cross contamination
Complex and small quantities of ingredients / preparations which require ventilation	May require a ventilated containment device when certain powders, aromatic products or hazardous products are compounded

8.3 Level C

What is included	Requirements
Hazardous drugs which are classified by NIOSH[15] as Group 1	Separate room
Hazardous materials classified by WHMIS[16] as a health hazard, such as those very irritating to the respiratory tract, the skin and the mucous membrane	Well-ventilated with appropriate air exchange, negative pressure
NIOSH group 2 and 3 drugs where large quantities of APIs are used routinely	Appropriate containment device (C-PEC) for materials being compounded

9 REQUIREMENTS FOR HAZARDOUS PREPARATIONS

Risk Assessment for Hazardous materials (as per Section G 5)	Must be reviewed at least every 12 months

[15] National Institute for Occupational Safety and Health (NIOSH), NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2014. Available from : http://www.cdc.gov/niosh/docs/2014-138/
[16] WHMIS at http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/index-eng.php

9.1 Facilities for handling hazardous products (Level C)

Facilities	Must be constructed to minimize the risk of exposure to compounding personnel and other pharmacy staff
Compounding Room (G 9.1.1)	Must be ventilated through HEPA filtration, have appropriate air exchange, and have a negative pressure relative to surrounding rooms
	Must contain an eyewash station and any other emergency or safety equipment required
	Must be constructed with smooth impermeable surfaces to promote adequate cleaning and decontamination.
	The heating, ventilation and air conditioning system must be constructed to prevent contamination of the areas surrounding the compounding room, and ensure comfort of personnel wearing PPE. (G 9.1.2)
	Windows and openings must not lead directly outside or to a non-controlled area (G 9.1.3)
	There must be an appropriate area for unpacking hazardous products. A Containment Primary Engineering Control (C-PEC) must be available for unpacking hazardous products which appear to be damaged (G 9.1.4)
Hazardous Product Storage	Hazardous products must be stored in a room with appropriate ventilation. (G 9.1.5)
	Areas for storing and preparing hazardous products must be identified with appropriate signage (G 9.1.6)

9.2 Equipment for handling hazardous products

Equipment (9.2)	A Containment Primary Engineering Control (C-PEC) that provides appropriate personnel and environmental protection must be installed and maintained (G 9.2.1)
	All reusable equipment and devices must be adequately deactivated, decontaminated and cleaned (G 9.2.2)

	Personal Protective Equipment (PPE) approved for compounding of hazardous preparations must be worn during compounding activities (G 9.2.3) - chemotherapy gloves - disposable, impermeable gown - head, hair shoe and sleeve covers - respiratory protection - eye and face protection

9.3 Deactivating, Decontaminating and Cleaning in areas reserved for the compounding of hazardous non-sterile preparations

Cleaning of the premises and equipment	Compounding area, equipment and accessories must be meticulously cleaned (9.3).
	Cleaning must also eliminate chemical contamination by deactivating, decontaminating and cleaning the areas and equipment (G 9.3.1)
	Cleaning personnel must comply with hand hygiene and garbing procedure for handling hazardous products (G 9.3.2)
	The work surface of the Containment Primary Engineering Control (C-PEC) must be deactivated, decontaminated and cleaned before starting the compounding of a different compound (G 9.3.3)

9.4 Incident and accident management

Incidents and accidents	Policies and procedures must be developed and followed for cases of accidental exposure of personnel to hazardous products. (G 9.4.1)
	Personnel must be trained to prevent spills, and on appropriate procedures to clean up spills, including the use of a spill kit. (G 9.4.2)

	Must be documented and followed up to prevent recurrence. (G 9.4.3)

9.5 Hazardous waste management

Hazardous Waste (G 9.5)	Procedures must be in place for destruction and/or disposal of pharmaceutical waste in compliance with environmental protection legislation.
	All personnel involved in the management of hazardous product waste must receive appropriate training and have access to all necessary PPE and cleaning supplies

9.6 Verification of controlled rooms and the containment primary engineering control (CPEC)

Environmental Verification (G 9.6)	The compounding room must be examined and certified every 6 months and the Containment Primary Engineering Control (C-PEC) according to manufacturer's recommendations (and more often in case of new equipment installation, repairs or a contamination problem). (G 9.6.1)
	Manufacturer's certificates issued in the factory for all High Efficiency Particulate Air (HEPA) filters and Containment Primary Engineering Controls (C-PECs) shall be retained for the service life of the equipment. (G 9.6.2)
	An environmental verification program must be established to ensure safety standards (G 9.6.3)
	All completed documentation concerning components of hazardous product contamination testing of controlled rooms, and equipment must be filed and retained with other compounding records, as per provincial/territorial pharmacy authorities. (G 9.6.4)

Abbreviations and Glossary of Terms as well as the Bibliography can be found in the Guidance Document

Ontario College of Pharmacists
Putting patients first since 1871

COUNCIL BRIEFING NOTE
MEETING DATE: DECEMBER 2017

FOR DECISION	X	FOR INFORMATION

INITIATED BY: President Vaillancourt

TOPIC: Governance

ISSUE: Competency-based screening process for elected members of Council

BACKGROUND:

- The *Protecting Patients Act* includes amendments which will increase the authority of the Minister of Health and Long-Term Care to make regulations controlling all aspects of the structure and composition of College statutory committees.
- The Advisory Group for Regulatory Excellence (AGRE) is developing an Eligibility and Competency-Based Appointment Framework to inform the drafting of the regulations respecting appointment of individuals to statutory committees.
- The College of Nurses of Ontario is proceeding with implementing a revised governance structure which includes the concept of competency-based boards/councils.
- A competency based screening process for applications by members interested in serving as Non Council Committee Members on OCP statutory committees was initiated in 2017.

DISCUSISON:

- Building on the activity to date, the Executive Committee proposes that we take steps to introduce a competency screening process for members seeking election to College Council.
- A Task Force be struck to examine the legal and practical requirements of instituting such a screen within the parameters of the existing legislative/regulatory framework.
- To provide an objective perspective unencumbered by current aspirations and informed by reflective experience, the Task Force be comprised of past presidents who are no longer on Council.
- The Task Force will endeavor to deliver a proposed approach together with any required enabling by-laws to Council for approval in time for the 2018 council election process – target March 2018 Council meeting.

RECOMMENDATION: That Council strike a Task Force to study and make recommendations on introducing a competency screening process for candidates for election to College council.

Ontario College of Pharmacists
Putting patients first since 1871

COUNCIL BRIEFING NOTE
MEETING DATE: DECEMBER 2017

FOR DECISION	FOR INFORMATION	X

INITIATED BY: Nancy Lum-Wilson, CEO and Registrar

TOPIC: Report to December 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: I respectfully submit a report on the activities that have taken place since the September 2017 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. Attached for Council's information is an update of progress made on the various strategic directions since the September 2017 Council meeting.

Preparation has commenced for the spring 2018 Strategic Planning session and details are attached (see memorandum from the Vice President, appendix 9).

Ministry/Government Activities

This reporting period saw continued momentum in the number of meetings with various officials from multiple branches of the Ministry of Health and Long-Term Care. Together with senior team members, we shared information with the Ontario Public Drug Programs Division and the Health Workforce Planning and Regulatory Affairs Division, as well as Deputy Minister of Health on some of the initiatives we are working on. These meetings allow us to inform them of our work and explore alignment of our strategic priorities with those of the Ministry.

I also met with senior members from the Ministry of Labour to discuss Bill 148 (*Fair Workplaces, Better Jobs Act, 2017*) to gain some insight on the Ministry's plan and the potential impact this will have on the profession. The Ministry of Labour has asked the College to assist with consultations to provide a public safety perspective (please refer to update in the following section on Legislative Initiatives).

In late October, I attended a Health Professions Appeal and Review Board (HPARB) meeting with other stakeholders at which the Board's process regarding disclosure of file information to parties to a complaint review was shared. Stakeholders also received information on relevant cases arising from divisional court challenges and board statistics.

Legislative Initiatives

Protecting Patients Act 2017

This legislation, formerly known as Bill 87, was introduced by the Ontario government to further protect patients by strengthening and reinforcing Ontario's zero tolerance policy on sexual abuse of patients by any regulated health professional. The Act includes, among others, a schedule to amend the *Regulated Health Professions Act, 1991* (RHPA).

As previously reported, the College has been fully engaged with all three political parties leading up to the passage of the *Protecting Patients Act*, participating within the Legislative Committee with written and oral communications to discuss related issues that would directly impact us and our ability to protect patients.

At the end of September, following communication by the Ministry for a need to modernize the *RHPA,* College staff were invited to participate in a dialogue through the McMaster Health Forum on Modernizing the Oversight of the Health Workforce in Ontario. A summary of that event can be found on page 6 of my report under “McMaster Forum”.

Employment Standards Act consultation

The College has been asked to provide the Ministry of Labour with a formal written submission on whether the profession’s exemptions from the *Employment Standards Act, 2000* (ESA) should be maintained. This is part of a broader exercise being undertaken by the Ontario government for workers in industries that currently have exemptions, special rules or exclusions from the ESA. Taking an approach that aligns with its mandate to serve and protect the public interest, the College is undertaking a consultation to inform this submission. The consultation will close on December 15 and the report will be submitted to the Ministry of Labour by January 31, 2018.

Federal/Provincial Initiatives

Opioid Crisis

The opioid crisis continues to be of significant concern in the province. Building on efforts already being made by government and health care professionals, the Minister of Health and Long-Term Care (MOHTLC), Dr. Eric Hoskins and Premier Kathleen Wynne announced several more initiatives over the last couple of months in an effort to combat this public health crisis.

As previously reported, the Minister announced an additional $222 million over three years to support the following programs:

- Adding more front-line harm-reduction workers across the province
- Expanding the supply of naloxone, including more access for at-risk individuals by distributing the overdose reversal drug through emergency departments, and exploring more opportunities to make nasal spray naloxone available to people in Ontario
- Expanding Rapid Access Addiction Medicine Clinics across the province, which provide people with immediate and ongoing addiction treatment, counselling and other mental health supports and boosting access to community-based withdrawal management services and addictions programs
- Expanding proven harm-reduction services, such as needle exchange programs and supervised injection site
- Partnering with the Centre for Addiction and Mental Health to expand addictions treatment and care provided in family health teams across the province

- Collaborating with the Ontario College of Family Physicians to mentor health care providers on appropriate prescribing of opioids for pain management and treating patients with addiction
- Working with Indigenous communities to enhance culturally appropriate mental health and wellness programs and funding for new or expanded Indigenous Mental Health and Addictions Treatment and Healing Centres
- Developing addictions treatment and services targeted to the unique needs of youth
- Improving data collection and monitoring to support early warning activities.

On September 7, 2017, the Premier and Minister Hoskins delivered a joint statement, indicating that the Province would accelerate the funding for harm reduction. On October 4, 2017, the Minister announced the establishment of an Opioid Emergency Task Force that will include front-line workers in harm reduction, addiction medicine, and community-based mental health and addiction services. The Task Force will also advise the government on a targeted public education campaign to raise awareness about the risks associated with opioid use. During the announcement, Minister Hoskins referenced the government's work with pharmacists, to include an insert about the possible health risks of opioids that will be included with a patient's opioid prescriptions.

Work continues on the College's own comprehensive Opioid Strategy which was approved by Council in September 2017. Please see the Strategic Priorities progress report for an update on activities.

Bill 160, the *Strengthening Quality and Accountability for Patients Act, 2017*
Following a summer-long consultation on whether pharmaceutical companies should disclose payments made to physicians and other health care professionals, on September 27, 2017, Minister Hoskins introduced omnibus legislation to strengthen transparency and accountability for patients. Bill 160, the *Strengthening Quality and Accountability for Patients Act, 2017*, which, if passed, would make it mandatory for the medical industry, including pharmaceutical and medical device manufacturers, to disclose payments made to health care professionals and organizations, as well as other recipients. The NDP has introduced a possible amendment to Bill 160 that, if passed, will give the Executive Officer the ability to require group insurance plans and manufacturers to maintain patient choice in provider. The proposed amendment will require all party approval to pass.

Additionally, Bill 160 will introduce the *Oversight of Health Facilities and Devices Act, 2017* to enable a new regime for Community Health Facilities. Under this Act, the *Independent Health Facilities Act, Private Hospitals Act* and *Healing Arts Radiation Protection Act* will be repealed. The Act defines the role of an Executive Officer and sets out provisions for inspection bodies to carry out functions related to the community health facilities.

The College provided a submission to the Standing Committee that reminds government to follow through with College oversight of drug distribution in Long Term Care Homes and other institutions.

Legalization of Cannabis
In April 2017, the federal government introduced the *Cannabis Act,* which will legalize and regulate cannabis across Canada by July 2018. The federal plan calls on the provinces and territories to establish a framework to regulate the distribution, sale and consumption of cannabis, among other matters. In early September, the government introduced Ontario's plans to distribute recreational cannabis. There is no intention, at this time, to change the current

process for accessing cannabis for medical purposes.

At the September 2017 meeting, Council agreed to establish a task force to review and make recommendations on the role of pharmacy related to cannabis for medical purposes. The Task Force has been established and the first meeting is scheduled for December 12, 2017.

Scope of Practice

On September 20, 2017, the Ministry of Health announced that it was taking steps to expand the scopes of practice of several regulated health care professionals. The province will be moving forward on assessing requests for the expansion of specific roles and responsibilities of chiropractors, dietitians, midwives, nurses (including nurse practitioners, registered nurses, and registered practical nurses), pharmacists, physiotherapists, as well as other health care providers.

The government's goal in expanding scope of practice is to improve Ontarians' access to health care services, particularly in rural and remote areas. As reported earlier, I continue to remain fully engaged with the Ministry and Minister's Office in discussing the scope and standards of pharmacy practice in Ontario to ensure the changes support our College's mandate of public protection.

Engagement with LHINs

The College is developing opportunities to work with the Local Health Integration Networks (LHINs), in recognition that collaboration with the broader health system is required to help achieve the strategic priorities of the Council (implement core programs, optimize practice within scope, and support inter- and intra-professional collaboration). On November 2, 2017, the College launched a new partnership with the North East LHIN that will develop a regional pharmacy strategy for rural hospitals with a goal to bring the 16 hospitals that compound sterile preparations up to standard, with a strong focus on quality outcomes and performance. In addition, the College is also exploring opportunities to work with the Toronto Central LHIN to identify best practice models that directly link community pharmacy with primary care as well as address transitions of care. It is expected that these models will involve inter-professional collaboration with the primary care sector and better linkages to hospital, optimizing pharmacy practice within scope and furthering the College mandate to serve and protect the public interest.

Medication Errors

On October 26, 2017, the College announced its selection of Pharmapod Ltd to implement the medication error reporting system. The goal of identifying 100 pharmacies for the first phase of implementation has been achieved, and training for these pharmacies will begin in January 2018. Full implementation for all Ontario pharmacies is anticipated before the end of 2018.

In addition to providing the medication safety reporting platform, Pharmapod will assume the responsibility of providing training and continuous quality improvement processes and tools for Ontario pharmacies, and will analyze provincial medication incident data and provide reports to individual pharmacies. The data received by the College will help identify and monitor trends for shared learnings and improved quality (see attached memorandum for a more detailed progress update).

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.

The *Protecting Patients Act, 2017* (*PPA*) continues to be discussed at this table. The Federation established a PPA Implementation Working Group to facilitate information-sharing and discussion among member Colleges.

The FHRCO Board met on October 30th and discussed matters of mutual concern among the member colleges. Among these was an update on the Public Engagement Project and, a presentation by the AGRE (Advisory Group for Regulatory Excellence) colleges regarding governance, and in particular, the Eligibility and Competency-Based Committee Appointment Framework which addresses ideas for the composition of regulatory Colleges' statutory committees. The Framework is based on AGRE's governance project, reflects government's priorities, responds to changes set out in the *Protecting Patients Act, 2017*, and anticipates the Minister's regulations and future direction.

Other Stakeholder Meetings

Ontario Pharmacists Association (OPA)

In November, the Executive Committee held a conjoint meeting with the OPA to share information on issues of mutual concern and explore opportunities for collaboration to improve patient outcomes.

National Association of Pharmacy Regulatory Authorities (NAPRA)

During this reporting period, I had the opportunity, through the Council of Pharmacy Registrars, (CPRC), to attend meetings with the Office of Controlled Substances, Veterinary Drugs Directorate and Therapeutics Products Directorate.

The CPRC and NAPRA also held their last biennial meetings under the former governance model in November. The transition to the new governance model took effect and the new Board was constituted. CPRC will no longer function as a separate committee. I will serve as Vice-Chair of the new Board over the next year.

At this final CPRC meeting, I also brought forward the need to establish a common data set for medication incident reporting across Canada. NAPRA will strike a working group, which will be co-chaired by Ontario and New Brunswick, to move forward on this initiative. PEI and Quebec continue to work on the establishment of a medication safety program for their respective provinces. There was significant discussion across the country around the challenges in shared accountability for patient safety and outcomes between pharmacy managers/owners and front-line pharmacists. Please see the NAPRA report from the ON Council representative for details regarding the NAPRA meeting.

NAPRA's Annual Report for 2016-2017 highlights the work done by the organization over the past year.

Health critic meetings

Along with our ongoing discussions and dialogue with the Ministry of Health and Long-Term Care and Minister's Office, over the past several weeks, our Communications Manager, Todd Leach, and I have held meetings with provincial health critics, Ms. France Gélinas, MPP Nickel Belt (NDP) and Mr. Jeff Yurek, MPP, Elgin-Middlesex-London (PC). The purpose of these discussions was aimed at establishing important relationships and to provide updates on key College initiatives and other priorities that are advancing our mandate to serve and protect the public interest. The discussions were very positive and have set the stage for future engagement and communication opportunities.

Canadian Foundation for Pharmacy (CFP) – Pharmacy Forum
I was invited by the CFP to participate in a Canadian panel to discuss, among other issues, value based pharmacy. I gave a presentation on indicators and use of evidence to drive better patient outcomes using system outcomes that focus on pharmacy.

Canadian Society for Hospital Pharmacists – Council presentation
I recently presented to the governing body of the Ontario Branch of the Canadian Society for Hospital Pharmacists regarding hospital assessments, scope of practice and College priorities. The meeting provided the opportunity to engage with and listen to hospital pharmacy stakeholders as I also reinforced the College's patients-first mandate and our drive toward advancing system-aligned quality outcomes and safe pharmacy care for all.

Miscellaneous Items

McMaster Forum
A Stakeholder Dialogue to examine the challenge of Modernizing the Oversight of the Health Workforce in Ontario was convened by the Ministry of Health and Long-Term Care, using the McMaster University Health Forum. The question of how the health system can best respond to the evolving needs of Ontarians (for example an aging population and increasing prevalence of multi-morbidity) along with emerging technology and practices is paramount. Participants included regulators, professional associations, and representation from public health, LHIN's, community care access and community support. Informed by an evidence brief, which included the views of a citizen panel, the framework within which regulatory colleges operate and are held accountable for optimal patient care was considered. Consensus among participants was that a combination of three approaches (risk of harm, the use of competencies, and a performance measurement and management system) is preferable and will be proposed to the Minister of Health and Long-Term Care. The importance of change management, transparency and strategic communication was recognized in the context of continuous measureable improvement. A copy of the evidence brief as well as a consultation document from the UK on the same issue is appended to this briefing note.

Cancer Care Ontario (CCO)
Together with Susan James, Director of Quality, I initiated meetings with CCO for the purpose of maintaining a collaborative relationship with this key stakeholder organization and to discuss common issues and apprise them of the direction in which the College is heading.

Communications Plan 2018
To help strengthen public trust and confidence in our evolving mandate as a regulator in a time of significant change within the health and regulatory environments in the province, the College has developed a communications plan for 2018 that makes public, patient and stakeholder facing communication a top priority. The plan includes strategies, objectives and activities aimed at positioning the college as a progressive, outcomes-driven regulator focused on advancing the interests of patients first and providing value within an integrated health care system. An overview of the plan has been shared with the Patient Relations Committee, which will play an increasingly important role in advising on opportunities to build awareness of College programs and priorities among the general public and promote quality practice among registrants.

Fall Regional Meetings
The College hosted a series of regional meetings during the fall - in Toronto (October 10), Ottawa (October 12), London (October 26) and Sudbury (November 1). See attached for a summary of the meetings and evaluations received to date.

Citizen Advisory Group

This past October, the College participated in its first collaborative Citizen Advisory Group (CAG) session with other FHRCO members. The CAG was introduced earlier this year as an important mechanism for participating colleges to engage with members of the public on matters of common interest. The October session focused on Definition of a Patient; a summary of the session was shared with the Patient Relations Committee. This is a timely topic as it relates specifically to the *Protecting Patients Act 2017*. Draft regulations around the definitions and minimum criteria regulators will be required to use to help determine the existence of a provider-patient relationship when investigating sexual abuse allegations are expected to be released imminently. Feedback from the inaugural CAG session has been positive and the College plans to continue to explore opportunities to engage the group with its regulatory partners as part of a broader public and patient communication plan for 2018.

Public Input on the Website and Public Register

The College will be hosting a series of facilitated focus groups with members of the public later this fall to collect feedback on their experience with the public register since its last major redesign more than 18 months ago. The engagement sessions will also help the College gain insight into the extent to which the information on the register satisfies public expectations as well as identify other opportunities to improve overall public website content, design and navigation as the College begins work towards a major redevelopment of the site in 2018.

Ontario College of Pharmacists
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Strategic Priorities 2015 - 2018

Progress Update – December 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

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

Strategic Priority #1: CORE PROGRAMS – FULFILLMENT OF MANDATE - Processes meet or exceed societal expectations. *(Members, Premises)*						
Values – Transparency, Accountability, Excellence						
Outcomes/KPI	**Activity**	**Strategic Initiatives Focus**			**Last Quarter Accomplishments (June – August 2017)**	**Noteworthy Accomplishments this Quarter (September - November 2017)**
		PF	**EC**	**CQI**		

Fair and objective assessment framework.	Refine assessment tools and activities.
	Premises: Current authority and others i.e. long-term care, family health teams.
	Members: Pharmacists - at entry, in practice, (site based and standardized).
	Pharm techs – as above.
		High	Med	High	• Performance indicators for the pharmacy technician practice assessment have been identified.
					• Scheduling of Practice Assessments has met target of 60% for this period; ratio of member to pharmacy assessments reached 1.3 to 1 for scheduled assessments.
					• CPA consistency with Ideal Assessment model based on measures document reached 90%.
					• Feedback survey for complaints introduced. 26 responses received (2015/2016 council year), representing an 18% response rate. 58% of complainants reported being very or somewhat satisfied while 35% of complainants reported being very or somewhat dissatisfied with the process.
					• On-line complaint intake form launched to improve efficiency.
					• Implementation plan for I&R related changes stemming from the *Protecting Patients Act* developed.
						• Draft behavioural based interview tool for pharmacy technicians (community and hospital) complete.
						• Launched North East LHIN strategy to develop a regional model for achievement of hospitals standards, including NAPRA model standards for sterile compounding.
						• Exceeded 95% target for scheduling of Practice Assessments. As of November all Community Practice Advisors have scheduled their Q1 2018 assessments.
						• Achieved 100% CPA consistency with Ideal Assessment model.
						• 38% response rate (670 of 1751) to Community Practice Assessment Feedback Survey and 34% response rate (68 of 200 assessments) to Hospital Assessment Feedback Survey. Analysis of feedback in process.
						• 99% of community respondents and 93% of hospital respondents were satisfied or very satisfied with the assessment process.
						• Article on Beyond Use Dating (BUD) published in Fall Pharmacy Connection to support members' compliance with NAPRA model standards for sterile compounding.
						• Report on On-line Complaint Form (OCF) launched August, 2017. From Q3 to Q4, the % of online intakes increased from 15% (17/110) to 38% (43/114); the average number of days to enter the intake decreased from 21 days to 11 days, an improvement of almost 50%.
						• Implementation of the Protecting Patients Act
						  • Process for withdrawal of complaints implemented and mapped
						  o Registrar has approved one withdrawal request
						  • Process for Interim Orders implemented and mapped
						  o 2 Interim orders have been made by ICRC with 2 more in process.
						  • First draft of process map for Funding for Therapy and Counselling completed.
						• Business Process Re Legal Engagement in I&R commenced; Stakeholder survey finalized.

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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 (June – August 2017)**	**Noteworthy Accomplishments this Quarter (September - November 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	• Discipline Committee implemented standardized tools for 1) deliberation, 2) credibility and 3) penalty orders for allegations related to sexual misconduct. • Standardized tools and best practices for conducting investigations into allegations of sexual abuse introduced relating to 1) interviewing vulnerable witnesses, 2) investigation plans, and 3) completing a witness statement. • Incorporated a standardized harm assessment rating in the ICRC's deliberations and dispositions. • Standardized template for penalty orders provided for use by college prosecutors. • Secured Policy Manager to add capacity/expertise.	• Discussions with Health Quality Ontario, academic institutions, and insurance providers prompted development of an initial menu of pharmacy indicators to support informed decisions and track outcomes. • Implemented Zone Approach to email management as part of risk management strategy. • Signed the data sharing agreement with MOHLTC – Data Maintenance Unit to support data integrity on transfer of data with the Narcotic Monitoring System.
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	• Standardized criteria for selection of coaches, assessors and mentors developed. Resource catalogue for remediation based on identified gaps now available to committee.	• Standardized criteria for selection of coaches, assessors and mentors applied.

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

Strategic Priority #2: OPTIMIZE PRACTICE WITHIN SCOPE – Patients receive quality health care services from pharmacy professionals.						
Values – Transparency, Accountability, Excellence						
Outcomes/KPI	**Activity**	**Strategic Initiatives Focus**			**Last Quarter Accomplishments (June – August 2017)**	**Noteworthy Accomplishments this Quarter (September - November 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	• Conflict of Interest guidance and communication:
					  • YTD website pageviews: 29,830
					  • impressions (reach) of Pharmacy Connection (including a spread poster insert): 24,580
					  • 10 stories have been featured in bi-weekly eConnect email newsletter, reaching approximately 26,000
					  • social media channels in this quarter, with a three-month reach of 187,000 Twitter impressions and 692,000 Facebook impressions
					  • posters distributed to 200 professionals at the OPA conference
					• Completed 1910 pharmacist member assessments as of August 18, 2017 (61% of 2017 target of 3150).
					• 2 presentations delivered to hospital pharmacists regarding professional expectations.
					• 1 presentation delivered at OPA conference.
						• Launched North East LHIN strategy to develop a regional model for achievement of hospitals standards, including NAPRA model standards for sterile compounding.
						• Completed 85% of 2017 target pharmacist member assessments as of November 30 (2559 of 3000); project 90% for 2017 – below target due to changes in assessment process, practice site issues and a staff shortage.
						• Code of Ethics and education tools/resource materials made available to over 700 regional meeting attendees.
						• Education resources re opioids made available on website including:
						  o Opioid practice tool on website as a hub for resources
						  o Guidance on dispensing of Naloxone
						  o Pharmacy Connection articles on interprofessional collaboration of prescribers and dispensers, and opioid and narcotic security.

Pharmacy Technicians consistently practising to established expectations including Standards of Practice and Code of Ethics.	Develop and communicate Code of Ethics. Provide guidance and education on expectations of Standards of Practice and Code of Ethics. Provide guidance and education on specialty standards e.g. sterile compounding. Use OCP assessments and professional development to remediate/coach.	Med	High	Med	• Draft QA regulations finalized for September 2017 Council consideration. • Conflict of interest guidance and communication, as above. • 2 presentations delivered to hospital pharmacy technicians regarding professional expectations.	• Provided presentation to 240 pharmacy technicians at GTA Pharmacy Technician Conference early November on professional responsibilities and expectations. • Scope of practice strategy included in regional meeting topic line up; pharmacy technicians represented over a quarter of total attendees. • Scope of Practice workplan completed for 2018 initiatives. • Education resources re opioids available as noted above.

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

Strategic Priority #2: OPTIMIZE PRACTICE WITHIN SCOPE – Patients receive quality health care services from pharmacy professionals.						
Values – Transparency, Accountability, Excellence						
Outcomes/KPI	**Activity**	**Strategic Initiatives Focus**			**Last Quarter Accomplishments (June – August 2017)**	**Noteworthy Accomplishments this Quarter (September - November 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	• Completed 1631 pharmacy assessments as of August 18, 2017 (72% of 2017 target of 2250). • Completed 116 hospital pharmacy assessments as of August 18, 2017 (70 % of 2017 target of 165).	• Completed 97% of 2017 target for pharmacy assessments as of November 17 (2184 of 2250). • Completed 96% of 2017 target of hospital pharmacy assessments as of November 21 (151 of 159). • Updates on practice assessments and focus on optimization of practice included in regional meetings and in Pharmacy Connection in Fall 2017. • Community Practice Advisors increased focus on assessment and education re narcotic reconciliation in all 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	• Digital Health Drug Repository data connected to 2 provincial clinical viewers (Clinical Connect and Connecting Ontario) and began to onboard community pharmacies. • Engagement with Canada Health Infoway at launch of PrescribeIT electronic prescription transmission so that NAPRA Pharmacy Practice Management Standards are strongly considered for incorporation. • Established relationship with Health Quality Ontario. Secured a commitment to cooperate on data collection and establishment of indicators for pharmacy.	• Secured a vendor (Pharmapod) for the College's new Medication Safety program. Vendor offers technology solution that will support effective implementation of a provincial program. • Communication strategy for launch of Pharmacy 5in5 completed. Roll out scheduled for early 2018.

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 (June – August 2017)**	**Noteworthy Accomplishments this Quarter (September - November 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	• Scope of Practice Strategy communicated to stakeholders in Pharmacy Connection - workplan established. • Workplan established for Opioid Strategy, commitment to existing operational initiatives that support the strategy.	• Hosted 4 regional meetings in communities throughout the province, attracting more than 700 attendees and over 1,100 registrants. • Regional meeting topics included key initiatives such as the Opioid Strategy, Medication Safety, and Protecting Patients Act.
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	• Met with the coordinator of the Extension of Community Healthcare Outcome Program (ECHO); confirmed that pharmacists' participation is welcomed and encouraged. • OCP facilitated access to links to ECHO's chronic pain opiates program through OCP's website and practice tools. • The program now included in community practice assessors' toolkits.	• Task Force established to inform development of a cannabis strategy that reflects the changing landscape of Cannabis in Ontario. • Completed prioritization and planning of short and long term initiatives under opioid strategy including focus on pharmacy role in the health care team. Opioid Strategy communication plan implemented. Focus on Opioids in November issue of Pharmacy Connection. • Opioid Working Group recruitment underway. First meeting to take place in February 2018.

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Memo

TO:	**Nancy Lum-Wilson, CEO and Registrar**
DATE:	**November 16, 2017**
CC:	
FROM:	**Margo Orchard, Manager Strategic Policy, Planning and Analytics**
RE:	**Status update on Continuous Quality Assurance (CQA) for medication safety program**

COMPLETED WORK:

- In August 2017 the College prepared and released a request for proposal (RFP) to identify a vendor to manage a medication incident reporting platform, perform data analysis and reporting, and provide training and technical support related to the use of the reporting platform.
- The selection of vendor followed a formal transparent competitive RFP process in keeping with standard procurement practices. A total of five proponents submitted proposals and three were invited to present to a seven-member evaluation team consisting of College staff and external experts. The evaluation team's decision to move forward with the preferred proponent was unanimous. The College announced its selection of Pharmapod Ltd as the successful vendor on October, 26, 2017.
- Pharmapod's alliance with the Canadian Pharmacists Association (CPhA) will support successful buy-in and implementation among community pharmacies.
- The Pharmapod platform is a pioneering cloud-based solution designed by community pharmacists for community pharmacists.
- The College has engaged in a number of in-depth scoping sessions with Pharmapod to confirm project governance, infrastructure and integration, and reporting platform details such as data fields, reporting requirements and continuous quality improvement tools and resources.
- Planning for "Phase 1" implementation is well underway:
    - Over 100 pharmacies have been recruited, covering diverse practice environments across Ontario.
    - In-person training sessions will occur in January 2018.
    - All 113 sites are expected to be implementing the medication reporting system by the end of January 2018.
    - Practice advisors will also undergo comprehensive training in February 2018 to ensure they are prepared to support pharmacies and pharmacy professionals in meeting the CQA Program requirements.
    - Feedback from the Phase 1 participants will inform the design and implementation of the final program.
    - In addition, Todd Boyle (St. Francis Xavier University), the Canada Research Chair in Quality Assurance in Community Pharmacy, will evaluate Phase 1 implementation.
- Discussions have also begun at the national level to explore the identification of standardized data fields that would support a national medication incident database.

NEXT STEPS:

- The first set of anonymous reports is expected by May 2018.
- A detailed evaluation plan for full roll-out of the CQA Program will be finalized by September 2018, with program roll-out expected to begin in December 2018.

Ontario College of Pharmacists
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Memo

Date: **November 20, 2017**

To: **Executive Committee**

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

Re: **National Association of Pharmacy Regulatory Authorities (NAPRA) Meeting Update – November 2017**

The November 2017 NAPRA Board of Directors meeting occurred in Winnipeg, November 8th & 9th, 2017. This was to be the last series of meetings under the current governance model, and during a special meeting of the Board on November 9th, the directors voted that the current governance model would cease to exist, and the new NAPRA Board of Directors and governance model would commence immediately thereafter. Thus, this is the last report from an OCP appointed member, and the current Ontario representative on NAPRA is now the OCP Registrar, Nancy Lum-Wilson.

Of particular note, following much discussion, the Board passed a motion to approve the draft model standards of practice for non-sterile compounding. Board members stated the profession should welcome the new standards from a patient safety viewpoint.

NAPRA is currently in discussions with Health Canada on the future of National Drug Scheduling and how it relates to the self-care framework, including non-prescription drugs, natural health products and self-care products, being developed by Health Canada. There is an openness to explore other options for drug scheduling, different from the way it is currently done.

To address cost of living increases, the Board approved the motion to accept a 2.5% increase to member fees for 2018. A similar increase for the IPG Gateway Program registration fee, from $325 to $330, was also approved, but other program fees, including the Self-Assessment and Readiness tools, remain the same.

NAPRA continues to be invited to various tables. Discussion on the role, need, and optics of NAPRA sitting and participating at some of those tables was discussed and debated. For example, while there was general support for NAPRA to have observer status at the Pharmacist Labour Market Working Group, some members felt it was inappropriate for an organization of regulators to participate in labour market discussions. As such, NAPRA will excuse itself from participating in this particular project.

I would like to thank OCP Council for the opportunity to serve and represent OCP on the NAPRA Board of Directors for almost two years. It has been a privilege to sit at this national table on your behalf.

Respectfully submitted,

Mark F. Scanlon, R.Ph.
OCP Representative on NAPRA

Evidence Brief

Modernizing the Oversight of the Health Workforce in Ontario

21 September 2017

McMaster University | McMaster HEALTH FORUM

EVIDENCE >> INSIGHT >> ACTION

Evidence Brief:
Modernizing the Oversight of the Health Workforce in Ontario

21 September 2017

McMaster Health Forum

For concerned citizens and influential thinkers and doers, the McMaster Health Forum strives to be a leading hub for improving health outcomes through collective problem solving. Operating at regional/provincial levels and at national levels, the Forum harnesses information, convenes stakeholders, and prepares action-oriented leaders to meet pressing health issues creatively. The Forum acts as an agent of change by empowering stakeholders to set agendas, take well-considered actions, and communicate the rationale for actions effectively.

Authors

Kerry Waddell, M.Sc., Co-lead Evidence Synthesis, McMaster Health Forum

Kaelan A Moat, PhD, Managing Director, McMaster Health Forum

John N. Lavis, MD, PhD, Director, McMaster Health Forum, and Professor, McMaster University

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Conflict of interest

The authors declare that they have no professional or commercial interests relevant to the evidence brief. The funders played no role in the identification, selection, assessment, synthesis or presentation of the research evidence profiled in the evidence brief.

Merit review

The evidence brief was reviewed by a small number of policymakers, stakeholders and researchers in order to ensure its scientific rigour and system relevance.

Acknowledgments

The authors wish to thank Fanny Cheng and Rex Park for their assistance with reviewing the research evidence. We are grateful to Steering Committee members and merit reviewers for providing feedback on previous drafts of the brief. The views expressed in the evidence brief should not be taken to represent the views of these individuals. We are especially grateful to David Lamb, Camille Orridge and Meredith Vanstone for their insightful comments and suggestions.

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KEY MESSAGES

What's the problem?

- Ontario's health-system leaders are attempting to position the health system to respond to the evolving needs of Ontarians (e.g., an aging population and increasing prevalence of multimorbidity) and an array of new health-system challenges (e.g., rapidly evolving health technologies and growing anti-microbial resistance). To do this, a number of large-scale reforms have been introduced over the last decade and a half, however, the number and scale of these reforms has not been matched by commensurate efforts to position Ontario's health workforce to respond to the evolving needs of Ontarians and emerging health-system challenges. The result has been an approach to health-workforce oversight which many may argue no longer serves the health system. This problem can be conceptualized in relation to six distinct features of the approach to workforce oversight currently in place in Ontario:
  - the oversight mechanisms in place have not kept pace with the changing health system;
  - the current oversight framework is focused on regulating individual categories of health workers, rather than groupings of them, and captures many but not all health workers;
  - the oversight framework has a different focus than the framework used in the education and training of health workers;
  - the financing and funding of oversight bodies are not explicitly designed to optimize public-protection efforts;
  - it is difficult to find information on how the health workforce and its oversight bodies are performing; and
  - citizens are not consistently engaged in meaningful ways in oversight activities.

What do we know (from systematic reviews) about three viable options to address the problem?

- Element 1 – Use a risk-of-harm approach to health-workforce oversight
  - One scoping review and two primary studies were identified that related to the element, albeit at a very general level. The evidence focused largely on implementation considerations, including the need to collectively define risk, establish the amount of risk that an organization is prepared to accept, and put in place a robust and efficient surveillance system.
- Element 2 – Use competencies as the focus of oversight
  - One systematic review and four primary studies were identified that relate to this element. The systematic review highlighted the lack of consensus on nursing competencies in Canada, while two studies assessed the use of competencies in training and in recruiting professionals, and found significant improvements in non-clinical skills and the identification of stronger candidates, respectively.
- Element 3 – Employ a performance-measurement and -management system for the health workforce and its oversight bodies
  - One systematic review and three primary studies were identified that relate to this element. The systematic review suggests that successful mandatory reporting schemes for health workers require a high bar for reporting impairment, a fair and timely response, and the availability of preventive assistance. One primary study highlighted that an inclusive approach to developing performance measures improved the commitment of stakeholders to implementing and reporting on the measures.

What implementation considerations need to be kept in mind?

- Recent discussions in the province around the need to update workforce-oversight mechanisms, combined with the upcoming provincial election, present a window of opportunity for modernizing the oversight of the health workforce in Ontario. However, pursuing element 1 in particular may encounter a number of barriers, including the challenge of gaining consensus in government and, to the extent that the government feels it is needed, among workforce oversight bodies (and possibly among associations of health workers).

REPORT

As with other jurisdictions across the country and around the world, Ontario's health-system leaders are attempting to position the health system to respond to the evolving needs of Ontarians (e.g., an aging population and increasing prevalence of multimorbidity) and an array of new health-system challenges (e.g., rapidly evolving health technologies and growing anti-microbial resistance). At the same time, these leaders are increasingly committed to achieving the 'triple aim' of improving the patient experience, improving population health, and keeping per capita costs manageable.(1)

Some of the larger reforms that have been introduced over the last decade and a half to achieve these aims include:

- strengthening governance, financial and delivery arrangements by:
  - delegating authority to 14 Local Health Integration Networks (LHINs) for planning, funding and integrating care, and more recently for functions previously handled by Community Care Access Centres;
  - using funding models – Health-Based Allocation Model and Quality-Based Procedures – to ensure more resources get to communities with greater needs and to improve care for priority health conditions;
  - enhancing health-system performance measurement and reporting and supporting continuous quality improvement through Health Quality Ontario (through the *Commitment to the Future of Medicare Act, 2004*), and making it mandatory for many types of health organizations to submit annual quality-improvement plans to Health Quality Ontario (through the *Excellent Care for All Act, 2010*);
- improving care both within and across key sectors, such as:
  - in primary care by introducing interprofessional teams (i.e., Family Health Teams), adjusting physician remuneration (from fee-for-service to blended models), and expanding the role of nurses working in team-based settings (e.g., Nurse Practitioner-led Clinics) and of pharmacists working in community settings (e.g., as part of Family Health Teams);
  - across home care, primary care and specialty care by introducing Health Links to support

Box 1: Background to the evidence brief

This evidence brief mobilizes both global and local research evidence about a problem, three elements of a potentially comprehensive approach to address the problem, and key implementation considerations. Whenever possible, the evidence brief summarizes research evidence drawn from systematic reviews of the research literature and occasionally from single research studies. A systematic review is a summary of studies addressing a clearly formulated question that uses systematic and explicit methods to identify, select and appraise research studies, and to synthesize data from the included studies. The evidence brief does not contain recommendations, which would have required the authors of the brief to make judgments based on their personal values and preferences, and which could pre-empt important deliberations about whose values and preferences matter in making such judgments.

The preparation of the evidence brief involved five steps:

1) convening a Steering Committee comprised of representatives from the partner organization, key stakeholder groups, and the McMaster Health Forum;
2) developing and refining the terms of reference for an evidence brief, particularly the framing of the problem and three elements of a potentially comprehensive approach to address it, in consultation with the Steering Committee and a number of key informants, and with the aid of several conceptual frameworks that organize thinking about ways to approach the issue;
3) identifying, selecting, appraising and synthesizing relevant research evidence about the problem, options and implementation considerations;
4) drafting the evidence brief in such a way as to present concisely and in accessible language the global and local research evidence;
5) incorporating input from three citizen panels; and
6) finalizing the evidence brief based on the input of several merit reviewers.

The evidence brief was prepared to inform a stakeholder dialogue at which research evidence is one of many considerations. Participants' views and experiences and the tacit knowledge they bring to the issues at hand are also important inputs to the dialogue. One goal of the stakeholder dialogue is to spark insights – insights that can only come about when all of those who will be involved in or affected by future decisions about the issue can work through it together. A second goal of the stakeholder dialogue is to generate action by those who participate in the dialogue, and by those who review the dialogue summary and the video interviews with dialogue participants.

frequent service users;
- across home care, primary care and public health by introducing sub-LHIN regions to support local planning and coordination; and
- improving care for select conditions, treatments and populations, such as:
  - centralizing access to and putting in place a robust performance-measurement and -management system for cancer care, and beginning to do the same for mental health and addictions care (initially for children and youth);
  - expanding access to prescription drugs, most recently for young Ontarians; and
  - creating supports specific to the needs of Indigenous peoples.

The number and scale of these reforms has not been matched by commensurate efforts to position Ontario's health workforce to respond nimbly to the evolving needs of Ontarians and emerging health-system challenges, or to work collaboratively to achieve the 'triple aim.' As a first step in this direction, the Ontario Ministry of Health and Long-Term Care asked the McMaster Health Forum in 2016 to prepare an evidence brief (2) and convene a stakeholder dialogue (3) about planning for the future health workforce. One of the themes that emerged from the deliberations in September 2016 was the need to review how the health workforce is regulated in Ontario. As a second step towards better positioning Ontario's health workforce, the same ministry asked the McMaster Health Forum to broaden this theme and examine how to modernize the oversight of the health workforce. This includes both how to update the current regulatory framework to meet health-system needs as well as to consider whether changes could be made to the current mechanisms in place to oversee the health workforce and the agencies and organizations involved. This evidence brief is part of our response.

There are at least four reasons why many health-system leaders believe that the time has come to seriously consider modernization. First, the primary legislation for the oversight of the health workforce in Ontario – the *Regulated Health Professions Act, 1991* (RHPA) – has not been reviewed to ensure it has evolved alongside the health system in the face of: 1) changing public expectations (which are in part due to greater access to health information and health records and to the greater use of digital tools outside the health system); 2) growing concern among citizens about the system's ability to deliver high-quality, patient-centred care; and 3) changing care-delivery models (e.g., interprofessional team-based care) and other shifts introduced by the reforms noted above.

Box 2: Equity considerations

A problem may disproportionately affect some groups in society. The benefits, harms and costs of elements to address the problem may vary across groups. Implementation considerations may also vary across groups.

One way to identify groups warranting particular attention is to use "PROGRESS," which is an acronym formed by the first letters of the following eight ways that can be used to describe groups†:
- place of residence (e.g., rural and remote populations);
- race/ethnicity/culture (e.g., First Nations and Inuit populations, immigrant populations and linguistic minority populations);
- occupation or labour-market experiences more generally (e.g., those in "precarious work" arrangements);
- gender;
- religion;
- educational level (e.g., health literacy);
- socio-economic status (e.g., economically disadvantaged populations); and
- social capital/social exclusion.

The evidence brief strives to address all Ontarians, but (where possible) it also gives particular attention to two groups:
- individuals who seek the majority of their care from health workers not regulated under the RHPA; and
- individuals who have had a negative experience with a health worker.

Many other groups warrant serious consideration as well, and a similar approach could be adopted for any of them.

† The PROGRESS framework was developed by Tim Evans and Hilary Brown (Evans T, Brown H. Road traffic crashes: operationalizing equity in the context of health sector reform. *Injury Control and Safety Promotion* 2003;10(1-2): 11–12). It is being tested by the Cochrane Collaboration Health Equity Field as a means of evaluating the impact of interventions on health equity.

Second, piecemeal legislative and oversight amendments to the legislative framework have created a particularly complex landscape to the oversight of the health workforce in Ontario (Table 1). The many

pieces of legislation and agencies or organizations involved in the oversight of health workers makes determining lines of accountability difficult. There are currently 29[1] regulated health professions with 26[2] professional regulatory colleges. Further, there are many categories of health workers that are not currently included in the RHPA, such as personal-support workers (of which there are many) as well as assistants of many kinds (e.g., dental, medical laboratory, physiotherapy and osteopath), athletic therapists, hearing instrument practitioners, lactation consultants, marriage and family therapists, medical geneticists, paramedics, pedorthists, phlebotomists, and personal-service workers of many kinds (e.g., ear piercers, tattoo artists). While some of these categories of health workers are overseen through other mechanisms (e.g., paramedics are regulated through the *Ambulance Act, 1990*), many repeatedly seek inclusion in the RHPA. Adding to the complexity, workers in the social-services field who often work closely with health workers are not covered by the same oversight mechanisms as health workers (unlike in the U.K., where health and social care are often handled together). As of 2011, the professionals covered under the RHPA are decided through the use of a risk-based approach, whereby professional bodies must demonstrate that their practice poses sufficient risk to warrant self-regulation. Decisions are made based on referrals to the Health Professions Regulatory Advisory Council.

Table 1: Examples of some of the key acts involved in the oversight of the health workforce

Act*	Contribution
Regulated Health Professions Act, 1991	• Provided the legislative framework for the self-governance of the now 29[1] regulated health professions in Ontario by the now 26[2] professional regulatory colleges
Medicine Act, 1991	• Confirmed physicians as self-regulating professionals, outlined the responsibilities of the College of Physicians and Surgeons of Ontario for governing the medical profession, and described the duties, scope of practice and authorized acts of physicians
Midwifery Act, 1991	• Brought midwives under the *Regulated Health Professions Act, 1991* with the profession overseen and regulated by the College of Midwives of Ontario
Health System Improvements Act, 2007	• Included the requirement for greater transparency for professional regulatory colleges, and the establishment of new transitional profession regulatory colleges – naturopathy, homeopathy, kinesiology and psychotherapy • Provided the beginning of the reform to the complaints process
Regulated Health Professions Statute Law Amendment Act, 2009	• Expanded the scope of practice of many regulated health professionals (e.g., nurse practitioners, pharmacists, physiotherapists, dietitians, midwives and medical radiation technologists) and changed the rules related to various aspects of drug administration by select health professionals (nurse practitioners, pharmacists, midwives, chiropodists, podiatrists, dentists and dental hygienists) • Mandated that all regulated health professionals have professional liability insurance, professional regulatory colleges make team-based care a key component of their quality-assurance programs, and professional regulatory colleges with professions providing the same or similar services develop common standards for those services
Naturopathy Act, 2015	• Brought naturopathy under the *Regulated Health Professions Act, 1991* with the profession overseen and regulated by the College of Naturopaths of Ontario
Protecting Patients Act, 2017	• Increased the ability of the Ministry of Health and Long-Term Care to oversee professional regulatory colleges, for example by compelling the colleges to provide additional performance metrics

*In addition to those listed, 23 other profession-specific statutes have been passed

Third, recent amendments to the composition of professional regulatory college councils and committees through Bill 87 highlighted substantial differences in how 'self-regulation,' among other key concepts, have

[1] Audiology, chiropody, chiropractic, dental hygiene, dental technology, dentistry, denturism, dietetics, homeopathy, kinesiology, massage therapy, medical laboratory technology, medical radiation technology, medicine, midwifery, naturopathy, nursing, occupational therapy, opticianary, optometry, pharmacy, pharmacy technicians, physiotherapy, podiatry, psychology, psychotherapy, respiratory therapy, speech-language pathology, and traditional Chinese medicine

[2] Audiologists and speech-language pathologists are regulated by a single professional college, as are chiropodists and podiatrists and pharmacists and pharmacy technicians.

come to be understood in Ontario, both within and across professions. Specifically, this has been illustrated through the differences in responses from professional bodies to a subsection within Bill 87 that provides new regulation-making powers to the Minister of Health and Long-Term Care. Across the professional regulatory colleges, the response to this provision differed substantially, with some seeing it as infringing upon their rights to self-governance and to set the standards for their profession. While some groups employ this broad definition of self-governance, in Ontario it actually has a narrower meaning (e.g., professional council members are elected by their profession, and professionals are involved in developing, implementing and enforcing regulations within a regulatory framework set by government).

Fourth, other jurisdictions have introduced many innovations in the oversight of health workers so there is now a broader array of options against which to compare Ontario's current oversight mechanisms. These options include both regulatory models (e.g., agency regulation, complementary regulation, compliance-based regulation, co-regulation, direct government regulation, voluntary regulation, and self-regulation - which can be thought of as a spectrum of models with government regulation at one end to profession-led regulation at the other end, with government agencies and hybrid models in between) and approaches to oversight including risk-of-harm approaches, focusing on competencies, controlled acts and/or scopes of practice, and performance measurement and management – each of which have been defined in the elements section of the brief.

Taken together, and combined with recent events that often received extensive media coverage and could reduce public trust and confidence in the current oversight mechanisms in the province (e.g., the Wettlaufer trial and the Handa licence suspension), these reasons provide a strong rationale for pursuing a discussion about whether the modernization of the oversight of the health workforce in Ontario would better advance the public interest than the status quo and, if so, what type of modernization would best do so. As a first step in considering the best approaches for the province, this evidence brief will build on the concepts and themes outlined above and mobilize the best-available global and local research evidence to clarify the problem(s) related to the oversight of the health workforce in Ontario, present three elements of a potentially comprehensive approach for addressing the problem, and highlight key implementation considerations.

THE PROBLEM

Many factors contribute to the need for modernizing the oversight of the health workforce. Some of the factors that emerged in discussions with health-system stakeholders, which are revisited in detail below, include:

1) the oversight mechanisms in place have not kept pace with the changing health system;
2) the oversight framework is focused on regulating individual categories of health workers, rather than grouping of them, and captures many but not all health workers;
3) the oversight framework has a different focus than the framework used in the education and training of health workers;
4) the financing and funding of oversight bodies are not explicitly designed to improve public-protection efforts;
5) it is difficult to find information on how the health workforce and its oversight bodies are performing; and
6) citizens are not consistently engaged in a meaningful way in oversight activities.

In aligning the features of the problem with the rationale laid out above, the first and second features of the problem relate to the first and second rationales for modernization described in the previous section (the RHPA hasn't been adapted, and a complex oversight landscape). Further, the first three features of the problem intersect with the types of healthcare delivery arrangements with which health workers will be familiar, whereas the fourth moves us into financial arrangements, and the fifth and sixth into higher-level governance arrangements.

Box 3: Mobilizing research evidence about the problem

The available research evidence about the problem was sought from a range of published and "grey" research literature sources. Published literature that provided a comparative dimension to an understanding of the problem was sought using three health services research "hedges" in MedLine, namely those for appropriateness, processes and outcomes of care (which increase the chances of us identifying administrative database studies and community surveys). Published literature that provided insights into alternative ways of framing the problem was sought using a fourth hedge in MedLine, namely the one for qualitative research. Grey literature was sought by reviewing the websites of a number of international organizations, such as the names of bodies that play a role in workforce regulation in other countries (e.g., Professional Standards Authority and the Health and Social Care Council in the U.K., and the Ministry of Health in New Zealand) or in studying it (e.g., King's Fund).

Priority was given to research evidence that was published more recently, that was locally applicable (in the sense of having been conducted in Ontario or in Canada), and that took equity considerations into account.

The oversight mechanisms in place have not kept pace with the changing health system

As previously mentioned, the legislative framework for the oversight of health professionals in Ontario, which is largely based on the *Regulated Health Professions Act, 1991* (RHPA), has not evolved to keep pace with many changes in the health system, including: 1) changing public expectations; 2) growing concern among citizens about the system's ability to deliver high-quality, patient-centred care; and 3) changing care-delivery models (e.g., interprofessional team-based care).

First, changing public expectations, facilitated in part through greater public access to health information about what and how services should be provided (and what their own records say about what they received), has placed pressure on the health workforce to adapt. These expectations reflect changes in other service industries and include a call for an increase in the implementation of technology across the health system, increased choice related to the settings in which care is received, improved convenience in receiving services, and enhanced levels of personalization. Overall, members of the public now expect more than ever that the health system and the workers providing services to patients within it, have the primary goal of ensuring an excellent patient experience. To meet these expectations the health workforce requires flexibility and a nimbleness towards patient care that the current legislative approach does not provide.

Secondly, there is a growing concern among citizens about the system's ability to continue to deliver high-quality, patient-centred care. This includes increased questioning about whether current oversight mechanisms (e.g., scope of practice and controlled acts) allow professionals to be sufficiently flexible to provide an individualized approach, to work closely to coordinate and collaborate on patient care, and to keep up the delivery of high-quality care as the system evolves. In particular, the need for professionals to significantly adapt their approach to providing services has rapidly increased in recent years, including the requirement to deliver a new type of services (e.g., medical assistance in dying), incorporate new technologies (e.g., electronic medical records), or treat new conditions (e.g., SARS or Zika). However, current oversight mechanisms have not kept up to date with these changes.

Finally, the ways in which healthcare services are delivered in Ontario has changed dramatically since the RHPA was developed, which primarily focused on independent professional practice and institution-based care. The regulatory framework was established with an implicit assumption that these points of emphasis in the health system would remain relatively static. However, given the many reforms and shifts experienced by the system since then (most notably changes in demographics and in the burden of chronic diseases in the population), the current approach appears out of date. As the focus of the health system has shifted away from acute treatment, we have been forced to re-examine how best to provide patients with the care they

need. This has meant a long-term move towards interprofessional team-based care as well as moving services out of institutions and into the community.

While these adaptions have led to improvements in access and quality of care for patients, they also represent new challenges in protecting the public from harm through appropriate oversight mechanisms. These include, among others, challenges in standardizing care in the community, a lack of clarity in how accountability is defined, and the potential for uncertainty in attributing harm when health workers are providing patient care as part of an interdisciplinary team.

The oversight framework is focused on regulating individual categories of health workers, rather than groupings of them, and captures many but not all health workers

As mentioned in the second component of the rationale above, through the development of an independent designated professional regulatory college for (almost) every regulated profession in Ontario, the oversight framework has focused on regulating each profession individually rather than groups of similar professions. The 26 professional regulatory colleges that currently operate in Ontario are largely independent of one another. This mostly uncoordinated and siloed approach means that each of the professional regulatory colleges is allocating resources to the same functions of professional registration, quality assurance, education, investigations and discipline. This is in contrast to other jurisdictions (e.g., the U.K., Australia, Ireland and New Zealand), which have chosen to group professionals based on their risk of harm, functional area, or geographic area, into a smaller number of oversight bodies.

In addition, the current regulatory structure has failed to cover many categories of health workers despite having a substantially larger number of oversight bodies than comparator jurisdictions. Furthermore, existing regulation (most notably the RHPA) does not account for how different types of health workers could be overseen using different approaches along a continuum of regulatory mechanisms (e.g., from voluntary registration and accreditation to required licensing), an approach that has been adopted in other jurisdictions (e.g., the U.K.). Categories of health workers that are not currently captured under the RHPA include paramedics, assistants of many types and personal-support workers, to name a few. While other mechanisms are in place to protect the public's interest through either the sectors in which these health workers work (e.g., *Ambulance Act, 1990*), the type of organizations in which they work (e.g., *Public Hospitals Act, 1990*), or through voluntary associations (e.g., Ontario Paramedic Association), these are often not well documented, and due to changes in the health system and a recent evolution in the importance of their roles (e.g., increased focus on community care), these mechanisms may no longer be adequate to protect the public's safety. Further, the inconsistent oversight of these health workers presents additional challenges in terms of data collection, health-workforce planning, and standardization of training and education.

The oversight framework has a different focus than the framework used in the education and training of health workers

The approach to health-workforce oversight in Ontario has focused on professional scopes of practice and controlled acts, which, within the RHPA, define what services professionals can deliver, where they can practise, and under what supervision. While oversight bodies have accommodated the recent shift towards the competencies that are now the focus of health professionals' education programs (e.g., the use of the CanMEDS framework by the College of Physicians and Surgeons of Ontario), entry-to-practice exams and continuing professional-development requirements, they continue to have to work within an oversight framework that stops a health professional from embracing a broader scope of practice or engaging in a controlled act even if they can demonstrate that they have developed an appropriate level of competency.

These distinct areas of focus create a gap between how health professionals think about what they have been trained to do and what they are actually allowed to do. This gap may mean that access to high-quality care is being unnecessarily limited, for example, through the restriction of some professionals taking on the delivery of additional services.

Financing and funding of oversight bodies are not explicitly designed to optimize public-protection efforts

The mechanisms in place for financing oversight bodies (e.g., through member contributions for professional regulatory colleges) and for funding workforce oversight (e.g., for determining what professional regulatory colleges should be spending resources on) have not been designed with the primary goal of ensuring public safety. For example, professional regulatory colleges are financed through fees that are set by the colleges and paid by their members. This financing mechanism creates inconsistencies between professions as well as between health professionals and other health workers. Specifically, professional regulatory colleges representing higher-earning professions or professions with more paying members have access to larger amounts of resources (or pay lower membership fees). The current approach to financing also creates a challenge with regards to other categories of health workers who often belong to voluntary associations, and many of whom are charged with the responsibility of protecting and promoting the public's well-being. However, unlike professional regulatory colleges, these associations do not have fees that they charge their members for this work, which potentially diminishes their ability to protect the public's safety.

The approaches to funding workforce oversight is also a challenge. Specifically, there is a lack of understanding in the health system of what levels of resource allocation to what oversight mechanisms maximize the benefits of each function. For example, there is little theoretical work or empirical evidence to clearly show the presumed or actual relationship between resource allocation for oversight and improvements towards achieving health-system goals on the one hand (e.g., the 'triple aim' of improving the patient experience, improving population health, and keeping per capita costs low), and outcomes more explicitly tied to patient protection and safety in healthcare on the other hand. The challenges associated with understanding what to fund are likely linked to the siloed approaches taken by professional regulatory colleges in Ontario, with the potential for streamlining and efficiencies possible with a more coordinated and collaborative approach.

It is difficult to find information on how the health workforce and its oversight bodies are performing

In Ontario, it is largely unclear who holds the responsibility for collecting and publicly reporting on performance measurement and management of health professionals or their oversight bodies. While professional regulatory colleges are required to publish some information on their websites, this information is not always as useful to the public as information about whether health professionals are adhering to their professional and ethical codes, as well as the volume of activities being undertaken to address professional non-adherence. While some professional regulatory colleges openly provide this type of information, it is not consistently available or as easily accessible to the public across the 26 professional regulatory colleges. For example, citizens may have to read through lengthy annual reports to find this information.

To further complicate the performance-measurement and -management landscape, there is an abundance of commissions, councils, agencies and boards both external and internal to the Government of Ontario, each of which perform roles that complement, overlap or support the professional regulatory colleges in Ontario in protecting the public's interest (Table 2). For the most part, however, discerning the roles and mandates of each of these bodies is quite challenging and leads to confusion among citizens, health workers and policymakers as to who is responsible for collecting data about and publicly reporting on the performance of health workers, and for taking action to reduce the risk of harm and to address harm when it happens.

In addition, reporting on the performance measurement and management of professional regulatory colleges themselves has been largely absent in Ontario. The enduring emphasis on regulating professionals and not on 'watching the watchers' (e.g., professional regulatory colleges themselves) has meant that there has been little effort (with the exception of annual reports) to measure and publicly report on the extent to which professional regulatory colleges are meeting their mandate and protecting the public interest, as happens in countries like the U.K.

Table 2. Bodies performing roles that complement overlap or support the professional regulatory colleges in Ontario

	Key functions
Government of Ontario	
• Legislation- and regulation-making bodies	• Establish the acts and regulations that govern the bodies that train and (self) regulate – and in some cases (e.g., hospitals) employ – the health workforce
• Fairness Commissioner	• Provides guidance about, assesses adherence to guidance about, and reports on non-adherence to guidance about the registration practices of certain regulated professions and trades
• Ministry of Advanced Education and Skills Development (MoAESD) o Postsecondary Education Division	• Develops policy directions for and distributes government funds to colleges and universities, including for the health workforce
• MoAESD-linked agencies – example: o Postsecondary Education Quality Assessment Board	• Makes recommendations to MoAESD regarding the degree programs that can be offered, including for the health workforce
• Ministry of Health and Long-Term Care (MoHLTC) o Health Workforce Planning and Regulatory Affairs Division	• Develops policy directions for the planning and regulation of the health workforce and for labour relations in the health system
• MoHLTC-linked agencies – select examples: o Health Professions Appeal and Review Board o Health Professions Advisory Council	• Monitors the activities of the professional regulatory colleges' Inquiries, Complaints and Reports Committees and Registration or Accreditation Committees (and hears appeals concerning physicians' hospital privileges in Ontario, pursuant to the *Public Hospitals Act, 1990*)
o Cancer Care Ontario	• Plans, funds and manages the performance of cancer services (as well as the provincial renal network and access-to-care initiatives)
o Health Quality Ontario	• Defines, measures and publicly reports on quality and supports quality improvement across the health system
o HealthForceOntario Marketing and Recruitment Agency	• Assists with the planning, recruitment, retention, transition and distribution of the health workforce
• Other MoHLTC-linked bodies – select examples: o Health Professions Regulatory Advisory Council	• Advises the minister about whether unregulated professions should be regulated, whether regulated professions should no longer be regulated, and whether the RHPA and related acts and regulations require amendment, among other topics
o Patient Ombudsman	• Addresses complaints about private not-for-profit hospitals (called public hospitals in Ontario), long-term care homes, and what had until recently been called Community Care Access Centres (but which are now part of Local Health Integration Networks)
o Local Health Integration Network	• Plans, funds and integrates health services in each of 14 geographically defined regions, which includes distributing government funds to organizations that employ a significant proportion of the health workforce
o Publicly funded hospitals and other health organizations that employ health workers	• Employ and establish policies and procedures that influence what health workers do on a day-to-day basis
• Courts, tribunals, commissions (e.g., human rights; information and privacy), justices of the peace, and coroners	• Other bodies that can address complaints about members of the health workforce or the organizations where they work

Federal or national bodies	
• Federal/Provincial/Territorial Committee on Health Workforce	• Provides a national forum for strategic discussion, information sharing, advice to deputy ministers and action on priority health-workforce issues
• National professional bodies – example: o Royal College of Physicians and Surgeons of Canada	• Accredits the university programs that train resident physicians for their specialty practices, writes and administers the examinations that residents must pass to become certified as specialists, and coordinates maintenance-of-certification programs to ensure the continuing professional development required for continued certification
Municipal bodies	
• Boards of health	• Govern the local public health agencies that hire the public health workforce needed to fulfill key public-health functions

Citizens are not consistently engaged in meaningful ways in oversight activities

While all 26 professional regulatory colleges are required to have a set proportion of their governance board be members of the public, as defined in each of their professional acts (i.e., *Medicine Act, 1991; Nursing Act, 1991; and Homeopathy Act, 2007),* these bodies differ substantially in the extent to which they have made efforts to meaningfully involve citizens and fully understand their perspectives. This includes, for example, convening panels or advisory panels and producing resources specifically for citizens.

Without these efforts, particularly those that help to explain the available oversight mechanisms to citizens, many members of the public remain unaware of the professional regulatory colleges and other oversight bodies, and how to access them, even for routine activities such as registering complaints. Furthermore, inconsistent or inadequate engagement of the public in oversight activities might also contribute to making citizens feel there is a lack of transparency in how health workers are overseen in Ontario, which creates opacity around lines of accountability in the system more generally, and could contribute to the erosion of public trust in the system.

Additional equity-related observations about the problem

While the challenges outlined in this section of the brief have important implications for the individuals receiving care, the professionals who deliver it and the oversight bodies responsible for ensuring public safety, two aspects of these challenges are particularly salient for groups prioritized in this brief (i.e., individuals who seek the majority of their care from health workers not regulated under the RHPA, and individuals who have had a negative experience with a health worker).

First, as mentioned in the section focused on financing and funding above, the current approaches for financing professional regulatory colleges (i.e., contributions from members) creates capacity imbalances between health professionals and other categories of health workers. Specifically, while mechanisms are in place to protect the public interest, associations representing health workers who are not regulated under the RHPA do not have access to the same resources as professional regulatory colleges, potentially diminishing their ability to protect the safety of the patients that seek the majority of care from these health workers (e.g., those who rely on home-care services). While not as critical across all categories of health workers, for those who are increasingly playing larger roles in the health system (e.g., personal-support workers), it is an important issue.

Second, as mentioned in the problem section, Ontario has a multitude of organizations that are involved in or intersect with the oversight of the health workforce. This busy landscape may mean that those individuals who are seeking to make a complaint or are in need of the protection that the oversight bodies provide are unable find the right organization to hear their case.

Citizens' views about key challenges related to modernizing the health workforce in Ontario

During three citizen panels convened on 11, 18 and 25 August 2017, 38 ethno-culturally and socio-economically diverse citizens were provided a streamlined version of this evidence brief written in lay language. During the deliberation about the problem, citizens were asked to share what they view as the key challenges related to modernizing the oversight of the health workforce in Ontario, and what they view as being needed to recognize it as an issue that warrants attention and effort to address. To prompt discussion, citizens were specifically asked to consider their concerns (if any) about the oversight of the health workforce in Ontario. Citizens were encouraged to draw on their own experience in interacting with health workers and think of how risks are distributed across sectors, settings of care, and categories of health workers, as well as to consider challenges they have encountered in accessing oversight bodies. We summarize the key challenges identified by citizens in Table 3.

Table 3: Summary of citizens' views about challenges related to modernizing the health workforce in Ontario

Challenge	Description
Oversight bodies have not adapted to changes in the delivery of care	• Participants generally agreed that they were worried about the oversight of health workers in Ontario, and expressed that they felt the oversight system had not kept up to changes in how services are delivered • Related to this point, a number of participants described a range of specific concerns, including: o insufficient oversight of, and an overburden of work for, specific categories of health workers, such as personal-support workers, paramedics, phlebotomists, and nurse practitioners, as well as physicians; o insufficient training for and supervision of best practices in specific settings, such as home and community care settings, hospitals, and long-term care homes; o insufficient oversight and limited accountability of third-party home- and community-care providers (e.g., accountability between CCAC and personal-support workers) o an inability among patients to advocate for themselves should they be harmed when accessing healthcare services, particularly vulnerable populations including those with dementia, elderly adults, Indigenous peoples, and those with physical or intellectual disabilities; and o lack of flexibility in the oversight of health workers to consider those settings with increased risk (e.g., rural communities)
The many bodies responsible for the oversight and administration of the health workforce makes navigating the oversight system challenging and may be inefficient	• Participants expressed that they were largely unclear about what the roles and responsibilities actually were for the oversight bodies (i.e., professional regulatory colleges), professional associations, healthcare organizations and the government in overseeing health workers • One participant noted how this led to blurred lines of accountability and uncertainty about who to contact in the event of a harmful incident • Several participants described how this confusion would deter them and other Ontarians from registering complaints about health workers, with one participant sharing an experience that confirmed this • Similarly, two participants expressed frustration with the extent of administration that went into the oversight of the health workforce, both in terms of redundancies across oversight bodies and in the extensive administrative placed on health workers, and some participants expressed concerns that this inefficiency could take away from the time spent on patient care
There is insufficient emphasis placed on the soft skills and personalization required to provide high-quality patient-	• Several participants expressed their frustration that health workers did not pay enough attention to developing their soft skills to address individual patient needs, including listening to unique experiences and carefully considering their history, appropriately communicating diagnoses, or exploring solutions outside of their usual practice (e.g., undertaking additional research to determine other approaches, or considering complementary and alternative therapies)

centred care in the current oversight framework	• Participants attributed this to a number of factors including: o lack of training in soft skills (e.g., communication, compassion, and administration to improve coordination of care); o lack of emphasis on soft skills in practice guidelines and in oversight frameworks; o fear among professionals of diverging from treatment guidelines due to possible repercussions should the patient have an adverse reaction; and o overburdening of health workers, particularly in community settings
Oversight bodies have not been set up in a way that prioritizes the interests of citizens and patients	• A few participants at each panel noted that they felt oversight bodies (specifically the professional regulatory colleges) prioritized the interests of their professional registrants rather than serving in the interest of citizens and patients, with one participant stating that "oversight bodies were often protective and defensive of their own professionals" • Two participants discussed how the large number of oversight bodies that exist create silos and competition among health workers, which they stated as one of the dynamics that has contributed to a focus on protecting professional 'turf,' rather than serving the public • One participant described how the complaints process that is critical to the work of oversight bodies is reactive, relying on individual patients to act as advocates for themselves when they have complaints, when it should be proactive and focused on ensuring high-quality care
Finding information about health workers and their oversight bodies is difficult and there are limited opportunities for patients to engage in oversight efforts	• Many participants expressed concern with accessing information on health workers and their oversight bodies, noting that they felt it was inconsistent to rely on patient complaints when in many cases they "did not know what each health worker was and was not allowed to do" • Other participants recalled their experiences in trying to locate information on health professionals and were frustrated that it was not all contained in a central location, and that what is available is hard to understand • Many participants noted that they felt there was not a formal process for them to provide feedback to their health worker • In particular, two participants discussed how this was contrary to other sectors which rely heavily on consumers' comments and evaluations to ensure continuous quality improvement, providing the example of student evaluations in university courses in the public sector, and platforms like 'Yelp' in the private sector • One participant noted how this lack of transparency and limited opportunity to contribute their own experiences served to erode public trust in the oversight of health workers
Oversight of the health system fails to address risk across an individual's entire care pathway	• Participants expressed feeling as though they were particularly at risk of harm when transitioning between categories of health workers and across different settings of care, with several describing gaps in services and a lack of care continuity following hospital discharge into the community • Participants described how in these circumstances many health workers did not appear to have the necessary administrative competencies required to coordinate care effectively with other individuals and organizations in the system, were not held accountable for ensuring successful transitions between providers and across settings, and were often ill-prepared during interactions to provide personalized services.

THREE ELEMENTS OF A POTENTIALLY COMPREHENSIVE APPROACH TO ADDRESSING THE PROBLEM

Many approaches could be selected as a starting point for deliberations about how to proceed with modernizing the oversight of the health workforce in Ontario. To promote discussion about the pros and cons of different ways forward, we have selected three elements of a larger, more comprehensive approach. The three elements were developed and refined through consultation with the Steering Committee and the key informants we interviewed during the development of this evidence brief. The elements are:

1) use a risk-of-harm approach to health-workforce oversight;
2) use competencies as the focus of oversight; and
3) employ a performance-measurement and -management system for the health workforce and its oversight bodies.

The elements could be pursued separately or simultaneously, or components could be drawn from each element to create a new (fourth) element. They are presented separately to foster deliberations about their respective components, the relative importance or priority of each, their interconnectedness and potential of or need for sequencing, and their feasibility.

The principal focus in this section is on what is known about these elements based on findings from systematic reviews. We present the findings from systematic reviews along with an appraisal of whether their methodological quality (using the AMSTAR tool) (9) is high (scores of 8 or higher out of a possible 11), medium (scores of 4-7) or low (scores less than 4) (see the appendix for more details about the quality-appraisal process). We also highlight whether they were conducted recently, which we define as the search being conducted within the last five years. In the next section, the focus turns to the barriers to adopting and implementing these elements, and to possible strategies to address the barriers.

Box 4: Mobilizing research evidence about elements of a potentially comprehensive approach for addressing the problem

The available research evidence about regulatory models for health professionals in general and for each of the elements of a potentially comprehensive approach for addressing the problem was sought primarily from Health Systems Evidence (www.healthsystemsevidence.org), which is a continuously updated database containing more than 6,000 systematic reviews and more than 2,500 economic evaluations of delivery, financial and governance arrangements within health systems. The reviews and economic evaluations were identified by searching the database for reviews addressing features of each of the approach elements and sub-elements.

The authors' conclusions were extracted from the reviews whenever possible. Some reviews contained no studies despite an exhaustive search (i.e., they were "empty" reviews), while others concluded that there was substantial uncertainty about the element based on the identified studies. Where relevant, caveats were introduced about these authors' conclusions based on assessments of the reviews' quality, the local applicability of the reviews' findings, equity considerations, and relevance to the issue. (See the appendices for a complete description of these assessments.)

Being aware of what is not known can be as important as being aware of what is known. When faced with an empty review, substantial uncertainty, or concerns about quality and local applicability or lack of attention to equity considerations, primary research could be commissioned, or an element could be pursued and a monitoring and evaluation plan designed as part of its implementation. When faced with a review that was published many years ago, an updating of the review could be commissioned if time allows.

Given very few relevant systematic reviews were identified, we also conducted complementary searches for locally relevant single studies in PubMed using the same keyword strategies. Those interested in pursuing a particular element may want to search for a more detailed description of the element or for additional research evidence about the element.

Citizens' values and preferences related to the three approach elements

To inform the citizen panels, we included in the citizen brief the same three elements of a potentially comprehensive approach to address the problem as are included in this evidence brief. These elements were used as a jumping-off point for the panel deliberations. During the deliberations we identified several values and preferences from citizens in relation to these elements, which we summarize in Table 4.

Table 4: Citizens' values and preferences related to the three elements

Element	Values expressed	Preferences for how to implement the element
Use a risk-based approach to health-workforce oversight	• Equity in efforts to assess risk across all categories of health workers • Efficient use of oversight resources based on risk • Collaboration among the Ministry of Health and Long-Term Care, existing oversight bodies, health workers, patients and citizens, in developing routine processes to support a risk-based approach to the oversight of health workers • Clear lines of accountability in the risk-based oversight of health workers	• Develop a common definition of risk and a standard process for assessing risk that is consistently applied to all categories of health workers • Ensure that the risk assessment tool allows for some flexibility based on a provider's sector or setting (e.g., home and community compared to the hospital sector; urban compared to rural settings) • Group categories of health workers and allocate resources according to their level of risk (e.g., low, medium or high, or 0 – 100) • Create one standard body responsible for processing complaints • Involve both patients and citizens in the development of a process for assessing the risk of harm presented by different health workers (or groups of health workers) • Meaningfully include patients and citizens in the boards of any newly developed oversight bodies that are created as a result of the new risk-based approach, with a minimum representation of one-third
Use competencies as the focus of oversight	• Patient-centred care that is of the highest quality through the establishment of soft skills as a core competency for all health workers • Trustworthiness and ability to establish trusting relationships with patients and other health workers included as a core competency for all health workers • Collaboration among Ministry of Health and Long-Term Care, existing oversight bodies, health workers, patients and citizens in the establishment and implementation of core competencies	• Use competencies as the focus of health-workforce oversight, emphasizing soft skills (e.g., bedside manner, desire to continue to learn, collaboration with other providers, communication and listening, ability to develop a trusting relationship, and administration and management for better care coordination) • Support in particular the participation of select categories of health workers, including nurse practitioners, pharmacists and personal-support workers, in establishing and adopting new competencies that would allow them to provide additional services • Work closely with the Ministry of Advanced Education and Skills Development to ensure that the education and training being provided matches the core competencies needed in practice • Involve government, health professionals, patients and citizens in determining core competencies for each profession • Strike a standing committee to frequently

		review core competencies across categories of health workers, with a suggested review every three to five years
Employ a performance-measurement and -management system for the health workforce and its oversight bodies	• Continuous quality improvement among health workers included in performance-measurement and -management efforts • Citizens' values and preferences as the basis for measuring the performance of health workers • Accountability for poor performance is central to the role of oversight bodies • Empower patients and citizens with information on the performance of health workers and their oversight bodies	• Provide patients with the opportunity to frequently evaluate the performance of the health workers they interact with • Introduce interdisciplinary peer oversight to improve collaboration and reduce the chance that professional self-interest will interfere with oversight processes • Design performance measurements based in part on patients' and citizens' preferences • Adjust complaints processes to account for patient-provider power differentials • Develop an online dashboard to publicly report performance measurements of health workers and their oversight bodies • Ensure that measurements are frequently updated, easy to access by the public and easily understandable

Element 1 – Use a risk-based approach to health-workforce oversight

This element focuses on taking a risk-based approach to health-workforce oversight, whereby risk is the statistical probability that a hazard will occur. Adopting this approach means carefully considering the following three factors before setting oversight priorities and allocating resources: 1) the potential hazards (e.g., the event or occurrence that could be avoided through oversight) that members of the public are faced with when interacting with individual health workers, when engaging with workers practising within a broader profession, and as a result of the practices of the regulatory college that oversees workers and the profession; 2) the probability of these hazards occurring; and 3) the severity of the identified harms (e.g., the consequences associated with a hazard after it occurs).(4) This approach – also referred to as a 'risk-of-harm' approach – builds on the notion that oversight of health workers ought to be designed and implemented to reduce the likelihood of adverse events from occurring, and therefore that targeting high-risk areas is the most efficient use of oversight resources.

Transitioning towards a risk-based approach could mean pursuing any of the following sub-elements:

- develop a common definition of risk and determine how it should be applied to health workers; and
- using a risk-based approach to:
  - select categories of health workers for oversight;
  - group categories of health workers under a smaller number of oversight bodies (while ensuring that information sharing, collaboration and joint action takes place across groups as well);
  - implement different levels of oversight (i.e., 'right touch' as opposed to 'heavy handed' or 'light touch'); and
  - allocate resources to oversight functions.

These sub-elements align with the second feature of the problem (a focus on individual categories of health workers in the current approach to oversight) by supporting a systematic approach for determining which categories of health workers should be overseen by what mechanisms and providing a basis for their grouping, and further addresses the fourth feature of the problem (challenges with financing and funding) by specifically allocating resources with the aim of optimizing public-protection efforts.

One scoping review and two primary studies were identified that related to the element, albeit at a very general level. The scoping review provided a synthesis of the research evidence on risk-based regulation and highlighted three potential benefits associated with adopting a risk-based approach to oversight, including:

- it contributes to regulatory efficiency by targeting the approaches of the regulator to allocate resource where risk is the greatest;
- it can assist in providing a defensible rationale for decision-making, that can withstand external challenge from the court or potentially the media; and
- it can systematically improve decision-making processes by providing new evidence and insights into potential risk.(4)

One of the single studies identified suggested that a risk-based approach could help to re-orient the focus of oversight to protecting patient outcomes and improving collaboration across regulators.(5) The same primary study also provided insights into the key procedural elements of adopting a risk-based approach that ought to be considered, which include:

- explicitly deciding on a common definition of risk;
- establishing the amount of risk that an organization is prepared to accept or be exposed to at any given time (which includes acknowledging that zero risk is not an achievable target);
- putting in place a robust and efficient surveillance system that is based on both qualitative and quantitative data; and
- collaborating across oversight bodies to share monitoring data in order to develop a more precise and effective risk-based approach.(5)

The other primary study provided insights related to the dimension of the sub-element focused on using a risk-based approach to group categories of health workers under a smaller number of oversight bodies. The study highlighted that it is critical to consider the possibility that some categories of health workers that are not currently regulated under the RHPA may have some concerns about becoming regulated, especially when bundled with other regulated professions.(6) In particular, through conducting interviews with naturopaths, homeopaths and traditional Chinese medicine practitioners throughout the process of becoming regulated in Ontario, the study revealed four primary concerns from these providers: 1) increased financial burden; 2) reduced scope of practice; 3) unfair registration standards; and 4) medicalization of their practice.(6)

In addition to identifying research evidence, we conducted a jurisdictional scan to establish the extent to which Ontario and four other comparative jurisdictions have implemented a risk-based approach. Table 5 provides an overview of what harms are currently considered and the way in which a risk-based approach has been implemented in each of the jurisdictions, while Table 6 focuses on what categories of health workers are the focus of oversight and how some categories of health workers have been grouped together under workforce oversight bodies.

On the whole, scanning other jurisdictions suggests that there has been a focus on the potential risk of harm posed by individual health workers rather than on other levels within the health system (such as the risks posed by the broader category of health worker or by oversight bodies themselves). The exception to this appears to be in the U.K., where harms arising from inadequate workforce oversight have been considered through the role that the Professional Standards Authority plays in overseeing the functioning of each professional regulatory council. Furthermore, it should be noted that the harms detailed in Table 5 focus almost exclusively on factors intrinsic to health workers and health-workforce oversight bodies (e.g., features of professionals' practice, including intervention complexity, contexts and environments in which professionals work, professional agency, and patient vulnerability), rather than extrinsic factors such as the size of the profession or public risk perception.

In Ontario, as of 2011 an explicit risk-based framework has been used to determine what new categories of health workers should be selected for regulation. There are three primary criteria on which categories of health workers are judged: 1) whether the health workers are involved in duties, procedures, interventions or activities with the significant potential for physical or mental harm to patients; 2) whether the health worker is engaged in making decisions or judgments that can have a significant impact on a patient's physical or mental health; and 3) whether there is a significant potential of risk of harm occurring within the health workers' duties and activities.(7)

The explicit risk-based framework that has been implemented in Ontario (relatively recently and only for new candidate categories of health workers) differs from the approach used in Ireland, New Zealand and Australia where historical legacies of guilds and councils (rather than a systematic approach to evaluating potential for harm) have determined which categories of health workers have been regulated through a dedicated oversight body. In the U.K., despite there being some lasting legacies of councils (e.g., for some professions only, separate geographic councils), a particularly innovative approach has been used whereby the lowest-risk categories of health workers are subject to employer controls and the high-risk categories are subject to statutory regulation, with a voluntary level 'in between' for professionals who may at some point become regulated.

Table 5: Whether and how a risk-based approach is used in health-workforce oversight in Ontario and in select comparator jurisdictions

	Jurisdiction				
	Ontario	**Ireland**	**New Zealand**	**Australia**	**United Kingdom**
Harms considered	• Primary o Serious physical harm [that] may result from controlled acts or from an omission from them o Harms arising from inadequate professional conduct • Secondary o Harms arising from inadequate education and training o Harms arising from restrictions on mobility	• Harms arising from inadequate education and training and from inadequate professional conduct	• Harms arising from inadequate education and training and from inadequate professional conduct	• Harms arising from inadequate education and training and from inadequate professional conduct (and from constraints on inter-state mobility)	• Harms arising from inadequate education and training and from inadequate professional conduct • Harms arising from inadequate workforce regulation (with good practices articulated in the Standards of Good Regulation)
Bodies involved in preventing harm	• Primary o Professional regulatory colleges • Secondary o Health Professions Regulatory Advisory Council o Health Professions Appeal and Review Board o Patient Ombudsman o Postsecondary Education Quality Assessment Board o National professional bodies	• Primary o Councils	• Primary o Professional boards and councils o New Zealand Health Practitioners Disciplinary Tribunal (centralized body for investigations and discipline)	• Primary o National boards of health (albeit supported through state-level legislation) o Australian Health Practitioner Regulatory Authority (centralized body for investigations and discipline, with the exception of one state – New South Wales)	• Primary o Professional councils o Professional Standards Authority (centralized body for the regulation of the regulators)
Use of a risk-of-harm approach in	• Yes (since 2011)	• No	• No	• No	• Yes, with the lowest-risk occupations subject to employer

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selecting categories of health workers for regulation					controls and the high-risk occupations subject to statutory registration
Use of a risk-of-harm approach in grouping categories of health workers under the same oversight body	• No (almost as many professional regulatory colleges as professions)	• Yes (a 'catch all' council regulates 14 categories of health workers – versus one for each of physicians, nurses and midwives, pharmacists, dental professionals, and emergency care professionals)	• No	• No, with one exception (one national board of health covers all Aboriginal and Torres Strait Islander health workers)	• Yes (a 'catch-all' council and a tiered system of voluntarily regulated categories of health workers exist alongside 10 profession-specific councils) • No, all professional councils are overseen by the Professional Standards Authority
Use of a risk-of-harm approach in allocating resources to oversight mechanisms	• Yes, but inconsistent across professional regulatory colleges and oversight functions (e.g., some colleges use an alternative dispute resolution for low-risk matters rather than undertaking a full investigation)	• No	• No	• Yes (Australian Health Practitioner Regulatory Authority allocates a disproportionate share (70%) of their budget to the medical and nursing/midwifery national boards of health)	• Yes

Despite the fact that Ontario has taken steps towards using risk-of-harm assessments to inform decision-making processes about regulating new categories of health workers, little effort has been made in the province to use these insights as a way to logically group professional regulatory bodies with similar levels of risk. This contrasts the approaches taken in Ireland, Australia and the U.K., where professionals have been grouped by functional area. In the case of the U.K., geographic considerations are used to group professionals as well (e.g., Pharmaceutical Society of Northern Ireland).

As previously mentioned in the brief, grouping professionals based on their potential for harm may allow for more consistent oversight across colleges, and provide a voice for smaller categories of health workers that might otherwise get lost amidst larger oversight bodies. Furthermore, it could be used as a way to gain efficiencies through economies of scale by reducing the number of oversight bodies in Ontario. The reorganization of professional regulatory colleges also presents the opportunity to bring health workers who are not currently regulated by the RHPA under existing oversight bodies based on their risk of harm, functional area, or using a 'catch-all' approach such as in the case of Ireland or the U.K., (e.g., Health and Care Professions Council acts as the regulatory body for biomedical scientists, arts therapists, chiropodists, dietitians, occupational therapists, and paramedics, to name a few).

Regardless of how groups are formed, all jurisdictions have chosen to leave a number of health workers without oversight bodies. While it can be argued that these omissions may pose challenges in terms of ensuring patient safety, developing consistent standards of education, and collecting data about these health workers (e.g., their demographic characteristics, geographical distribution, level of training, etc.), there is also a balance to strike between pursuing oversight mechanisms that actually improve patient safety and ensuring that they do not become detrimental to patient care. Therefore, as mentioned above, the U.K. has proposed a potential middle ground of voluntary regulation (or voluntary oversight). In this system, health-worker associations voluntarily participate in adhering to the standards set by the Professional Standard Authority (national body that oversees the 10 professional regulatory councils), and in return receive acknowledgment and accreditation under this program.

For those who want to know more about the primary studies summarized under this element (or obtain citations for the primary studies), a fuller description of the primary studies is provided in Appendix 1a.

Table 6: How health professions are grouped for oversight purposes in Ontario and in select comparator jurisdictions

	Jurisdiction				
	Ontario	**Ireland**	**New Zealand**	**Australia**	**United Kingdom**
Groupings of health professions - Overview	• Twenty-six professional regulatory colleges	• Five councils based on institutional history and a 'catch-all' council that regulates an additional 14 categories of health workers (with the potential of more to be added)	• Sixteen professional boards and councils based on functional areas • New Zealand Health Practitioners Disciplinary Tribunal	• Fourteen national boards of health based on functional areas • Australian Health Practitioner Regulatory Authority	• Ten professional councils based on functional areas and sometimes geography and a 'catch-all' professional council, as well as a tiered system of voluntarily regulated health workers • Professional Standards Authority
Groupings of health professions - Specifics	• Ad hoc groupings for select professionals: o nurses (registered nurses, nurse practitioners, and registered practical nurses) o pharmacists and pharmacy technicians o audiologists and speech-language pathologists	• Historically based councils: o physicians o nurses and midwives o pharmacists o dental professionals o emergency care professionals • 'Catch-all' council (CORU) regulates: o clinical biochemists o dietitians o dispensing opticians o medical scientists o occupational therapists o optometrists o orthoptists o physiotherapists o podiatrists o psychologists o radiographers o social-care workers o social workers o speech-language	• Professional boards and councils: o chiropractors o dental professionals o dietitians o physicians o laboratory scientists and operating technicians o radiation technologists o midwives o nurses o occupational therapists o optometry professionals o osteopaths o pharmacists o physiotherapists o podiatrists o psychologists o psychotherapists	• National boards of health: o Aboriginal health professionals o traditional Chinese medicine o chiropractors o dental professionals o physicians o medical radiation professionals o nurses and midwives o occupational therapists o optometry o osteopaths o pharmacists o physiotherapists o podiatrists o psychologists	• Functionally based professional councils: o chiropractors o dental professionals o physicians o optometry professionals o osteopaths o nurses and midwives o pharmacists • Functionally and geographically based professional councils: o pharmacists in Northern Ireland o social-care workers in Northern Ireland • 'Catch-all' professional council o arts therapists o biomedical scientists o chiropodists/podiatrists o clinical scientists o dietitians o hearing-aid dispensers o occupational therapists

		pathologists			○ operating department practitioners ○ orthoptists ○ paramedics ○ physiotherapists ○ practitioner psychologists ○ prothetists and orthotists ○ radiographers ○ social workers in England ○ speech and language therapists
Categories of health workers that are not part of the groupings	• Examples include: ○ assistants of many types, such as ▪ anesthesia ▪ dental ▪ medical laboratory ▪ physiotherapy ○ athletic therapists ○ clinical specialist radiation therapists ○ community health and development workers ○ community-support workers ○ family home visitors ○ hearing-instrument practitioners ○ herbalists ○ lactation consultants	• Examples include: ○ acupuncturists ○ anthroposophic medicine practitioners ○ ayurveda ○ chiropractors ○ herbal medicine ○ homeopaths ○ massage therapists ○ naprapaths ○ naturopaths ○ neural therapists ○ osteopaths ○ traditional Chinese medicine practitioners	• Examples of those seeking to be regulated under the act: ○ clinical physiologists ○ practitioners of traditional Chinese medicine ○ paramedics ○ perfusionists ○ Western medical herbalists	• Examples include: ○ acupuncturists ○ chiropractors ○ herbalists ○ homeopaths ○ kinesiologists ○ massage therapists ○ naturopaths ○ nutritional therapists ○ osteopaths ○ physical therapists ○ reflexologists ○ traditional Chinese medicine practitioners	• Those participating voluntarily with the Professional Standards Authority's accredited registers program ○ acupuncturist ○ adolescent psychotherapists ○ Alexander technique practitioners ○ Bowen therapists ○ child psychotherapists ○ Christian counsellors ○ Christian psychotherapists ○ clinical technologists ○ craniosacral therapists ○ foot-health practitioners ○ genetic counsellors ○ graduate sport rehabilitators ○ healthcare science practitioners ○ homeopaths ○ hypnotherapists ○ kinesiologists ○ massage therapists ○ naturopaths ○ nutritional therapists ○ psychotherapists

	o marriage and family therapists o medical geneticists o osteopaths o paramedics o pedorthists o peer-support workers o personal-service workers (e.g., ear piercers, tattoo artists) o personal-support workers o phlebotomists o Reiki practitioners				o reflexologists o Reiki healers o Shiatsu therapists o yoga therapists • Those not participating o physician associates o healthcare assistants o nursing associates o complementary therapy professionals not covered by relevant accredited registers o psychological therapy practitioners not covered by accredited registers o care workers; care assistants o home-care workers o personal assistants

Element 2 – Use competencies as the focus of oversight

The second element focuses on using competencies as any alternative to scopes of practice and controlled acts to guide health-workforce oversight. This is an alternative to the traditional focus on narrowly defined skill sets (sometime referred to as a learning-objective-based approach) in professional education, training and development. Competencies differ from more narrowly defined skills in that they can be considered to be a broader approach that includes whether or not the individual health worker has the technical knowledge and ability required for providing specific health services, but also the soft skills required to ensure high-quality, patient-centered services (e.g., listening and communication, ability to work with others, and the administration and management abilities that translate well to effective care coordination).

Adopting a competency-based focus to oversight may allow for health workers to more easily adapt the services they are allowed to provide, after demonstrating that they have the necessary competencies to perform them. This approach, however, also comes with a number of considerations, including the possible benefits (for example, improving access to services) and harms (for example, more health workers offering services with a particular competency, but possibly not the full spectrum of competencies required to react to the full range of things that could go wrong during the service). This shift in focus could mean pursuing any of the following:

- develop a process to get input from citizens, health workers and existing oversight bodies about how to define the core competencies for each category of health worker;
- determine an approach to update the core competencies as the health system evolves;
- expand the use of competencies across all categories of health workers in:
  - educational programs preparing candidates for entry into a category of health workers;
  - training programs involved in preparing health workers for changes to what they are allowed to do; and
  - continuing professional-development programs that support health workers to safely do what they are allowed to do under existing oversight mechanisms; and
- use competencies – instead of scopes of practice and controlled acts – as the focus of health-workforce oversight, including to evaluate the seriousness of complaints and other investigations.

These sub-elements align with features one and three of the problem (no adaptations to the oversight mechanism and a primary focus on scopes of practice) by supporting a more flexible approach to the oversight of health workers that is better able to adapt to changes in public expectations, emerging imperatives in the provision of high-quality care, and new models of service delivery. Further, taking a competency-based approach to workforce oversight helps to align current workforce supports, which are increasingly adopting a focus on competencies (e.g., training, entry-to-practice exams), with the way in which professionals are overseen.

We identified one systematic review and four primary studies that relate to the four sub-elements above. The systematic review sought to identify reliable tools to measure competencies among nurses internationally. While the review found that a number of tools are able to accurately predict the extent to which nurses employ the competencies they were taught during training, the competencies assessed in each tool varied significantly, indicating a lack of consensus on what core competencies are needed in the nursing profession.(8)

An older primary study addressed the first sub-element and detailed the process and lessons learned from an effort to define common competencies for registered nurses across Canada. The results suggested that a successful process for defining competencies across a profession requires the following characteristics:

- a clear but broad mandate to give those engaged the flexibility to decide on detailed goals, working processes, and a plan;
- the development of a work plan with targeted tasks and timelines to keep the project on track; and

- shared enthusiasm among involved stakeholders as well as the support of individuals in leadership positions during the transition.(9)

Two primary studies were found that spoke to the third sub-element, with one addressing the training of health workers and the other addressing the recruitment of health workers using a competency-based framework. The first study evaluated the Care of the Elderly Diploma Program implemented as part of Alberta's medical residency training and compared the results of training medical residents based on a learning-objectives curriculum (prior to 2010) to one based on core competencies (2010 onwards).(10) The study found no difference between the two programs in the learning of medical residents, however, it found significant improvements in specific dimensions of the CanMEDS framework, specifically the roles of communicator, collaborator, manager and scholar.(10) The second study assessed the use of a competency-based framework and competency-based interviews for the recruitment of nurses, midwives and allied health professionals in the National Health Service in the U.K. The study found that participants in interviews viewed a change away from standard entrance interviews positively, and felt that it resulted in the identification of stronger candidates at the application stage. However, the study also reported challenges in determining common competencies, and difficulties in defining values and competency-based interview questions.(11)

Finally, the other two primary studies identified barriers to and facilitators of implementing competency-based educational programs. The first (recent) study examined the implementation of a competency-based approach to professional education on pain management. The results suggested that successful program implementation was facilitated by the existence of an environment that was supportive of the shift towards a competency-based approach, and by administrative support throughout its implementation.(12) The second study identified five areas of resistance that presented barriers to the implementation of a competency-based medical education program:

- a lack of interest in change;
- concern regarding the evidence base supporting competency-based education in medicine;
- the administrative burden associated with implementing pilot programs to test the new approach;
- financial concerns regarding whether a competency-based approach will require more resources than a learning-objective-based approach; and
- difficulty balancing service requirements with education.(13)

In addition to this research evidence, we conducted a jurisdictional scan to highlight whether and how competencies have been used as the focus of workforce oversight in Ontario and four other comparator jurisdictions (Table 7). In Ontario, the use of competencies has been unevenly implemented across professional regulatory colleges, with the most advanced being the use of the Royal College of Physicians and Surgeons of Canada competencies for physicians and the use of competencies in the entry-to-practice exams for registered nurses. This is in contrast to Australia and the U.K. where competency-based oversight has been implemented more systematically across all oversight functions.

Table 7: Whether and how competencies are the focus of the oversight of the health workforce in Ontario and in select comparator jurisdictions

	Ontario	Ireland	New Zealand	Australia	U.K.
Use of competencies as the focus of the oversight of educational programs involved in preparing candidates for	• Not consistently within or across categories of health workers (e.g., not all medical schools use the Royal College of Physicians and	• No	• Yes	• Yes	• Yes

entry into the profession	Surgeons of Canada (RCPSC) CanMEDS competencies)				
Use of competencies as the oversight of training programs involved in preparing candidates for entry into areas of specialty	• Not consistently (e.g., yes for residency programs given RCPSC requirements)	• No	• Yes	• Yes	• Yes
Use of competencies as the focus of the oversight of training programs involved in preparing health workers for changes to what they are allowed to do	• Not consistently	• No	• Yes	• Yes (national boards of health define competencies for each profession and accredit the institutions and programs training them)	• Yes
Use of competencies as the focus of the oversight of continuing professional-development programs involved in ensuring that health workers can safely do what they are allowed by regulation to do	• Not consistently	• No	• Yes,	• Yes	• Yes
Use of competencies as the focus of professional regulatory colleges and many of the functions they perform	• Not consistently (e.g., fellowship in the RCPSC as a requirement for registering as a specialist has this effect)	• No	• Yes	• Yes	• Yes

For those who want to know more about the systematic reviews and primary studies summarized under this element (or obtain citations for the reviews and primary studies), a fuller description of the systematic reviews and primary studies are provided in Appendix 2a and Appendix 2b.

Element 3 – Employ a performance-measurement and -management system for the health workforce and its oversight bodies

This element focuses on implementing a performance-measurement and -management system for the health workforce and its oversight bodies to help improve the ability of citizens and policymakers to judge whether or not the needs of the public and of the health system are being met.

Sub-elements of this option may include:

- establishing how oversight mechanisms affect performance-measurement indicators;
- introducing an independent body to develop and implement a performance-measurement and -management system;
- developing metrics that allow citizens and policymakers to judge and, when needed, demand improvements to the performance of the health workforce or its oversight bodies; and
- establishing clear processes for regular audits of the performance of oversight bodies, which would include:
  - clarifying who could be accountable for what parts of a performance-management system;
  - separating complaints management from professional registration;
  - allocating the licensing and registration of all categories of health workers to a single independent body; and
  - giving an explicit role in the oversight mechanism to key organizations in the health system (e.g. LHINs and healthcare institutions).

These sub-elements align with features five and six identified in the 'problem' section of this evidence brief (difficulty finding information on how the health workforce and its oversight bodies are performing, and inconsistent engagement of citizens in meaningful ways in oversight activities) by clearly defining what performance-measurement indicators should be collected, who is responsible for their collection and reporting, and ensuring that the performance-measurement and -management indicators are easily interpreted and meaningful to the public.

In searching for research evidence, we found one systematic review and two primary studies that looked at aspects of performance measurement and management for the health workforce.(14-16) The systematic review focused on the characteristics of complaints registered with oversight bodies, while the two primary studies focused on mandatory reporting.(14-16)

The review found that whose who are less likely to register a formal complaint with an oversight body are significantly older, live with a disability, or reside in either an economically deprived area or a rural community.(16) The review suggested that these categories of individuals should be kept in mind when making changes to complaints processes.(16)

One of the two primary studies examined the characteristics of reports from a mandatory reporting scheme in Australia and found that most reporting of health-worker misconduct came to the attention of oversight bodies through a third party – usually a patient or a colleague – and was often from those within the same category of health worker. The study found that even with wide-reaching mandatory reporting there are still four types of barriers to notifying oversight bodies:

1) uncertainty or unfamiliarity with legal requirements;
2) fear of retaliation;
3) lack of confidence that appropriate action will be taken; and
4) loyalty to colleagues.(14)

The second primary study found that successful mandatory reporting schemes relied on three key factors:

1) a high bar for the reporting of impairment;
2) appropriate response to reports that are considered fair and timely; and

3) availability of preventive assistance.(15)

With regards to performance measurement and management of oversight bodies, we found one primary study that addressed mechanisms to regulate and improve the transparency of oversight bodies. The study focuses on developing metrics that can inform decision-making. It found that implementing a performance-management program requires an inclusive approach that includes all key stakeholders.(17) According to the study, this facilitated the development of a framework and a set of measures that meet the needs of stakeholders and maximize their commitment to implementing and reporting on the measurements.(17)

In addition to examining the research evidence, we conducted a jurisdictional scan to see whether and how the performance of health workers and their oversight bodies is measured and managed in Ontario and in four comparator jurisdictions. In all jurisdictions except the U.K., the primary bodies responsible for reporting on metrics to the public are the oversight bodies themselves (e.g., the professional regulatory colleges or councils). In the U.K., an overarching body called the Professional Standards Authority is responsible for collecting and reporting on these metrics, as well as for conducting annual audits on each of the professional councils.

In Table 8 we have grouped indicators by the oversight functions that oversight bodies perform. Compared to the four other jurisdictions, Ontario publicly reports on relatively few performance indicators, with notable gaps in both complaints and discipline indicators, and in offence indicators. It is important to note, however, that in Ontario, the quantity and quality of measurements available to the public differs substantially across oversight bodies. This is not the case for either Australia or the U.K., where a central authority has been delegated the responsibility to regularly report on each of these metrics, providing a much more comprehensive and consistently applied approach across all categories of regulated health workers.

Table 8: Whether and how performance is measured and managed in Ontario and in select comparator jurisdictions

	Ontario	Ireland	New Zealand	Australia	U.K.
Primary bodies responsible for reporting metrics	• Professional regulatory colleges*	• Councils*	• New Zealand Health Practitioners Tribunal (for professions) • Professional boards and councils	• Australian Health Practitioner Regulatory Authority (for professions)	• Professional Standards Authority (for professional councils) • Professional councils (for professions)*
Registration indicators	• Number of new registered professionals • Number of active professionals • Students enrolled in accredited programs • Source of registrants • Periodic assessment of indicators related to transparency of	• Number of registered professionals	• Number of candidates who sat professional exams • Number of candidates who passed professional exams • Number of registered professionals • Status of registered professionals • Number of professionals	• Number of registrants by profession • Applications for registration by profession and by outcome • Number of open notifications • Change to status of open notification	• Number of health professionals in training for each regulatory council • Number of registered professionals • Registrants by profession • Status of registered professionals • Number of revalidated

	Ontario	Ireland	New Zealand	Australia	U.K.
	registration processes		practising within each scope of practice		professionals
Complaints and discipline indicators	• Public registry of complaints and outcomes (including pending and completed cases) • Number of hearings referred to a disciplinary committee	• Public registry of complaints and outcome	• Number of referrals to conduct committee • Number of referrals to the Health Practitioners Tribunal • Number of referrals to the performance-assessment committee • Source of referral for council meeting for performance processes	• Volume of notifications received by profession • Number of interim actions by outcome and by time frame • Number of notifications considered for acceptance and outcome of acceptance process • Number, timeliness and outcomes of assessments by profession • Number, timeliness and outcomes of investigations	• Volume of registered complaints • Public registry of all complaints and their outcomes • Volume of inquiries on professionals' fitness to practise • Volume of assessments of health professionals' fitness to practise • Volume of investigations of professionals' fitness to practise • Outcomes of complaint investigations • Source of complaints
Offence indicators	• None found	• Number of conditions imposed • Number of cancellations under the Health Practitioners Competence Assurance Act by outcome	• Number of professionals currently on probationary period • Number of suspended professionals • Number of orders of attendance at education program following performance assessment • Number, nature, source, and outcomes of professional charges	• Number of statutory offences by profession • Number of statutory offences by type and by outcome	• Number of statutory offences by profession

	Ontario	Ireland	New Zealand	Australia	U.K.
Monitoring and compliance indicators	• Number of applications open for reinstatement of registration (included in public registry) • Monitoring cases open by profession	• None found	• Monitoring cases open by profession	• Monitoring cases open by profession • Monitoring cases open by monitoring stream	• None found
Public engagement and transparency indicators	• Number of policy consultations • Number of calls taken through advisory services • Number of website visits and social media numbers	• Number of public consultations • Number of website visits • Number of individuals registered for newsletter	• None found	• None found	• Number of responses to public consultations

For those who want to know more about the systematic review and primary studies summarized under this element (or obtain citations for the review and primary studies), a fuller description of the systematic reviews and primary studies are provided in Appendix 3a and Appendix 3b.

Additional equity-related observations about the three elements

No reviews were identified that directly addressed any of the prioritized groups, but one of the single studies related to element 1 had insights that could be relevant to one of the groups (individuals who routinely seek care from health workers who are not regulated under the RHPA). Specifically, the study suggested that some health workers feared moving towards regulation, because it could affect:

1) how expensive it is to practise given the additional financial obligation to register with a college; and
2) the nature and scope of practice, as a result of tighter restrictions, which could result in challenges delivering the care patients seek.(6)

Taken together, these could have knock-on effects for the patients who seek care from health workers who are not currently regulated under the RHPA in the event they became regulated. Specifically, the first issue could affect how much it costs patients to access their services, and the second may result in significant restrictions that make it challenging for these health workers to continue providing the type of care sought by their patients.

IMPLEMENTATION CONSIDERATIONS

A number of barriers might hinder the implementation of the three elements of a potentially comprehensive approach to modernizing the oversight of the health workforce in Ontario. These barriers need to be factored into any decision about whether and how to pursue any given element (Table 9).

While potential barriers exist at the levels of the patients/citizens, health workers, organizations and the system, perhaps the biggest barrier (particularly to pursuing element 1) lies in gaining political consensus in government and, to the extent that the government feels it is needed, among workforce oversight bodies (and possibly among associations of health workers). The way in which health workers are overseen in the province provides many categories of them with a significant amount of autonomy, which some groups of them may feel is being threatened with a shift towards a new approach and warrants strong resistance.

One medium-quality systematic review found the following elements critical to success when changing governance arrangements in workforce oversight:

- a clear strategy;
- good leadership that focuses on communication and building trust;
- engaging all relevant stakeholders throughout the process;
- fostering a culture that supports the change and allocates resources to facilitate the change process; and
- a flexible and reasonably paced approach.(18)

Table 9: Potential barriers to implementing the elements

Levels	Element 1 – Use a risk-of-harm approach to health-workforce oversight	Element 2 – Use competencies as the focus of oversight	Element 3: Employ a performance-measurement and -management system for the health workforce and its oversight bodies
Patient/citizen	• None identified	• None identified	• None identified
Health worker	• Some categories of health workers may resist being grouped with other categories of health workers for fear of reducing their independence • Some categories of health workers may not agree with the approach chosen for how to assess risk of harm	• Some categories of health workers may be concerned that they will not be given as fulsome an opportunity to provide input in defining core competencies as other categories • Some categories of health workers may interpret expanding competencies to include soft skills such as professional demeanour as infringing on their autonomy to determine how they practise • Some categories of health workers may not agree with the chosen set of core competencies for each profession	• Health workers and their oversight bodies may oppose having more detailed information on their performance publicly available
Organization	• Some oversight bodies may resist changes that imperil their existence in the form they've operated in the past • Oversight bodies may have 'legacy' cases that will continue for some time after any transition	• Oversight bodies will likely be required to invest additional resources in updating performance-measurement standards to reflect a new competency-based approach	• Oversight bodies may resist the administrative burden of recording and reporting significant amounts of data • Oversight bodies may resist an additional layer of accountability that they may fear infringes on their autonomy

System	• Policymakers will face resistance among some vocal groups of health workers • Policymakers will face a one-time cost associated with making the change towards a risk-based approach	• Policymakers will likely be required to allocate additional resources towards updating performance-measurement standards to reflect a competency-based approach	• Policymakers will likely be required to allocate additional resources towards implementing a performance-measurement and -management system

Despite these challenges, there is a current interest in oversight mechanisms both in government and among stakeholders, which is a combination that does not regularly present itself (Table 10). Further, the coming election in 2018 may introduce a window of opportunity for introducing new oversight mechanisms. A large empirical study of policymaking processes found that two variables were consistently associated with large-scale policy reform in provinces across Canada: 1) electoral processes (e.g., new government or government leaders, campaign commitment to reform, appointment of a champion once in power, and a policy announcement in the first half of a mandate); and 2) presence of perceived fiscal crisis.(19) Both of these factors, combined with the current attention from government and stakeholders, are present in Ontario, making this an opportune time to discuss the current approach to the oversight of the health workforce and what if any changes need to be made.

Table 10: Potential windows of opportunity for implementing the approach elements

Type	Element 1 – Use a risk-of-harm approach to health-workforce oversight	Element 2 – Use competencies as the focus of oversight	Element 3 – Employ a performance-measurement and -management system for the health workforce and its oversight bodies
General	• The current focus on oversight mechanisms in the province, combined with the coming 2018 election may open a window of opportunity for a new approach to workforce oversight • Both variables that are associated with large-scale policy reforms are present in Ontario (i.e., electoral processes and presence of a perceived fiscal crisis)		
Element-specific	• Increased 'tightening' of resources in the health system may help to support a more efficient allocation of resources across oversight mechanisms	• Having already adopted a competency-based focus in certain professional regulatory colleges for the training and professional development of health workers may ease the transition towards a focus on competency-based oversight • Other jurisdictions (e.g., the U.K. and Australia) with whom Ontario often compares its health system have adopted a competency-based focus for workforce oversight	• Increasing transparency in relation to health workers and their oversight bodies may increase public trust

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APPENDICES

The following tables provide detailed information about the systematic reviews identified for each option. Each row in a table corresponds to a particular systematic review and the reviews are organized by element (first column). The focus of the review is described in the second column. Key findings from the review that relate to the option are listed in the third column, while the fourth column records the last year the literature was searched as part of the review.

The fifth column presents a rating of the overall quality of the review. The quality of each review has been assessed using AMSTAR (A MeaSurement Tool to Assess Reviews), which rates overall quality on a scale of 0 to 11, where 11/11 represents a review of the highest quality. It is important to note that the AMSTAR tool was developed to assess reviews focused on clinical interventions, so not all criteria apply to systematic reviews pertaining to delivery, financial, or governance arrangements within health systems. Where the denominator is not 11, an aspect of the tool was considered not relevant by the raters. In comparing ratings, it is therefore important to keep both parts of the score (i.e., the numerator and denominator) in mind. For example, a review that scores 8/8 is generally of comparable quality to a review scoring 11/11; both ratings are considered "high scores." A high score signals that readers of the review can have a high level of confidence in its findings. A low score, on the other hand, does not mean that the review should be discarded, merely that less confidence can be placed in its findings and that the review needs to be examined closely to identify its limitations. (Lewin S, Oxman AD, Lavis JN, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP): 8. Deciding how much confidence to place in a systematic review. *Health Research Policy and Systems* 2009; 7 (Suppl1):S8.

The last three columns convey information about the utility of the review in terms of local applicability, applicability concerning prioritized groups, and issue applicability. The third-from-last column notes the proportion of studies that were conducted in Canada, while the second-from-last column shows the proportion of studies included in the review that deal explicitly with one of the prioritized groups. The last column indicates the review's issue applicability in terms of the proportion of studies focused on modernizing the professional regulation. Similarly, for each economic evaluation and costing study and for primary studies, the last three columns note whether the country focus is Canada, if it deals explicitly with one of the prioritized groups and if it focuses on modernizing the professional regulation.

All of the information provided in the appendix tables was taken into account by the evidence brief's authors in compiling Tables 1-10 in the main text of the brief.

Appendix 1a: Primary studies relevant to Element 1 – Use a risk-of-harm approach to health-workforce oversight

Sub-element	Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
Develop a common definition of risk and determine how it should be applied to health workers	Implementation of a risk-based regulatory system and its use in health and social care (5)	*Publication date:* 2008 *Jurisdiction studied:* U.K. *Methods:* Health reform description	Health and social care providers working in the National Health System	Description of the 2005 and 2006 decision of the health commission of the National Health Service to implement a risk-based approach to quality assurance	The overview of the health reform described that regulators who adapt a risk-based approach either demonstrated or expected to attain the following benefits: optimizing use of resources; focus on risks; sound and consistent basis for justifying their approach and actions; and preventing adverse outcomes in terms of the tolerance for risk. Over the course of its implementation for three years, the new risk-based approach was found to result in improved efficiency by decreasing audit visits to 30% of establishments each year. The overview of the reform identified a number of issues and improvements that could be made to the risk-based approach that has been implemented in the U.K. These include: challenges defining and interpreting risk; adopting a robust and efficient surveillance system; ensuring there is continual updating of risks; fostering a risk-based learning organization; and the need to share information across regulators.
Use a risk-based approach to choose categories of health workers for oversight	Explore the experiences and perspectives of Ontario naturopaths, homeopaths and Chinese medicine practitioners as they passed through the transition to being regulated under the *Regulated Health*	*Publication date:* 2015 *Jurisdiction studied:* Ontario, Canada *Methods:* Cross-sectional survey	A total of 1,047 practitioners were identified and surveyed. Of these respondents, 273 naturopaths, 234 homeopaths, and 181 Chinese medicine practitioners were included, as they provided answers to the qualitative question about their opinions of the regulatory process,	In 2006 and 2007, the Ontario government announced that it would begin regulating naturopathy, homeopathy and traditional Chinese medicine/acupuncture practitioners under the *Regulated Health Professions Act, 1991*. To lay the framework for each profession's regulation, the Ontario government appointed a regulatory Transitional Council for each group. The	Overall, the practitioners had a pro-regulatory stance, with approximately three-quarters of all respondents showing significant support for regulation. Respondents believed that regulatory changes would enhance their occupations' credibility, increase availability of third-party insurance coverage for their services, and help protect the public from untrained practitioners. Despite this, quantitative findings across the naturopathic, homeopathic and Chinese medicine practitioner groups showed that many respondents (48%, 44% and 33% respectively) were worried about regulation. Overall, four themes emerged from the respondents' 'worries.' The first was that

Sub-element	Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
	Professions Act, 1991 (6)		which was the focus of the paper.	members of Transitional Councils consisted of both practitioners from within the profession being regulated, as well as 'general' members who were not practitioners. Although each of the three occupational groups were previously at notably different stages of professionalization, resulting in different trajectories for each group's regulatory process, the Ontario government took the step of regulating each of these groups around the same time. At the time of the study, Chinese medicine practitioners fully implemented their regulations (in April of 2013), whereas naturopaths and homeopaths were expected to complete this process in 2015.	the new regulation might produce an unwanted financial and administrative burden on practitioners, such as increased registration dues and paper work. The second worry was that it could detrimentally affect groups' practice scopes. Concerns regarding reduced scope predominated in naturopaths' survey responses, where concern around overlapping scopes repeatedly appeared in homeopaths' and Chinese medicine practitioners' responses. Thirdly, there were concerns that the new regulations might implement inappropriate or unfair registration standards. Homeopaths and Chinese medicine practitioners, groups that had no national education or regulatory standards at the time, were concerned about how regulations might assess practitioners' qualifications for professional entry and how such standards would be set, as there are many ways to practise that benefit the patient. Lastly, the fourth theme was that the new regulations might compromise occupational groups' paradigmatic foundations. For example, several homeopathic respondents expressed concern that with the new regulations, their profession may become less homeopathic and more medical.

Appendix 2a: Systematic reviews relevant to Element 2 – Use competencies as the focus of oversight

Sub-element	Focus of systematic review	Key findings	Year of last search	AMSTAR (quality) rating	Proportion of studies that were conducted in Canada	Proportion of studies that deal explicitly with one of the prioritized groups	Proportion of studies that focused on oversight models
Expand the use of competencies across all categories of health workers	Identifying tools to assess nursing competencies (8)	The review included seven studies that indicated the availability of some tools that allow for the assessment of clinical competences in nursing education. The review found that each jurisdiction has custom measures and tools for nursing competencies based on their national guidelines. The review highlighted that despite the existence of reliable tools to measure the extent to which nurses have adopted competencies, there is a clear need to move forward and develop common nursing competencies across jurisdictions and to allow for comparisons across graduates in different jurisdictions.	2013	4/9 (AMSTAR rating from the McMaster Health Forum's Impact Lab)	0/7	0/7	7/7

Appendix 2b: Primary studies relevant to Element 2 – Use competencies as the focus of oversight

Sub-element	Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
Develop a process to get input from citizens, health workers and existing oversight bodies about how to define the core competencies for each category of health worker	Advocate for implementation of core competencies in pain assessment and management, and provide recommendations for how to incorporate the competencies into entry-level nursing curricula (12)	*Publication date:* 2015 *Jurisdiction studied:* U.S. *Methods used:* Description of consensus-building process, informed by a literature review to develop core competencies for pain management	Assessment of 21 core pain assessment and management competencies	There were a total of 21 core pain assessment and management competencies that were grouped into four domains These domains are: (a) Multidimensional nature of pain: What is pain?; (b) Pain assessment and measurement: How is pain recognized?; (c) Management of pain: How is pain relieved?; and (d) Context of pain: How does context influence pain management? The author suggested that when assessing competency, multiple measurement points of varying complexity should assess the student in varying environments and with diverse cases.	Several studies have identified deficits in nursing knowledge and skills related to pain management. This inadequate pain education is a barrier to providing high-quality pain care to the population. The authors offered several strategies for integrating the pain competencies into pre-licensure nursing education. These included: asking students to share their own experience about pain (for domain one); using pain assessment tools during clinical experiences and discussing the benefits and limitations of each tool for specific populations (for domain two); including pain-related content in pharmacology courses and specific discussions around non-opioids, opioids, and adjuvant analgesics (for domain three); and having students attend support group meetings for individuals with chronic pain disorders (for domain four). The authors also note challenges that exist that hinder the progress of the pain-education agenda. These challenges may arise from the lack of appreciation of the consequences of pain in addition to the seasoned health professional attitudes and behaviours regarding pain. Furthermore, there may also be resistance from educators about adding new content into existing and packed curricula. The authors recommend interactive, problem-based curricula centred on competencies to facilitate greater student learning. This requires learning and knowledge assessment to shift from traditional disease-related topics, such as anatomy and physiology, to performance and patient outcomes in real-world contexts. The author further explains that competencies need to evolve, and be dynamic and representative of the increasing complexity of pain and assessment for patients across the lifespan and in differing contexts. This requires supportive

Sub-element	Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
					context, administrative support, and effective facilitation methods. Meeting the core competencies in pain management will improve pain care in the U.S. and help nurses be stronger partners in interprofessional teams committed to quality pain care.
Expand the use of competencies across all categories of health workers in education programs preparing candidates for entry to the profession	Implementation of competency-based education in plastic surgery (13)	*Publication date:* 2014 *Jurisdiction studied:* Canada *Methods used:* Non-systematic review and development of a theoretical framework	The study reviews the current state of literature on competency based education and documents the development of a competency-based curriculum in plastic surgery	No intervention was used to conduct this study.	The study reviews the adoption of competency based education by the Royal College of Physicians and Surgeons of Canada, finding that competency-based medical education may accelerate training, allow progress that is based on individualized learning curves and improve standardization among residency programs. The study highlights five themes related to the resistance of implementing competency-based medical education, these are: lack of interest in change; concerns regarding evidence; administrative burden; financial concerns; and balancing service requirements with education. However, the study notes that changes to the current learning environment are making traditional instructional methods less effective and instead refers to literature that has found simulation laboratories to be successful for supplementing skills training. The study defines a nine step framework for the development of competencies which includes: establishing need to develop competencies; forming a committee; literature review; consultation with experts and educational specialists; draft competencies; consensus exercise; revise competencies; circulate competencies among stakeholders; and finalize and continually review competencies.
	Explore staff and candidates' experiences of using values and competency-based interview selection methods for	*Publication date:* 2016 *Jurisdiction studied:* U.K. *Methods used:* Mixed methods of focus groups, interviews	Staff participants included eight human resource staff, one values and competency-based interview training provider, and 12 senior National Health	Values and competency-based interviews are used as a method to select nursing, midwifery and allied health professionals. This style of interview is a more rigorous and robust process in selecting candidates, and to	All participants viewed values and competency-based interviews as a positive change to the selection process. Participants felt that the values and competency-based interviews resulted in higher-quality candidates at the application stage, improved quality of interviews, empowered panel members, and was more accurate in identifying strong candidates. Despite this, participants saw some challenges, including difficulty in designing

Sub-element	Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
	nursing, midwifery and allied health professionals (11)	and questionnaires	Service (NHS) leaders who had either been an interview panel chair, or interview panel member, for nursing, midwifery and allied health professional (NMAHP) selections in the past year. Additionally, 12 candidates provided feedback.	succeed, candidates are required to provide examples of each competency from their past experiences as a part of their applications and interviews. It is thought that exploring past behaviour is more effective at predicting future behaviour compared prospective questioning.	values and competency-based interview questions, difficulty conducting the interviews, amount of time required to prepare for and conduct interviews, non-attendance by candidates, and guiding candidates who struggled with the interview format. Additionally, limitations were also noted by participants, primarily candidates' lack of awareness and understanding of what was required to succeed in values and competency-based interviews. Overall, from the 12 candidates who interviewed, they all perceived their VCBI experience as positive and welcomed the new style of interview. Candidates who undertook a second values and competency-based interview had clear expectations of the process and found the overall process more comfortable.
	Describe the process used by 10 Canadian jurisdictional regulatory bodies to determine standardized entry-level competencies for registered nurses (9)	*Publication date:* 2008 *Jurisdiction studied:* Canada *Methods used:* Description of the process for developing and refining competencies for registered nurses	Provincial nursing regulatory bodies within Canada	Project participants held monthly teleconferences, exchanged electronic communications, and formed sub-working groups to advance discussion. Two face-to-face meetings were held to write the competency statements themselves. RNs and regulatory body staff regularly contributed input in the form of surveys and focus groups.	The result of the collaborative work among the 10 Canadian regulatory bodies was a comprehensive document of 119 competency statements organized in a standard-based framework of five categories: professional responsibility and accountability; knowledge-based practice; ethical practice; service to the public; and self-regulation. Project participants attributed their success to several factors. First, the clear yet broad mandate gave the participants the flexibility to decide on detailed goals, working processes and plans. Second, participants found that the work plan, which took the form of a visual chart with work components and targeted timelines, was extremely useful in keeping the project on track. Participants also emphasized the importance of enthusiasm and support from project contributors and leadership. At the time of the article's publication, these common competencies had not yet been implemented, with

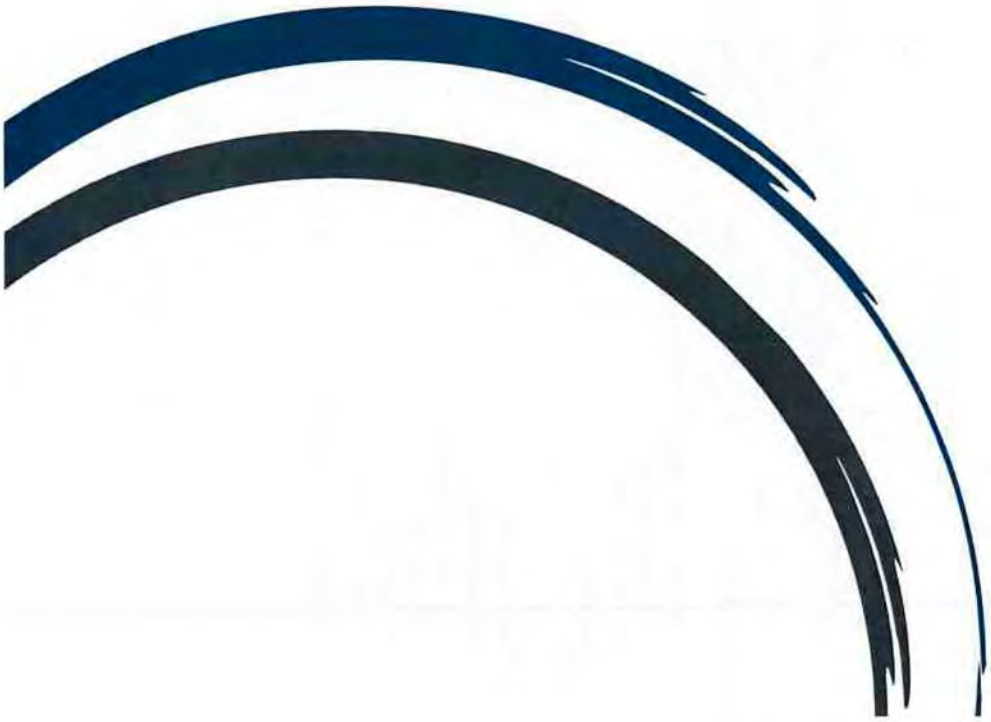
Sub-element	Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
					each jurisdiction reviewing the document to determine how best to use the generated competencies in their jurisdictions.
Expand the use of competencies across all categories of health workers in training programs preparing candidates for entry into a specialty	Implementing a competency-based program for medical residents in Canada (10)	*Publication date:* 2016 *Jurisdiction studied:* Alberta, Canada *Methods used:* Between-group analysis of preceptors' evaluations of residents' skills/abilities	The study involved residents in the Care of the Elderly Diploma Program of the Department of Family Medicine at the University of Alberta. Nine residents training from 2007-2009 were part of the pre-intervention period, while eight residents training from 2010-2013 were in the post-intervention period.	The Care of the Elderly (COE) Diploma Program is a six-to-twelve-month program that provides supplementary training on geriatric care to family physicians. This program was originally based on learning objectives (LO), but was redesigned in 2010 to focus on 85 core competencies (CCs) over 12 domains instead. The intervention is defined as the implementation of the CC COE Diploma Program in 2010.	There was no difference in the overall residents' learning between the LO and CC programs. However, differences were seen when examining the CanMEDS roles individually. For the Family Medicine Expert role, the average evaluation score was higher for male residents in the LO program, and higher for female residents in the CC program. For the Communicator/Collaborator/Manager and Scholar roles, the average evaluation score was significantly higher for residents in the CC program than the LO program. For the Professional/Advocate role, there were no significant differences between the two programs. Evaluation scores in the LO program were far more variable than the scores in the CC program for the Family Medicine Expert and Communicator/Collaborator/Manager roles. For training experience, the admission process and evaluation process of the residents, and orientation to the program were rated significantly higher in the CC program than the LO program. Ratings for the other seven components did not vary significantly between the two programs.

Appendix 3a: Systematic reviews relevant to Element 3 – Employ a performance measurement and management system for the health workforce and its oversight bodies

Sub-element	Focus of systematic review	Key findings	Year of last search	AMSTAR (quality) rating	Proportion of studies that were conducted in Canada	Proportion of studies that deal explicitly with one of the prioritized groups	Proportion of studies that focused on oversight models
Developing metrics that allow citizens and policymakers to judge and, when needed, demand improvements to the performance of the health workforce or its oversight bodies	Approaches to regulating healthcare complaints and disciplinary processes (16)	The review included 118 studies that examined patterns of complaints to regulatory colleges. The review found that most complaints involved an adverse event, of which 93% were preventable. The review cited one study that found that one of every 200 people who had cause to complain actually registered a complaint with the Commissioner. The studies included in the review also provided insights into those who do and do not complaint. Certain socio-demographic factors lead to a greater likelihood of complaining, with non-complaints being higher among those who are elderly, live with a disability, reside in a socio-economically deprived area, or live in a rural community. One study cited in the review found that people may not complain for three primary reasons: perceived futility of the complaints process; poor knowledge about how to complain; and feeling too weak to go through the process. Generally, there is evidence that complaint rates are low when compared to preventable adverse events and that those involved in the events are far more likely to complain informally rather than formally. Further, there are significant variations between the formal complaints process and outcomes depending on the jurisdictions and regulatory body.	Not reported in detail	3/9 (AMSTAR rating from McMaster Health Forum)	Not reported in detail	Not reported in detail	118/118

Appendix 3b: Primary studies relevant to Element 3 – Employ a performance measurement and management system for the health workforce and its oversight bodies

Sub-element	Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
Developing metrics that allow citizens and policymakers to judge and, when needed, demand improvements to the performance of the health workforce or its oversight bodies	Mandatory reporting on the performance of health professionals (14)	*Publication date:* 2014 *Jurisdiction studied:* Australia *Methods used:* Retrospective review of allegations of health professional misconduct	A total of 819 mandatory notifications made of professional misconduct between January 2011 and December 2012	Multivariate analysis of allegations of misconduct involving health professionals	The study found that of 819 mandatory notifications made, 501 related to a breach of accepted professional standards. These were largely deviations from set standards of clinical care. The study found that nurses and doctors were responsible for the majority of reports, both in the role of those notifying and those responding. Psychologists had the highest rate of notifications, followed by physicians, nurses and midwives. Notifications were made against male providers more frequently than female providers.
	Primary care performance measurement framework for Ontario (17)	*Publication date:* 2017 *Jurisdiction studied:* Ontario *Methods used:* Summit meeting of senior leaders from key primary care data collectors to discuss performance measurements informed by an environmental scan of primary care performance measurement in Ontario	Environmental scan of 19 performance measurement frameworks, initiatives and data sources in Ontario	Facilitated discussion of findings from the environmental scan and performance measurement priorities in Ontario	Following the summit of senior leaders in Ontario, specific measures for the measurement priorities were selected in eight domains of the primary care performance measurement framework: access; integration; efficiency; effectiveness; focus on population health; safety; patient centeredness; and appropriate resources. Within each o the eight domains, a series of specific measurements have been developed. These include measurements at both the system and practice level. The study notes a number of lessons learned in the process of developing these measurements. These include: the importance of stakeholder engagement; tapping into experience and expertise of patients and family caregivers; and consensus building is often time-consuming and resource-intensive.



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Promoting professionalism, reforming regulation

A paper for consultation

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Foreword

The regulation of healthcare professionals must change in order to protect patients, to support the transformation of our healthcare services and to meet future challenges. It needs to be faster, simpler, better and less costly.

When people access healthcare, they trust that the professionals they encounter are properly trained and qualified, that they will treat them with dignity and respect, and that they will not mistreat or harm them.

Professional regulation is central to the systems of assurance that underpin this trust. The nine regulatory bodies that regulate healthcare professionals across the four countries of the United Kingdom (UK) are the gatekeepers to the professions that they regulate. They set the educational requirements needed to enter a profession and the standards required to practise safely and effectively in each profession. They keep registers of people who meet these standards, are qualified and fit to practise. The regulators also set the standards of conduct, performance and behaviour required of professionals and take action where these standards are not met.

As such, they not only oversee the professionalism of every individual practitioner that they register, but are the guardians of the ethos and culture of each profession as a whole. As the professions adapt to the opportunities and challenges of the economic, demographic, technological and epidemiological changes of the coming decades, it is vital that the professional regulators are able to respond to these changes. They must be able to lead the adaptation of professional standards to the changing realities of ensuring safe, effective and respectful clinical care in a way that is efficient, effective and affordable.

There are approximately 1.5 million people registered to practise in the healthcare professions regulated by statute in the UK. The system we have today is a historical patchwork, periodically mended and amended, with different aspects of the resulting regulatory regime reflecting the particular concerns and constraints of the time they were reformed. As a result there is inconsistency, in both practice and legislation.

While the healthcare regulators are generally effective in protecting the public from serious harm, there has been criticism, not least from the regulators themselves, that the system is slow, expensive, complicated, reactive, overly adversarial and confusing for patients, professionals and employers. This complexity makes it difficult for the regulators to operate as effectively and efficiently as they would wish. It also makes it difficult for patients to know when and how to raise concerns about the care provided by a healthcare professional.

Better and more responsive healthcare professional regulation is a shared ambition for both the regulators and all four UK governments.

The way that healthcare is delivered across the UK is changing. In England the NHS *Five Year Forward View*[1] has set out a blueprint for how to meet the challenges that face the healthcare system as a result of a growing, ageing population and advances in medicine and clinical practice. In Scotland, *A National Clinical Strategy*[2] sets out how clinical services will support sustainable health and social care services. In Northern Ireland, *Health and Wellbeing 2026: Delivering Together*[3] sets out a 10 year vision for transformation of the health and social care system to ensure the best possible outcomes for patients. In Wales the approach to prudent healthcare is aimed at ensuring the delivery of healthcare that fits the needs and circumstances of patients and actively avoids wasteful care that is not to the benefit of patients.

The UK's healthcare workforce needs to change to meet the challenges set out in these plans. Future workforce strategies will focus on the development of innovative health and care roles and ensuring that professionals have the flexibility to work across traditional boundaries. We need a UK-wide system of professional regulation that contributes to the delivery of this ambition and supports the development of high quality professionals. This needs to be complemented by a culture that enables professionals to learn from their experiences, including from their mistakes. All too often professionals encounter a culture of blame rather than learning.

This consultation considers what reforms are needed across the UK healthcare regulatory system in order to support workforce development while maximising public protection in a more efficient way. The four UK governments want to take this opportunity to design a flexible model of professional regulation which secures public trust, fosters professionalism and improved clinical practice, while also being able to adapt swiftly to future developments in health care.

We look forward to hearing the views of patients, the public, employers and professionals, as well as the regulatory bodies, on the direction and proposals contained in this document.

Executive summary

The UK's model of professional regulation has its roots in a system of self-regulation in which professionals themselves were largely responsible for policing their own conduct, performance and behaviour. This system lacked independence and transparency. Through a series of reforms over recent decades a system of independent regulation, in which both the public and professionals have oversight of regulation, has been put in place. Regulation is now more transparent, the processes of the regulatory bodies are more robust and it is expected there are higher levels of patient, public and professional confidence.

Alongside this, new measures have been put in place to provide assurance of those healthcare practitioners practising in unregulated professions. The Health and Social Care Act 2012[4] established the Professional Standards Authority for Health and Social Care (PSA)'s accreditation scheme for voluntary registers. Designed to complement statutory regulation, the PSA accredits organisations that register health and social care practitioners who are not regulated by law.

Where once regulatory bodies may only have contacted professionals at the point of registration, to collect fees or, rarely, to investigate a complaint, now professionals are in more regular contact with their regulator checking their continuing competence and supporting their professional development. Measures have been introduced through revalidation and other systems to assure continuing fitness to practise. This provides assurance that professionals continue to have the necessary level of competence and demonstrate the right behaviours to deliver high quality care throughout their careers.

However, the regulators continue to be hampered by a legislative framework that is in parts more than 150 years old and with outdated procedures that have not kept pace with changes in the health and social care system.

From the perspective of patients and the public, the current system of regulation can be confusing, inconsistent and slow. People are not always clear which professionals are regulated by which regulatory body or against which standards. Staff working side by side in teams might be accountable to different bodies and working to different sets of standards. Different regulators might impose different sanctions for similar professional failings. Employers have to interact with numerous different professional regulators.

The current model of professional regulation deals with complaints about professionals in a largely reactive way, with a strong emphasis on dealing with concerns about a minority of registrants at the expense of supporting the vast majority. Investigations into allegations made about professionals to their regulators (known as fitness to practise procedures) are lengthy and can be frustrating for patients, registrants and employers. Having such an adversarial fitness to practise system at the centre of the regulatory bodies can affect their outlook and culture and does not support early identification and resolution of concerns. This needs to change.

The emphasis on dealing with concerns about registrants after issues have been raised limits the ability of the regulators to support the professional practice of their registrants before problems occur. Similarly, it can inhibit professionals from taking part in safety investigations because of a fear that information from such processes could lead to a fitness to practise referral.

While fitness to practise must remain a key function for the regulators, giving them powers to handle fitness to practise cases in a proportionate way will allow for a more preventative and supportive approach. This will provide the time and resources for regulators to support the ongoing professional development of all registrants.

In future we expect the professional regulators to work in partnership with employers and higher education providers to ensure that the recruitment, education and training systems they assure and operate are delivering the right people, that they are teaching the right things (through both the formal and informal curricula) and that behavioural problems identified early in a professional's career are properly addressed.

In taking forward reform of regulation of healthcare professionals, the four UK governments have five objectives. These are to:

- improve the protection of the public from the risk of harm from poor professional practice;
- support the development of a flexible workforce that is better able to meet the challenges of delivering healthcare in the future;
- deal with concerns about the performance of professionals in a more proportionate and responsive fashion;
- provide greater support to regulated professionals in delivering high quality care; and
- increase the efficiency of the system.

As part of this, the four UK governments need to examine which professions should be regulated on a statutory footing. The case for regulating some professions such as doctors, nurses, midwives and pharmacists on a statutory basis is clear. For other professions this is less obvious.

There is no clear rationale for the current position of having nine regulatory bodies. Some regulators have a large number of registrants and others have relatively few. Research suggests that efficiencies begin to accrue when a regulatory body has a registrant base of between 100,000 and 200,000[5]. Five of the regulatory bodies are smaller than this, contributing to additional costs of the regulatory system. In order to simplify the system, foster greater consistency and reduce costs, the four UK governments believe there is need for radical change. The four UK governments would be keen to understand what form a system containing a reduced number of regulators (possibly to three or four) might take.

Meeting the challenge of the changing healthcare systems in each of the four UK countries requires a regulatory system that supports the development of new models of care and more flexible professional roles. This means ensuring that regulators are able to respond quickly to changes in the way that healthcare is delivered without having to wait for changes to legislation. Giving the regulatory bodies greater autonomy to innovate, balanced with more effective accountability, will help to deliver this.

Through this consultation the four UK governments want to draw on the knowledge, skills and experience of those working in the sector and those using its services. We are seeking views on the approach and proposals set out in this document. These views will inform decisions on how to reform healthcare professional regulation. In particular we want to:

- design a more responsive model of professional regulation which can swiftly adapt to changing patterns of healthcare, develop new roles and new ways of working without the need for frequent legislative change;
- establish clear criteria to assess which level of professional regulatory oversight is appropriate for different professional groups;
- consider whether the current number and set up of healthcare regulatory bodies is delivering effective and efficient public protection;

- ensure that regulatory bodies have a consistent and flexible range of powers that allow them to take a prompt and proportionate approach to concerns about an individual's fitness to practise;
- enable regulators, working with professional bodies and others, to better support professionalism among registered groups and to provide assurance on an ongoing basis that practitioners are competent and up to date; and
- increase joint-working, sharing functions and services between the regulators.

1. Introduction

1.1. The primary purpose of the regulation of healthcare professionals is to protect patients and the public from harm. Health professionals are regulated in order to ensure that they have the skills, competence, health and attitudes that command public trust and patient confidence. Regulatory bodies:

- keep a register of qualified professionals who are fit to practise so that patients and service users know who is and who is not qualified;
- set the outcomes required from undergraduate (and in some cases postgraduate) education and training that must be met before registration is granted, as well as inspecting education and training providers;
- set the standards of conduct, performance and behaviour expected of a registered professional so that professionals deliver care safely and effectively;
- operate a system to ensure that registered professionals continue to meet those standards, that their knowledge and skills are up to date, and they remain fit to practise; and
- take action to restrict the practice of a registered professional where the required standards of conduct, performance and behaviour are not met

1.2. The UK Parliament is responsible for the regulation of health professions in England and Wales. Regulation of health and care professionals is a devolved matter in Northern Ireland. In Scotland it is devolved for health professionals who entered regulation after the passing of the Scotland Act 1998[6]. This consultation is supported by all governments in the UK.

1.3. There are 32 professions regulated by nine independent healthcare professional regulators. A further 55 occupations are covered by 24 accredited voluntary registers. As outlined in the 2007 Government White Paper *Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century*[7] the independence of the regulatory bodies is vital 'to sustain the confidence of both the public and the professions through demonstrable impartiality. Regulators need to be independent of government, the professionals themselves, employers, educators and all the other interest groups involved in healthcare'. Table 1 below lists the professional regulatory bodies and the professions regulated by each of them.

Table 1: List of Professional regulatory bodies and regulated professions

Regulatory body	Acronym	Professions regulated	Number of registrants (including premises where applicable) 2015/16
General Chiropractic Council	GCC	Chiropractors	3,109
General Dental Council	GDC	Dentists Clinical dental technicians Dental hygienists Dental nurses Dental technicians Dental therapists Orthodontic therapists	108,209
General Medical Council	GMC	Medical practitioners	273,761
General Optical Council	GOC	Optometrists Dispensing opticians Student optometrists Student dispensing opticians Optical businesses	29,136
General Osteopathic Council	GOsC	Osteopaths	5,102
General Pharmaceutical Council	GPhC	Pharmacists in Great Britain Pharmacy technicians in Great Britain Pharmacy business premises in Great Britain	89,377
Health and Care Professions Council	HCPC	Arts therapists Biomedical scientists Chiropodists/podiatrists Clinical scientists	341,745

		Dietitians Hearing aid dispensers Occupational therapists Operating department practitioners Orthoptists Paramedics Physiotherapists Practitioner psychologists Prosthetists/orthotists Radiographers Social workers in England Speech and language therapists	
Nursing and Midwifery Council	NMC	Nurses Midwives	692,550
Pharmaceutical Society of Northern Ireland	PSNI	Pharmacists in Northern Ireland Pharmacy business premises in Northern Ireland	2,852

1.4. Most of the regulatory bodies cover the whole of the UK. The exception to this is the GPhC which regulates pharmacists and pharmacy technicians in England, Scotland and Wales, and the PSNI which regulates pharmacists in Northern Ireland. Additionally the GPhC and the PSNI regulate pharmacy business premises and the GOC regulates optical businesses. The PSNI also has a professional leadership function that the other regulators do not.

1.5. The Children and Social Work Act 2017 received Royal Assent on 27 April 2017. The Act sets the legal framework and paves the way for regulatory reforms that will enable government to establish a new body corporate, Social Work England, which will be a new, bespoke regulator for the social work profession. The Act underpins the Government's ambition to improve the practice of social work and raise the status of the profession. Social Work England will ensure a relentless focus on social work practice – from initial education and training, to continuing professional development. This will be crucial to driving up the quality of social work practice. Reforming regulation in this way is a key plank of the government's stated ambition to improve the status and standing of the social work profession. This approach will be aligned with the principles behind the approach to regulation of all health and social care professions.

1.6. The work of the regulatory bodies is overseen by the PSA. The PSA scrutinises the work of the regulatory bodies by:

- reporting on the performance of the regulators on an annual basis;

- auditing decisions made during investigations into complaints about a registrant's practice;
- making referrals (or appeals) to the relevant court if it considers that a final fitness to practise decision does not protect the public;
- undertaking research and sharing best practice; and
- undertaking special investigations and providing advice to health ministers in all four UK Governments on regulatory issues.

1.7. The PSA's role will need to evolve to reflect changes in professional regulation and we have included questions on this in this consultation.

1.8. The PSA has published proposals for reform to ensure professional regulation is fit for the future (*Regulation Rethought*, October 2016)[8]. A summary of its proposals are set out in Table 2.

The Law Commissions' review of professional regulation

1.9. The Law Commissions of England and Wales, Scotland and Northern Ireland published a comprehensive review of the legal framework for professional regulation in the UK in 2014[9]. Alongside this, it also published a draft Bill. The reforms recommended by the Law Commissions aimed to consolidate and simplify the existing legal framework and impose greater consistency across the regulators in some areas, such as the conduct of fitness to practise hearings.

1.10. The government published its response to the Law Commissions' report in January 2015.[10] This consultation builds upon the Law Commissions' recommendations. In the majority of cases there has been no change in the government's position. A summary of where the government's original position on the Law Commissions' recommendations is being reconsidered through this consultation is at Annex A.

Pre-consultation events

1.11. To prepare for this consultation the four UK governments held a series of stakeholder engagement events throughout the United Kingdom during summer 2016. Nearly 400 people attended five events, including representatives of all four UK governments, regulatory bodies, professional bodies, patient representatives, high street employer representatives, NHS and social care organisations. Discussions took place to gather views and opinions and to identify potential areas for reform.

1.12. These events identified three key themes, which are covered in the following chapters:

- protecting the public;
- responsive regulation; and
- efficient regulation.

Table 2: Key PSA proposals in *Regulation Rethought* (2016)

Theme	**Professional Standards Authority proposal**
Shared Purpose	Agreement should be achieved regarding a common purpose across the professional regulatory sector. This should be informed through exploration of a common interpretation of regulation and the scope for harmonisation and agreement of common outcomes. There should be adoption of plain English in public-facing communications.
Single Register	Establishment of a shared public-facing register of all health and care professions and occupations.
Common Standards	Agreement on a statement of professional practice, i.e. common professional standards agreed by consensus between regulators and accredited voluntary register holders to apply to all registrants whether licensed or not. Profession/occupation-specific standards should be developed only where needed.
Licensing	Establishment of a licensing regime should be investigated. Language change should be adopted to align with a licensing process, similar to the Driver and Vehicle Licensing Authority. This should be informed through exploration of the scope for issuing licences within existing legislation and proportionate approaches to different professions.
Fitness to Practise	There should be adoption of a shared approach to key elements of the fitness to practise procedures; e.g. the investigation, prosecution and adjudication stages of a case (building on the Medical Practitioners Tribunal Service). Work should be undertaken to explore the scope to further harmonise sanctions and to explore the scope for achieving a more inquisitorial approach within the existing sets of legislation. Regulators should seek to use clearer, more public-focused language. There should be further co-operation with employers to achieve local resolution at an earlier stage where possible.
Co-operation with Others	There should be greater implementation of co-operative working, in particular to use regulatory data and insight in partnership with others to reduce harm.
Education	Work should be undertaken to explore and implement a new approach to align with the licensing regime, based on an assessment of the applicant. There is scope for greater harmonisation of standards and approach to education. Education should be reviewed in view of current and future needs.
Cost-effectiveness	Greater accountability should be introduced for regulators to ensure cost-effective working, including formal assessments of regulators' cost-effectiveness and efficiency.
Right-touch Assurance	Implement the methodology set out in Right-touch assurance: a methodology for assessing and assuring risk of harm.

Source: Regulation Rethought, PSA, 2016

2. Protecting the public

2.1. This chapter considers the architecture of professional regulation: how to decide the right level of regulatory oversight for professional groups and which regulatory bodies have oversight of which professions. Decisions about regulation have to be based on the risk of harm. The case for regulating doctors, nurses, midwives and pharmacists on a statutory basis seems clear. For other professions, particularly new professions, the need for statutory regulation is less clear.

2.2. There are currently no formal criteria for determining an appropriate level of regulatory oversight. As a result, professions have been brought into statutory regulation on what can appear to be an ad hoc basis. The HCPC is the only regulator that has the legislative power to recommend that a group should be statutorily regulated. As the HCPC has traditionally been the regulatory body to assume regulatory oversight of new groups, it could be seen to have a vested interest in expanding its registrant base. We therefore believe that the PSA, working with relevant stakeholders, would be better placed to provide advice on the regulation of professions. The ultimate decision regarding whether a group should be regulated would remain with Ministers. While the UK governments recognise that the PSA has powers to accredit voluntary registers, it is not believed this will create a conflict of interest.

2.3. The regulation of healthcare professionals should be used proportionately and only where the risks to public and patient protection cannot be addressed in other ways (for example through employer oversight or accredited registers). Without applying a clear criteria professions could be regulated inappropriately

2.4. Measuring the risk posed by any particular group of professionals is not easy, particularly in healthcare where professionals face complex situations on a regular basis. Establishing clear criteria to assess the appropriate level of oversight will bring consistency to the decision-making process, helping to ensure that patients and the public receive the right level of protection without placing unnecessary burdens on front-line staff or financial burdens on registrants.

2.5. The PSA has set out proposals for assessing whether professional groups should be regulated[11]. It has proposed a two stage assessment.[12] The first stage considers evidence of risk of harm in three key areas. These are:

- the complexity of the activities/intervention undertaken;
- where the intervention occurs (for example in a hospital or someone's home); and
- the vulnerability/autonomy of the patient and their ability to make an informed choice about their care.

2.6. The second stage considers wider external policy factors. These could include:

- the scale of the risk - the size of the professional group or number of patients who are treated;
- means of assurance - the range of different ways in which the risk of harm can be reduced;
- sector impact - the impact that regulation (or other means of oversight) would have on cost and supply of the workforce;
- risk perception - the effect that regulation (or other means of oversight) would have on the confidence levels for the relevant profession; and
- unintended consequences of the preferred form of oversight.

2.7. This two stage approach to assessing risk would create a risk profile for each professional group to support decisions about the appropriate level of regulatory professional oversight. This model could be applied to all professional groups, including those which are currently subject to statutory regulation, new and emerging professions and existing professions that are not regulated.

2.8. The PSA[13] has outlined a range of different types of assurance, on a continuum from routine employer controls to credentialing and voluntary systems of registration. Statutory regulation and licensing is the most stringent form of regulation and should only be applied to higher risk occupations.

2.9. In addition, the Law Commissions recommended that regulatory bodies be given powers to operate a form of negative register through the use of prohibition orders for those groups not subject to statutory regulation. Such a scheme allows individuals to be barred from practising a specified profession or from carrying out specific activities and would set the standards required of a certain occupation. Where these standards were not met in a way that places the public at risk of harm, the relevant regulatory body would issue a prohibition order that would prevent or restrict an individual from carrying out a certain role or providing certain services. A breach of such an order could be a criminal offence and employers could be required to check the register of those issued with prohibition orders.

2.10. The PSA published *Initial evaluation of the feasibility of prohibition order schemes for unregulated health and care workers in the United Kingdom*, December 2016[14]. A review of the use of prohibition orders has found that there is insufficient evidence on which to draw a conclusion about their effectiveness in a health context. The four UK governments are considering whether prohibition orders should be used as a regulatory approach for some groups of healthcare professionals.

Q1: Do you agree that the PSA should take on the role of advising the UK governments on which groups of healthcare professionals should be regulated?

Q2: What are your views on the criteria suggested by the PSA to assess the appropriate level of regulatory oversight required of various professional groups?

Q3: Do you agree that the current statutorily regulated professions should be subject to a reassessment to determine the most appropriate level of statutory oversight? Which groups should be reassessed as a priority? Why?

Q4: What are your views on the use of prohibition orders as an alternative to statutory regulation for some groups of professionals?

Number of regulatory bodies

2.11. There are currently nine regulatory bodies, which range significantly in terms of numbers of individuals regulated and number of professions regulated. Some regulators regulate just a few thousand professionals while others regulate several hundred thousand. The HCPC regulates 16 professions, the NMC regulates two, while others regulate just one profession. As well as regulating professions, the GPhC and the PSNI regulate pharmacy business premises and the GOC regulates optical businesses.

2.12. The four UK governments believe there is a case for exploring a reduction in the number of regulatory bodies, possibly to three or four. A reduction in the number of regulators would deliver a more consistent approach to regulation as well as delivering

savings in the cost of regulation. Having fewer regulators would simplify the landscape, making it clearer to employers, patients and the public who to contact when they have concerns. Fewer regulators would bring greater consistency of standards and in the fitness to practise decision-making process, achieving a fairer outcome for all. In addition fewer, larger regulatory bodies would be able to engage more effectively with all four of the UK governments.

2.13. The proposed role of the PSA in recommending which professional groups should be regulated will help inform decisions about how many regulatory bodies there should be and which professions they should regulate.

2.14. Reconfiguring the regulatory bodies has the potential to lead to:

- greater clarity for patients and their families/carers about which organisation to contact for what reason, and what can be expected from the process;
- a clearer system of professional regulation that delivers more effective public protection;
- greater consistency of approach for the regulatory bodies based on a consistent and flexible set of powers; and
- maximising the economies of scale that can be achieved by larger bodies.

2.15. The four UK governments are seeking views on the principles around reducing the numbers of regulatory bodies and will consider whether to develop proposals for a reduced number of regulators in light of responses to this consultation.

Q5: Do you agree that there should be fewer regulatory bodies?

Q6: What do you think would be the advantages and disadvantages of having fewer professional regulators?

Q7: Do you have views on how the regulators could be configured if they are reduced in number?

3. Responsive regulation

3.1. The UK's system of professional regulation needs the flexibility to adapt to new ways of working and to respond appropriately to individual cases. Increasing the responsiveness of the regulatory system will deliver improvements in three main areas:

- investigating and resolving complaints about registrants' fitness to practise more quickly while maintaining high standards of public protection;
- supporting the professional development of registrants in order to prevent problems emerging or escalating; and
- responding faster to healthcare delivery and workforce developments.

3.2. This chapter considers what improvements can be made to the system of investigating and resolving fitness to practise complaints. It also considers what more the regulatory bodies can do to support the professional development of registrants, ensuring the right training is in place to foster the right behaviours and deliver high quality healthcare. The proposals in this chapter are not dependent on the changes to either those groups that are regulated or to the number of regulatory bodies.

3.3. Increasing the responsiveness of professional regulation is not a new idea. The regulatory bodies have already made changes that allow them to work more flexibly. For example the introduction of case examiners who make decisions at the end of the investigation stage of the fitness to practise process at the GMC, the NMC, the GDC and the GOC has led to more consistent decisions being made more quickly. Additionally, the ability of some of the regulators to consensually dispose of cases, for example through the use of undertakings, has sped up the fitness to practise process with fewer cases proceeding to full hearings. This kind of flexible approach should be available to all of the professional regulators.

3.4. A range of flexible powers for the fitness to practise processes will not only mean that individual cases can be safely resolved more quickly but it will also allow the regulatory bodies to devote more of their time to supporting the professionalism of all registrants.

3.5. Regulators must be attuned to the circumstances in which they operate. Services continually evolve, appetite for risk varies and professional responsibilities change and the regulators need to remain responsive to this changing environment.

3.6. The GDC has identified a number of factors that can impact on the ability of professional regulators to operate efficiently. Appreciating these factors is essential to understanding where regulators can intervene to support professionalism ahead of problems occurring. How these factors interact is illustrated in Diagram 1, which highlights a number of external factors (alleviators) that support individuals to act in a professional way. It also shows factors (pressures) that can have a negative impact on the work of professionals. The proposals in this chapter aim to shift the regulatory focus upstream, to support professional standards before the need for fitness to practise proceedings arises.

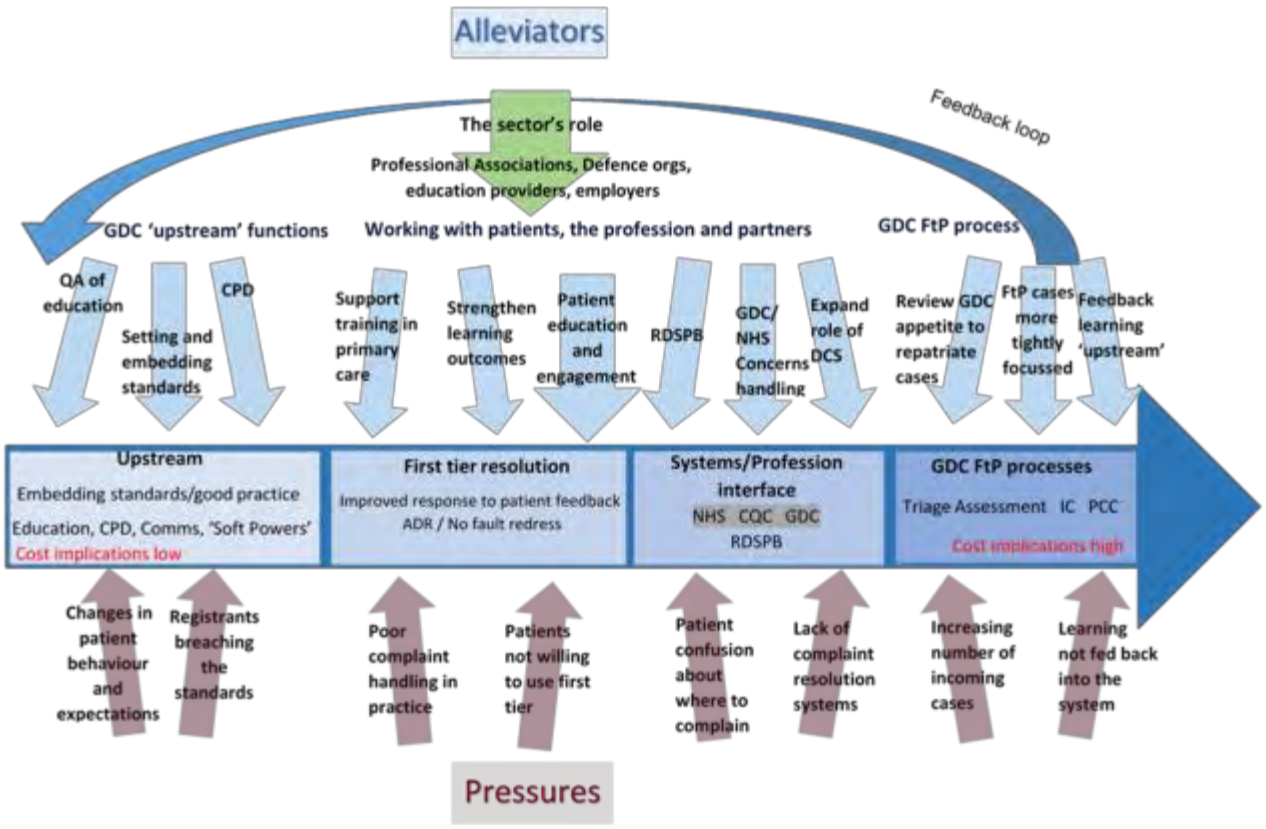


Diagram 1: factors that can impact on the ability of professional regulators to operate efficiently

Adapted from the GDC, 2016

A flexible and proportionate approach to investigation and fitness to practise

3.7. The current model of professional regulation places a heavy emphasis on dealing with concerns about registrants. Handling fitness to practise concerns must remain a key function of the regulators. However, the existing processes of dealing with allegations made about professionals to their regulators are cumbersome. These lengthy and costly processes are frustrating to patients, registrants and employers alike.

3.8. While it is essential that professional regulators provide patients, the public and employers with a clear route for raising concerns about the care that they receive, it is equally important that issues raised are dealt with in a timely, efficient and proportionate manner that delivers strong public protection.

3.9. The process for dealing with concerns about registrants varies from regulator to regulator. These processes are legalistic, adversarial, costly and time-consuming. To some extent this is a result of the legislative framework under which the regulators operate. For many of the regulators fitness to practise is their single largest expense. For example fitness to practise cases account for 61% of the General Dental Council's expenditure and 76% of the Nursing and Midwifery Council's expenditure (see Table 3 for more detail).

3.10. Table 3 below shows spending on fitness to practise among the regulatory bodies. The variation should not be interpreted as an indication of relative efficiency; differences

in numbers of fitness to practise cases, the processes and complexity of cases may explain the variation below.

Table 3: Fitness to practise (FtP) expenditure by regulatory body 2015/16

Regulator	FtP* expenditure (£000)	FtP expenditure % of total expenditure	FtP expenditure per registrant	Initial	Average cost per FtP concern
			(£)	FtP concerns	(£)
				received	
GCC	586	24%	188	54	10,846
GDC	28,502	61%	263	2,786	10,230
GOC	3,588	48%	173	343	10,460
GOsC	800	29%	157	52	15,384
GMC	63,234	62%	231	9,418	6,714
GPhC	5,440	25%	73	1,939	2,805
HCPC	13,186	47%	39	2,127	6,199
NMC	58,089	76%	84	5,415	10,727
PSNI	140	12%	61	22	6,361

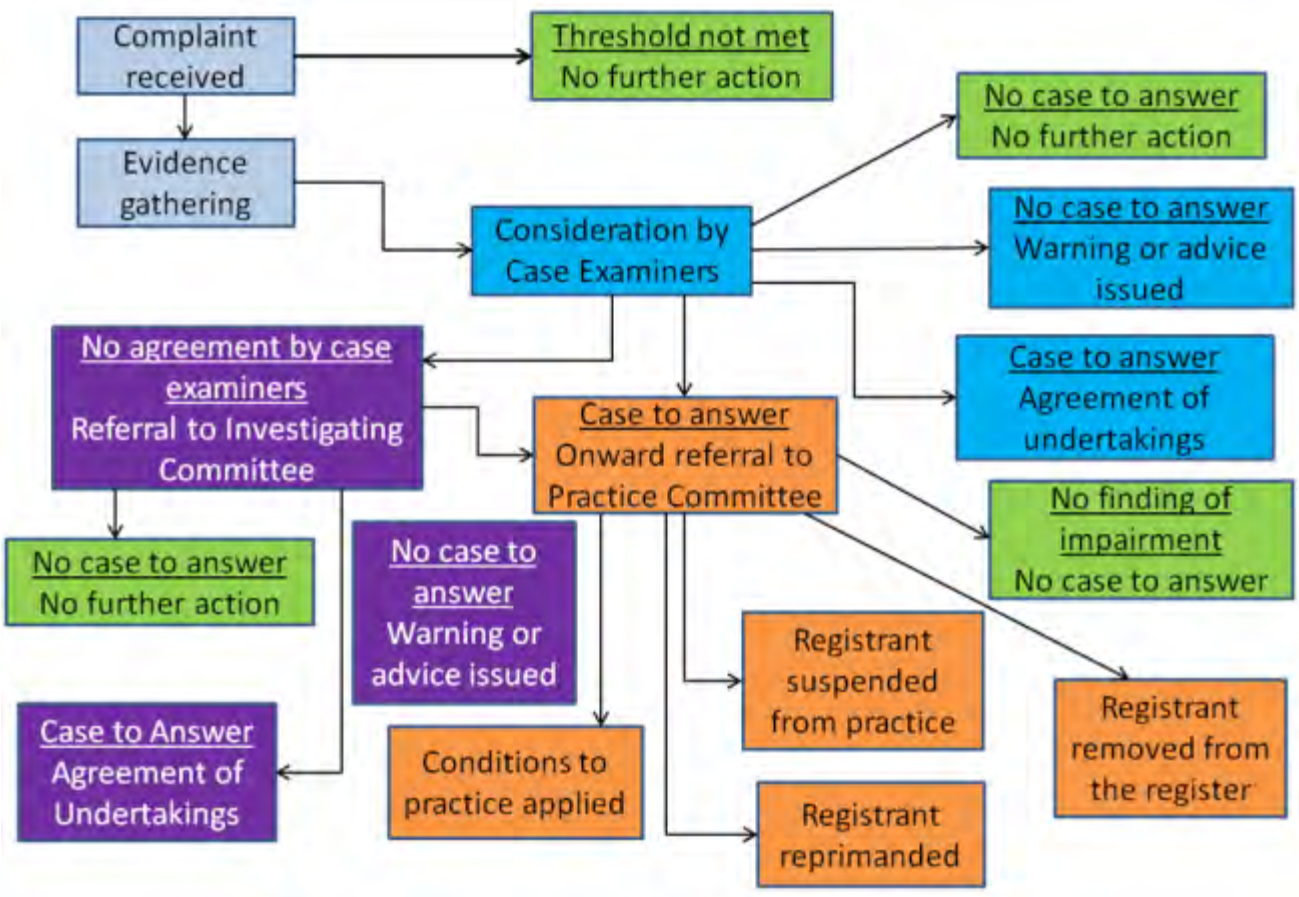
Source: Regulators' 2015-16 Annual Reports

**Includes triage of the initial allegation received by the regulatory body*

***No recent published FtP breakdown for GPhC and PSNI so 2012 CHSEO/PSA unit operating cost used*

3.11. Strong focus on fitness to practise and conducting cases in an adversarial way affects the outlook and culture of the regulatory bodies. The legalistic and defensive nature of the regulators can make them seem unapproachable and bureaucratic to both complainants and registrants. This needs to change. Diagram 2 illustrates the fitness to practise complaint process for the GDC.

Diagram 2: Stages of a Fitness to Practise (FtP) Complaint at the GDC



3.12. There will always be fitness to practise cases where full hearings are appropriate. The consequences of having registration removed are serious, usually resulting in the loss of a person's livelihood. However, this process is not necessary for less serious allegations or where the level of impairment is accepted by the registrant. In these cases a range of powers is required that allows cases to be handled proportionately and clearly protects the public.

3.13. The Law Commissions[15] recommended a number of improvements to the current procedures that would give the regulators greater flexibility and discretion over how to process and investigate fitness to practise cases. Other suggestions made during the pre-consultation stakeholder events included making the triage process more robust and increasing the use of dispute resolution and mediation to manage concerns.

3.14. The regulatory bodies already have a range of options available to address fitness to practise issues. The GMC currently has the broadest range of powers.

3.15. Where the Medical Practitioners' Tribunal Service (MPTS) finds that a doctor's fitness to practise is not impaired, it cannot impose a sanction. However, it may issue a warning if the doctor's conduct, behaviour or performance has significantly departed from the guidance in *Good Medical Practice*[16].

3.16. Where a tribunal finds a doctor's fitness to practise is impaired it can:

- take no action;
- accept undertakings that have been agreed between the doctor and the GMC (including any limitations on the doctor's practice) as an alternative to imposing a sanction;
- impose conditions on the doctor's registration for up to three years;
- suspend the doctor's registration for up to 12 months; and
- erase the doctor's name from the medical register, except in cases relating solely to their health and/or knowledge of English.

3.17. Interim orders tribunals (prior to assessment by the MPTS) can make an order to suspend a doctor's registration or to impose conditions on a doctor's registration for a maximum of 18 months. Such an order must be reviewed within six months of being imposed and at least every six months thereafter.

3.18. This range of powers should mean that regulators are able to take proportionate action in response to the issue that is before them. However, not all of the regulatory bodies have the full range of powers at their disposal. We propose that this range of powers should be available to all of the regulatory bodies.

3.19. More needs to be done to move to a more inquisitorial approach that seeks to establish the circumstances of a case rather than an adversarial approach. The government rejected the potential use of mediation as part of the fitness to practise procedures in response to the Law Commissions' recommendations. However we wish to reconsider this in light of the views received during the events held in summer 2016. Dispute resolution or mediation when dealing with enquiries and complaints that do not need a full fitness to practise investigation could help resolution of cases at an earlier stage. We would be interested in hearing views on the value of mediation as part of the system of professional regulation.

3.20. If our aim is for the regulatory bodies to support the professionalism of registrants, then they need to be held to account against standards that support and promote this function, as well as against how they handle fitness to practise cases. The PSA is reviewing its *Standards of Good Regulation*[17], and this review will consider how these standards can reflect the broader role of the regulatory bodies.

3.21. The PSA also has powers (under Section 29 of the *National Health Service Reform and Health Care Act 2002*[18]*)* to refer to court regulators' decisions in fitness to practise cases where it considers the decision is not sufficient for the protection of the public. It is our intention that these powers should be retained to ensure adequate public protection.

Q8: Do you agree that all regulatory bodies should be given a full range of powers for resolving fitness to practise cases?

Q9: What are your views on the role of mediation in the fitness to practise process?

Q10: Do you agree that the PSA's standards should place less emphasis on fitness to practise performance and consider the wider performance of the regulators?

Q11: Do you agree that the PSA should retain its powers to appeal regulators' fitness to practise decisions to the relevant court, where it is considered the original decision is not adequate to protect the public?

Supporting professionalism

3.22. There is more to regulation than fitness to practise. The regulatory system should also support the professional development of all registrants to ensure the workforce has the right skills and experience to deliver high quality care. This includes accrediting courses so that professionals receive good training and education that instil the right skills and behaviours to prevent problems occurring. It also means providing assurance that professionals' skills and behaviour remain fit for purpose throughout their career and supporting the development of a flexible workforce that is responsive to the changing healthcare needs of the population.

3.23. Professional regulation is only one component of the system in which professionals operate. Health professionals who are well-trained and well-motivated endeavour to provide excellent care. This is complemented by working in teams with people who are similarly motivated and in organisations which are well-led, are attuned to professional values and are dedicated to the patients and communities they care for.

3.24. The 2007 Government White Paper, *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*[19] set out a number of key principles that should underpin statutory professional regulation. It stated that "professional regulation should be as much about sustaining, improving and assuring the professional standards of the overwhelming majority of health professionals as it is about identifying and addressing poor practice or bad behaviour". Providing all regulatory bodies with powers to deal with fitness to practise complaints in a more flexible and proportionate way will enable regulators to free up more time to focus on supporting registrants to meet and maintain their professional standards.

3.25. This section sets out what more the regulators could do to support professionalism through education, revalidation and continuing professional development.

3.26. Progress in this area will be dependent on success in streamlining fitness to practise processes. This will allow the regulatory bodies, working with professional bodies and others, to focus more effort on supporting professionalism in all registrants. This will in turn help create a virtuous circle in which fewer cases require fitness to practise proceedings.

Improving patient consultations in osteopathy

Since 2013 the GosC has been collecting and aggregating data about complaints, indemnity insurance claims and concerns raised about practitioners by patients. This is a unique partnership between the regulator, insurers and the professional association aimed at understanding common patient concerns that occur in osteopathic practice. The work highlighted concerns about aspects of communication between osteopaths and patients and their impact on the consent process. In addition, research commissioned by the GosC identified factors supporting and inhibiting compliance with standards.

The GosC's response to this has taken a number of forms:

- including the requirement for compulsory activities around communication and consent in its new Contining Professional Development (CPD) scheme (bespoke learning materials to support the scheme);
- encouraging the development of local osteopathic communities to counteract the

challenge of professional isolation;
- proposing the provision of more learning resources to support communication, consent and other key areas;
- providing a variety of practice-focused information and case studies in its regular magazine and e-bulletins for registrants;
- working with other regulators and partners on the development of new tools that can be used in practice to support communication between patient and practitioner, and reduce areas of potential complaints; and
- facilitating sessions with providers of both undergraduate education and CPD to ensure that communication and consent are embedded in their activities.

Education

3.27. All of the regulatory bodies are responsible for approving higher education courses which enable entry into the professions that they regulate. They do this by setting the standards of education and training, and visiting education providers to assess whether they meet these standards. Typically, the standards will cover the level of qualification for entry to a profession and standards around admissions, course management and resources, curriculum content, practice placements and assessment methods.

3.28. This is a crucial role in assuring the ongoing quality of each profession. There is a wide range of practices across the regulators in the way that they carry this out. This reflects the fact that different occupations require different types and levels of education.

3.29. The PSA has suggested that there is some duplication between the regulatory responsibility of professional regulators and other regulators of higher education. It has also recommended that the health professional regulators should focus on setting and assessing the learning outcomes required for registration, leaving other regulators to deal with broader questions of course management.

3.30. In future we expect the professional regulators to work in partnership with employers and higher education providers to ensure that the recruitment, education and training systems they assure and operate are delivering the right people, that they are teaching the right things and that skills and behavioural problems identified early in a professional's career are properly addressed.

3.31. The UK governments support the PSA's recommendation of a review of the regulatory approach and responsibilities for the education of healthcare professionals. Such a review would aim to ensure that regulators have a clear focus and that they are not duplicating work. The main focus of the professional regulators in this area should be to assure that the higher education institutes produce high quality professionals who are suitable for registration at the end of the course, rather than detailed oversight of the course.

Continuing fitness to practise

3.32. Central to supporting professionalism is ongoing assessment of the fitness to practise of all registrants. All of the regulatory bodies have a system in place, or are devising one, for assessing the continuing fitness to practise of registrants.

3.33. For example, revalidation is a system of ongoing checks to encourage reflective practice and ensure practitioners are competent and up to date. It is designed to identify

good practice and address poor practice before it results in harm to patients. The system brings the registrant into much closer contact with their regulatory body.

3.34. The GMC has been operating a formal medical revalidation system since December 2012. This five yearly process requires licensed doctors to demonstrate that their skills and behaviours are up to date and they are fit to practise. It provides doctors with a framework against which to consider their practice. The key element of medical revalidation is a formal annual appraisal that is structured around the GMC's core guidance *Good Medical Practice*[20].

3.35. Revalidation was introduced by the NMC in April 2016. Nurses and midwives are required to revalidate every three years and demonstrate that they are continuing to practise safely and effectively in line with the NMC's code[21]. Revalidation for nurses and midwives covers a number of requirements including practice hours, CPD, practice-related feedback and reflection.

3.36. Other regulatory bodies have their own Continuing Fitness to Practise (CFtP) procedures to ensure that their registrants remain fit to practise and that their knowledge and skills remain up to date.

3.37. All the regulatory bodies provide advice and guidance to their registrants. For example the GMC's regional and employer liaison service aims to achieve closer engagement with registrants and with the healthcare system. The employer liaison service works to:

- establish good links with Responsible Officers to support an exchange of information about underperforming doctors, improving patient safety and the quality of referrals;
- share data about underperforming doctors, including regional trends;
- help Responsible Officers and their teams understand GMC procedures; and
- support the role of Responsible Officers and employers in relation to revalidation.

GMC's Regional Liaison Service

Much of the work of the GMC's Regional Liaison Service has been to explore with groups of doctors the practical application of its standards in their working lives. In 2015, the GMC ran workshops across the UK involving 16,733 doctors and 18,493 medical students. Almost 96% of those who responded said that the session they attended would help them reflect on their practice and 75% said they would change their practice as a result. Crucially, these sessions are organised around the feedback received from doctors themselves so that sessions are tailored to their needs and local circumstances.

Source: GMC

Q12: Do you think the regulators have a role in supporting professionalism and if so how can regulators better support registrants to meet and retain professional standards?

4. Efficient regulation

4.1. This section sets out a number of further changes relating to how the regulatory bodies work together and their governance arrangements. As with the changes to fitness to practise procedures, the changes set out in this section are not dependent upon which professional groups are regulated or on the number of regulators.

4.2. In 2015/16 the total operating costs of the 9 statutory regulators was £288m. As Table 4 below shows, they vary significantly in size and the number of professions they regulate.

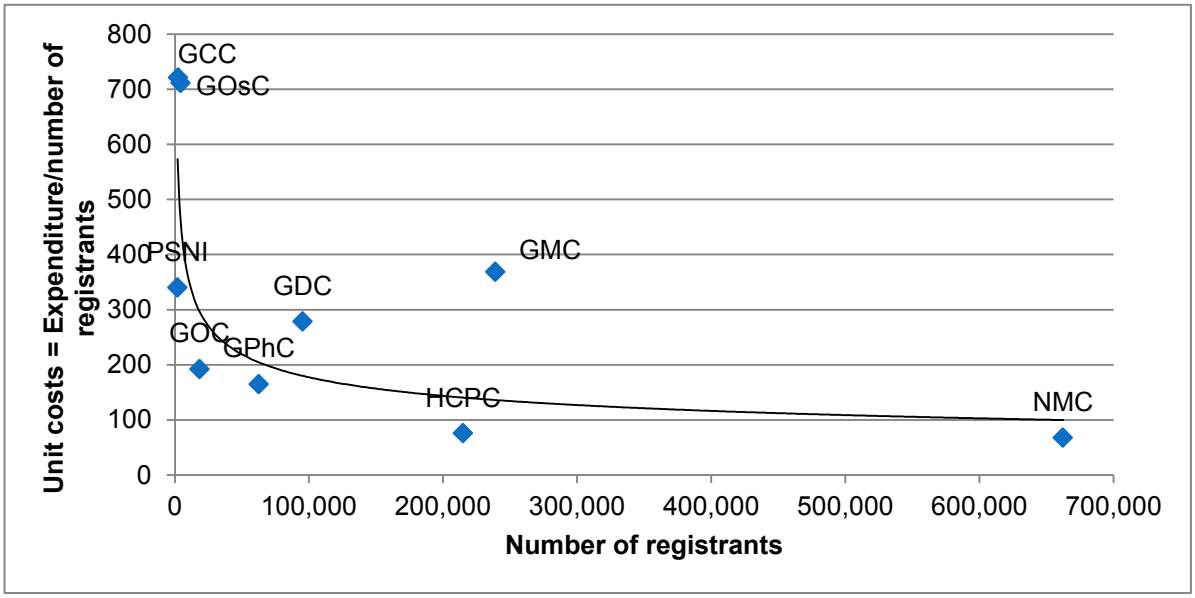
Table 4: Costs of statutory regulation 2015/16

Regulator	No of professions regulated	No of registrants (including business premises where applicable)	% of total registrants	Total operating costs (£'000)	Cost per registrant (£)
GCC	1	3,109	0.2	2,490	801
GDC	7	108,209	7.0	46,685	431
GMC	1	273,761	17.7	101,195	370
GOC*	2	29,136	1.9	7,553	259
GOsC	1	5,102	0.3	2,730	535
GPhC*	2	89,377	5.8	22,062	247
HCPC	16	341,745	22.1	28,287	83
NMC	2	692,550	44.8	76,344	110
PSNI*	1	2,852	0.2	1,124	394
Total	32	1,545,841	100	288,470	187

Source: Regulators' Annual reports, 2015/16
**GOC regulates optical business in UK. GPhC regulate business premises in Great Britain. PSNI regulates pharmacists and business premises for Northern Ireland only and has a professional leadership function for its registrants.*

4.3. In November 2012 the PSA analysed the cost effectiveness of the professional regulators[22]. It found a relationship between expenditure per registrant and size of the regulator and wide variation in the cost burden on individual registrants, even though the regulators were carrying out broadly similar statutory functions (Diagram 3).

Diagram 3: Relationship between size of a regulator and unit costs, 2012



Source: https://www.chseo.org.uk/downloads/report4-costefficiency.pdf page 12

4.4. Although this data should be interpreted with caution (definitional differences may still explain variation despite attempts by PSA to standardise costs), it does suggest significant economies of scale exist. As a regulator's size increases, unit operating costs (defined as operating costs per registrant) fall and plateau above 300,000 registrants. No significant diseconomies of scale in large regulators were identified.

4.5. Table 5 shows the total operating costs per registrant by core function. For example the amount spent on registration ranges between £11 and £142 per registrant. Variation could be due to a number of factors. These include economies of scale (larger regulators can spread fixed costs over a larger registrant base), complexity of regulation and effectiveness and efficiency. For example the technical complexity of the GMC's fitness to practise cases and their methods for investigating and adjudicating on these may explain some of their higher operating costs. Reporting differences in the allocation of costs to functions may also explain the variation.

Table 5: Total operating costs per registrant (unit costs), £ by function and regulator 2012

	Standards	Registration	Education & training	FtP	Continuing FtP	Governance	Total operating cost per registrant (unit costs)
NMC	5	11	3	42	1	6	68
GMC	6	64	20	244	12	22	368
HCPC	3	16	7	45	0	4	76
GDC	6	63	13	179	3	15	278
GPhC	6	34	22	73	10	20	165
GOC	10	32	24	73	19	34	192
GosC	132	142	53	206	75	105	711
GCC	25	104	0	410	74	108	721
PSNI	23	47	57	66	104	43	340

Source: https://www.chseo.org.uk/downloads/report4-costefficiency.pdf page 11

Joint working

4.6. Understanding the reasons for this variation can help to identify the scope for generating greater efficiency within the system and for developing best practice while delivering better public protection. Reducing the number of regulators as proposed in chapter 2 will not only deliver greater consistency in the way that professional regulation is carried out but could also provide an opportunity to deliver cost savings by spreading some fixed costs across a greater number of registrants. There are other changes that can be introduced that will reduce costs while continuing to provide strong public protection and which are not dependent on a reduction in the number of regulatory bodies. These are outlined in this chapter.

4.7. The nine UK regulatory bodies all carry out similar functions in relation to different professional groups but undertake these in different ways and under different legislative frameworks. Even without a reduction in the number of regulators there is substantial scope for sharing functions between regulators to deliver a more consistent and cost effective approach.

4.8. There have been a number of attempts to promote joint working within the professional regulatory system. These have included simple things such as regulators collaborating to share back-office functions (such as IT and HR) to more complex proposals such as the establishment of the Office of the Health Professions Adjudicator (OHPA). This was

intended to carry out the adjudication functions of all of the professional regulatory bodies beginning with the GMC and the GOC. For a variety of reasons these initiatives have not been taken forward.

4.9. Regulators have also collaborated in developing common standards. For example in 2015 the GMC and NMC worked together to produce joint guidance on registrants' duty of candour. This recognised that the aims and objectives of being open and honest were the same for all professions. This principle could be applied to other general standards for healthcare professionals.

4.10. There is a need for a fundamental shift from a system which allows the regulatory bodies to co-operate to one which creates an expectation or places a statutory duty on the regulators to work together.

4.11. Working with the regulatory bodies and the PSA, the four UK governments have identified four potential areas where joint working may improve public protection and at the same time generate efficiencies:

- A shared online register, search engine or online portal of all registered healthcare professionals. This will make it easier for patients, the public and employers to access details about whether a health professional is registered and about that professional's registration;
- A single set of generic standards for all healthcare professionals (underpinned by profession-specific standards owned by the individual regulators). This will ensure that all health professionals are working to the same core set of professional standards. The standards will only differ where there is a profession specific need. This model has been successfully operated by the HCPC for many years;
- A single adjudicator responsible for all fitness to practise decisions. This will provide greater consistency of decision-making on all fitness to practise cases, making the process fairer for regulated professionals and for patients and the public. This could build on the Medical Practitioners Tribunal Service which considers fitness to practise cases brought by the GMC; and
- A single organisation conducting back office functions such as HR, finance and IT. Each regulatory body is currently responsible for their back office services. If one organisation was responsible for these functions they are likely to be delivered more efficiently.

Q13: Do you agree that the regulators should work more closely together? Why?

Q14: Do you think the areas suggested above are the right ones to encourage joint working? How would those contribute to improve patient protection? Are there any other areas where joint working would be beneficial?

4.12. There also needs to be greater co-operation and data sharing between the professional regulators and other parts of the healthcare regulatory system. For example, the GMC, Health Education England and NHS Improvement worked together in response to concerns about the emergency department at North Middlesex University Hospital Trust. However such collaboration does not happen often enough.

4.13. There is a vast amount of intelligence gathered across the system but this is not systematically shared between regulatory partners to ensure that the right body takes the right action at the right time.

4.14. For instance, access to provider level data about the number of fitness to practise referrals coming from employers could indicate a problem in the system generally or in a particular organisation. Similarly information held by a system regulator such as the Care Quality Commission about performance at an organisational level might highlight issues with individual professionals which should be investigated by the appropriate professional regulator. The professional regulators will continue to work together and with other regulatory bodies in the health system to make improvements with regard to how they work together to intervene when there are issues with the quality of care.

Q15: Do you agree that data sharing between healthcare regulators including systems regulators could help identify potential harm earlier?

Autonomy and greater freedoms for the regulatory bodies

4.15. It is right that the powers and remit of the regulatory bodies are set in legislation. However, the legislation has been developed over many years and still frequently needs to be amended. Changes to the operating practices of the regulators often require an amendment to primary or secondary legislation. This is costly and time consuming. Where there is a public safety element the time taken to make these changes can compromise public protection.

4.16. Providing the regulatory bodies with powers to amend their own procedures would enable them to respond to the changing way that healthcare is delivered without requiring ongoing legislative intervention by government. In taking forward reform of professional regulation we propose to provide regulators with more flexible legislation that will allow them to set more of their own operating procedures.

4.17. This approach is not without risk. Autonomy must be balanced with robust accountability to the legislatures across the four countries. The PSA will continue to contribute to the accountability arrangements of the regulatory bodies in that it will continue to report to Parliament on their performance and through appearances before the Health Select Committee. The UK Parliament will continue to hold to account the PSA and the regulators covering the whole of the United Kingdom. The Northern Ireland Assembly will still hold to account the Pharmaceutical Society for Northern Ireland. Moving forwards the Scottish Parliament, the National Assembly for Wales and the Northern Ireland Assembly may also want to hold hearings or take evidence from the regulators and/or the PSA about the impact of their work in that jurisdiction. In addition the regulatory bodies should lay copies of their annual reports, potentially country specific, before all of the UK countries in which they operate to improve their accountability to each legislature.

Q16: Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?

Q17: Do you agree that the regulatory bodies should be more accountable to the Scottish Parliament, the National Assembly for Wales and the Northern Ireland Assembly, in addition to the UK Parliament?

Governance

4.18. The previous section set out the case for providing greater autonomy to the regulators. This must be balanced by effective governance. There has been much progress toward this over the last ten years. Moving from a system of professional self-regulation to independent regulation has led to greater scrutiny, as has regular accountability hearings before the House of Commons' Health Select Committee.

4.19. The councils of most of the regulatory bodies consist of 12 independent non-executive members half of whom are registrants. While this is a clear improvement there remain vestiges of the old system of self-regulation which need to be addressed. The concept of members of the councils representing the profession being regulated is at odds with a system of independent regulation. While the councils or boards of the regulators clearly need to have detailed knowledge of the professions that they regulate, which may well be provided by members of those professions, council members are not sitting in a representative role on behalf of their profession. Rather they are there to provide the skills, knowledge and expertise to hold the body to account. In addition, currently the councils do not include the executive members of the regulator. This can make it difficult for the councils to hold the regulator to account.

4.20. The Committee on Standards in Public Life published a report in September 2016, *Striking the Balance - upholding the 7 principles in regulation*[23], which highlights that the current two tier structure cannot support effective accountability to Parliament/government because the Councils make decisions but it is the executive that carries out the work. Therefore in practice it is the executive that is held to account for decisions it has not taken and may or may not have managed to influence.

4.21. The four UK governments believe that it is time to take the next step in the journey away from self-regulation and to explore a modernised governance structure for the regulators. This would involve the establishment of a new board structure which comprises both non-executive and executive directors. The non-executive directors, including the chair, would be selected to ensure that there is the right mix of skills and experience to ensure the regulator is robustly scrutinised. The distinction between representative and public members would be removed, although it would be extremely likely that the non-executive members would include people who are in the professions regulated, but these would not form more than half of the Board. The non-executive members would be appointed by the Privy Council as they are now to ensure independence from government.

4.22. The executive members of the Board would be the senior employees of the regulator and would be appointed by the non-executive members. Their presence on the Board would enable the non-executives to hold the executives to account in a thorough fashion.

4.23. The regulatory bodies have a role along with others within the healthcare system in ensuring we have the right workforce, with the right skills and behaviours, educated to the right professional standards, with the right professional values in place. It is therefore important that the regulatory bodies recognise this and work closely with employers who recruit and employ that workforce. The four UK governments wish to explore how this is best achieved.

Q18: Do you agree that the councils of the regulatory bodies should be changed so that they comprise both non-executive and executive members?

Q19: Do you think that the views of employers should be better reflected on the councils of the regulatory bodies, and how might this be achieved?

Q20: Should each regulatory body be asked to set out proposals about how they will ensure they produce and sustain fit to practise and fit for purpose professionals?

Registration fees

4.24. Regulators are responsible for the fees that they charge to registrants. Some regulators charge different fees for different professions, for example the GDC charges dentists £890 while other dental care professionals are charged a lower fee of £116. Additionally the PSA is funded by a fee raised from the regulatory bodies it oversees. The fees charged to registrants therefore also cover this cost. Table 6 below sets out the current fees charged.

Table 6: Annual retention fees, 2015/2016

Regulator	**Fee (£)**
GCC	800
GDC	116 - 890
GMC	425
GOC	320
GosC	570
GPhC	118 - 250
HCPC	90
NMC	120
PSNI*	326

Source: Regulators' 2015/2016 annual reports

**Leadership is not separated in PSNI in the same way as other regulators – a part of the fee is provided to a leadership body. The fee shown is that relating to the regulatory function only.*

4.25. The four UK governments have been clear that fee rises should be kept to a minimum. This continues to be our position. Reform of professional regulation is likely to deliver more efficient regulation and there is a case for passing on at least some of the savings to registrants in the form of lower fees, in addition to investing in work to support

professionalism. We would welcome the views of respondents about whether savings arising from changes to the fitness to practise process should be invested in supporting professionalism, should be returned to registrants in lower registration fees, or both. There may be other areas where any savings should be reinvested.

Q21: Should potential savings generated through the reforms be passed back as fee reductions, be invested upstream to support professionalism, or both? Are there other areas where potential savings should be reinvested?

5. Impact assessment

5.1. The aims of the reforms are to simplify, streamline and modernise the legislative framework for healthcare professional regulation. As part of this consultation a high level assessment of the options for delivering reform has been developed.

5.2. It is expected the impacts overall will be positive and deregulatory to business. The impacts of amending the legislative framework are expected to fall on a wide range of stakeholders including: the existing healthcare professional regulators; the PSA which oversees the activity of the regulators; the regulators' registrants (a proportion of whom undertake the majority of their professional activity in the private sector and therefore are classified as businesses); patients; the wider public and government. Most of the costs and savings will impact on the regulatory and wider healthcare sector.

5.3. Table 7 below sets out initial high level assessment of impacts.

5.4. There are likely to be health benefits to patients, families and wider society as a result of the reforms by providing better protection to the public and improving confidence in the regulatory bodies.

5.5. The four UK governments would like to gather further evidence on the scale of this as part of the consultation and would welcome views on the types of health benefits (improved public protection and patient safety) likely and, if possible, to quantity these benefits so they can be included in the impact assessment.

Q22: How will the proposed changes affect the costs or benefits for your organisation or those you represent?

- an increase

- a decrease

- stay the same

Please explain your answer and provide an estimate of impact if possible.

Q23: How will the proposed changes contribute to improved public protection and patient safety (health benefits) and how could this be measured?

Table 7: High level assessment of impacts

Stakeholders	**Positives**	**Negatives**
Patients/wider public	Improved patient safety Improved quality of care Faster resolution of concerns Greater transparency on processes Improved fairness of processes between professionals	Time taken to deliver reform
Individual registrants	Potential reduction in fees for regulated professionals Savings for any deregulated professions Better supported through improved standards/CPD Improved public perception of regulated professionals	Reduced status for de-regulated professional
Regulatory Bodies	Greater autonomy to amend own procedures Larger registrant base so higher income from fees Cost savings from ability to be more flexible in functions e.g. registration, fitness to practise.	Higher operating costs for merged regulators Smaller regulatory bodies closed down Transition costs involved in implementing changes
PSA	Fewer regulators, so increased PSA capacity for oversight of each one Opportunity for more economic use of resources e.g. away from FtP related towards preventative regulation Opportunity to ensure proportionate regulation	Increased use of consensual disposals could mean reduced oversight of FtP outcomes, therefore reduced ability to protect the public Impact of mergers could mean temporary dip in performance, therefore increased workload for PSA

Taxpayers/government	Lower central administrative costs of maintaining the legislation Small increase in tax revenue from registrants that are deregulated, as they will no longer be entitled to tax break. Improved fairness of processes between professionals	Upfront costs of delivery of reform.

6. Equality analysis

6.1. The Department of Health, the Devolved Administrations and the professional regulatory bodies are covered by the Equality Act 2010 and specifically the Public Sector Equality Duty.

6.2. The Duty covers the following protected characteristics: age, disability, gender reassignment, pregnancy and maternity, race (includes ethnic or national origins, colour or nationality), religion or belief (includes lack of belief), sex and sexual orientation.

6.3. There are three parts to the Duty and public bodies must, in exercising their functions, have due regard to them all. They are:

- the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010;
- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it; and
- foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

6.4. Having due regard to the need to advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it involves having due regard in particular to the need to:

- remove or minimise disadvantages suffered by persons who share a relevant protected characteristic that are connected to that characteristic;
- take steps to meet the needs of persons who share a relevant protected characteristic that are different from the needs of persons who do not share it;
- encourage persons who share a relevant protected characteristic to participate in public life or in any other activity in which participation by such persons is disproportionately low. The steps involved in meeting the needs of disabled persons that are different from the needs of persons who are not disabled include in particular steps to take account of disabled persons' disabilities.

6.5. Having due regard to the need to foster good relations between persons who share a relevant protected characteristic and persons who do not share it involves having due regard, in particular to the need to:

- tackle prejudice;
- promote understanding.

6.6. Section 75(1) of the Northern Ireland Act 1998 requires all public authorities in carrying out their functions relating to Northern Ireland to have due regard to the need to promote equality of opportunity between:

- persons of different religious belief, political opinion, racial group, age, marital status and sexual orientation;
- men and women generally;
- persons with a disability and persons without;
- persons with dependants and persons without.

6.7. In addition section 75(2) of the 1998 Act requires public authorities without prejudice to their obligations under subsection (1) to have regard to the desirability of promoting good relations between persons of different religious belief, political opinion and racial group.

Q24: Do you think that any of the proposals would help achieve any of the following aims:

- **Eliminating discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010 and Section 75(1) and (2) of the Northern Ireland Act 1998?**
- **Advancing equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it?**
- **Fostering good relations between persons who share a relevant protected characteristic and persons who do not share it?**

If yes, could the proposals be changed so that they are more effective?

If not, please explain what effect you think the proposals will have and whether you think the proposals should be changed so that they would help achieve those aims?

7. Summary of the questions

Q1: Do you agree that the PSA should take on the role of advising the UK governments on which groups of healthcare professionals should be regulated?

Q2: What are your views on the criteria suggested by the PSA to assess the appropriate level of regulatory oversight required of various professional groups?

Q3: Do you agree that the current statutorily regulated professions should be subject to a reassessment to determine the most appropriate level of statutory oversight? Which groups should be reassessed as a priority? Why?

Q4: What are your views on the use of prohibition orders as an alternative to statutory regulation for some groups of professionals?

Q5: Do you agree that there should be fewer regulatory bodies?

Q6: What do you think would be the advantages and disadvantages of having fewer professional regulators?

Q7: Do you have views on how the regulators could be configured if they are reduced in number?

Q8: Do you agree that all regulatory bodies should be given a full range of powers for resolving fitness to practise cases?

Q9: What are your views on the role of mediation in the fitness to practise process?

Q10: Do you agree that the PSA's standards should place less emphasis on the fitness to practise performance?

Q11: Do you agree that the PSA should retain its powers to appeal regulators' fitness to practise decisions to the relevant court, where it is considered the original decision is not adequate to protect the public?

Q12: Do you think the regulators have a role in supporting professionalism and if so how can regulators better support registrants to meet and retain professional standards?

Q13: Do you agree that the regulators should work more closely together? Why?

Q14: Do you think the areas suggested above are the right ones to encourage joint working? How would those contribute to improve patient protection? Are there any other areas where joint working would be beneficial?

Q15: Do you agree that data sharing between healthcare regulators including systems regulators could help identify potential harm earlier?

Q16: Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?

Q17: Do you agree that the regulatory bodies should be more accountable to the Scottish Parliament, the National Assembly for Wales and the Northern Irish Assembly, in addition to the UK Parliament?

Q18: Do you agree that the councils of the regulatory bodies should be changed so that they comprise of both non-executive and executive members?

Q19: Do you think that the views of employers should be better reflected on the councils of the regulatory bodies, and how might this be achieved?

Q20: Should each regulatory body be asked to set out proposals about how they will ensure they produce and sustain fit to practise and fit for purpose professionals?

Q21: Should potential savings generated through the reforms be passed back as fee reductions, be invested upstream to support professionalism, or both? Are there other areas where potential savings should be reinvested?

Q22: How will the proposed changes affect the costs or benefits for your organisation or those you represent?

- an increase
- a decrease
- stay the same

Please explain your answer and provide an estimate of impact if possible.

Q23: How will the proposed changes contribute to improved public protection and patient safety (health benefits) and how could this be measured?

Q24: Do you think that any of the proposals would help achieve any of the following aims:

- Eliminating discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010 and Section 75(1) and (2) of the Northern Ireland Act 1998?
- Advancing equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it?
- Fostering good relations between persons who share a relevant protected characteristic and persons who do not share it?

If yes, could the proposals be changed so that they are more effective?

If not, please explain what effect you think the proposals will have and whether you think the proposals should be changed so that they would help achieve those aims?

8. Responding to the consultation

Consultation process

8.1. This document launches a consultation on a number of proposals concerning UK healthcare professional regulatory reform.

8.2. The consultation is being run as far as is practical in accordance with the Cabinet Office Code of Practice on Consultations (reproduced below).

8.3. The closing date for the consultation is 23 January 2018.

8.4. There is a questionnaire on the gov.uk website which can be printed and sent by post to:

UK Healthcare Professional Regulatory Reform Team
Professional Regulation
Department of Health
2W09 Quarry House
Quarry Hill
LEEDS LS2 7UE

8.5. Completed questionnaires can also be sent electronically by email to: reformingregulation@dh.gsi.gov.uk

8.6. Alternatively you may also complete the online consultation response document at:

http://consultations.dh.gov.uk

8.7. It will help us to analyse the responses if respondents fill in the online consultation response document but responses that do not follow the structure of the questionnaire will be considered equally. It would also help if responses were sent in Word format, rather than in pdf format.

Criteria for consultation

8.8. This consultation follows the Government Code of Practice. In particular we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for a sufficient period;
- be clear about the consultations process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to and clearly targeted at those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- analyse responses carefully and give clear feedback to participants following the consultation;

- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

8.9. The full text of the code of practice is on the Better Regulation website at: www.bis.gov.uk/policies/better-regulation/consultation-guidance

Confidentiality of information

8.10. We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter: www.dh.gov.uk/en/FreedomOfInformation/DH_088010

8.11. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

8.12. If you want the information that you provide to be treated as confidential please be aware that under the FOIA there is a statutory Code of Practice which public authorities must comply with and which deals amongst other things with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not of itself be regarded as binding on the Department.

8.13. The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Summary of consultation responses

8.14. A summary of the responses to this consultation will be made available before or alongside any further action and will be placed on the GOV.UK website (www.gov.uk/dh).

Annex A: Law Commissions' recommendations

The Law Commissions of England and Wales, Scotland and Northern Ireland published a comprehensive review of the legal framework for professional regulation in the UK in 2014[24]. Alongside this, it also published a draft Bill. The reforms recommended by the Law Commissions would consolidate and simplify the existing legal framework and would impose greater consistency across the regulators in some areas, such as the conduct of fitness to practise hearings.

The government published its response to the Law Commissions' report in January 2015[25]. In the majority of cases there has been no change in the government's position. A summary of where the government's original position on the Law Commissions' recommendations is being tested is set out below.

No.	Recommendations	Original response	Original response (detail)	Original response still stands?	Current Policy/Approach
8	The formal role of the Privy Council in relation to health and social care professionals' regulation should be removed entirely.	Accept in part	It is the Government's view that the Privy Council should retain its powers. The exception is the case of approval of regulatory bodies' rules, which will be subject to the outcome of the Government's further consideration mentioned at recommendation 3. This position on the role of Privy Council is given further consideration under recommendations 9, 10, 16 and 19.	To test	This consultation seeks views on whether the Privy Council's role in professional regulation should be reduced, with the regulatory bodies being given greater powers to set their own rules. **See: 'Autonomy and greater freedoms for the regulatory bodies' section of consultation paper.** **Q16: Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?** This position also applies to the following recommendations made by the Law Commissions: 9, 10, 19, 16, 45 and 46
12	The regulators' annual reports,	Accept in	We do not agree that it is necessary to change	To test	The consultation is seeking views whether the regulatory

	strategic plans and accounts should be laid in the UK Parliament, Scottish Parliament, National Assembly for Wales and Northern Ireland Assembly.	part	the current position as to the Parliaments in which regulatory bodies are required to lay reports etc. These should reflect devolution arrangements.		bodies should be more accountable to the Scottish Parliament, the National Assembly for Wales and the Northern Irish Assembly, in addition to the UK Parliament. See: 'Autonomy and greater freedoms for the regulatory bodies' section of consultation paper. Q17: Do you agree that the regulatory bodies should be more accountable to the Scottish Parliament, the National Assembly for Wales and the Northern Irish Assembly, in addition to the UK Parliament?
31	The Government should have regulation making powers to establish barring schemes, to be run by the regulators. Such a scheme could be introduced in respect of a prescribed health or social care profession, a specified field of activity, a role involving supervision or management, and prescribed title.	Accept	The Government agrees that prohibition orders may have utility in the future in regards to specific areas of practice which are currently unregulated or in emerging areas of risk.	To test	In December 2016, the PSA published a report giving an initial evaluation of the feasibility of prohibition order schemes for unregulated health and care workers in the UK. The consultation seeks views on the use of prohibition orders as an alternative to statutory regulation. See: Section 2 – Protecting the Public. **Q4: What are your views on the use of prohibition orders as an alternative to statutory regulation for some groups of professionals?**
69	The Government's regulation-making powers	Do not accept	We share the Law Commissions' analysis of the appropriateness of mediation in the	To test	In light of the views received during the events across summer 2016 the consultation seeks views on

	should include the power to introduce mediation for one or more of the regulators.		fitness to practise context. It is not clear how mediation sits with the objective of the fitness to practise procedures to protect the public, uphold proper standards of conduct and behaviour and maintain confidence in the relevant profession. We also agree with the Law Commissions that mediation is likely to only be of utility where a referral has been made that does not amount to an allegation of impaired fitness to practise, as otherwise the regulatory body should be obliged to pursue regulatory action. Because of these reasons, the Law Commissions have proposed that any mediation scheme should be controlled by a Government regulation making power. However we do not think that such a power is required as we do not consider that mediation should have any statutory footing within the context of the fitness to practise procedures.		whether using dispute resolution or mediation could help the regulators to resolve concerns at an earlier stage in the process, before being referred in to the very expensive and stressful FtP procedures. See: 'A flexible and proportionate approach to investigation and fitness to practise' section of consultation paper. **Q8: Do you agree that all regulatory bodies should be given a full range of powers for resolving fitness to practise cases?** **Q9: What are your views on the role of mediation in the fitness to practise process?**

74	All fitness to practise hearings should be conducted by a panel of at least three members (including at least one lay member). Members of the regulatory bodies (including those from other regulators), members of the Professional Standards Authority's board, and investigators should be prohibited from membership of fitness to practise panels. The regulators would have rule-making powers on other aspects of panels, such as the appointment of advisers and legal chairs.	Accept	As set out in Chapter 1, the Government will wish to consider the best balance as to which provisions should be in any future Government Bill and which would be suitable for rules as well as suitable oversight arrangements. We agree that the membership of a fitness to practise panel should consist of at least one lay and one registrant member. We would also want to prohibit a registrant majority. This would mean that where a panel was constituted of three members, two would be lay. We may also want to expand the list of persons prohibited from sitting on a fitness to practise panel to secure, as far as possible, the separation between the investigation and adjudication of fitness to practise cases.	To test	This consultation seeks views on whether the regulatory bodies should be given a broad range of powers to consider fitness to practise, and more powers to set their own procedures. See: 'A flexible and proportionate approach to investigation and fitness to practise' section of consultation paper. **Q8: Do you agree that all regulatory bodies should be given a full range of powers for resolving fitness to practise cases?** This stance also applies to the following recommendations made by the Law Commissions: 77, 78, 83, 86, 87 and 88
107	The Government should have powers to make appointments to the Professional Standards Authority's board. The administration of appointments would be undertaken by	Do not accept	The Government does not agree with the removal of the Privy Council role in this appointments process. We feel the PSA board should continue to consist of a chair who is appointed by the Privy Council. Of the six non-executive members, three should be appointed by the	To test	This consultation seeks views on whether the Privy Council's role in professional regulation should be reduced, with the regulatory bodies being given greater powers to set their own rules. **See: 'Autonomy and greater freedoms for the regulatory bodies' section of consultation paper.**

	the Professional Standards Authority in accordance with its guidelines and standards.		Privy Council and one each by the administrations in Scotland, Wales and Northern Ireland.		**Q16: Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?**
111	A regulator may dispense with the duty to consult in a particular case if it considers that it would be inappropriate or disproportionate to consult, and approval has been given by the Professional Standards Authority.	Accept in part	As set out in Chapter 1 the Government intends to consider further the balance between primary legislation and rules and regulations and accompanying safeguards and oversight arrangements and within this it will need to consider such consultation duties and the scope (if any) for dispensing with them. The Government agrees that a regulatory body may dispense with the duty to consult where it considers such a step to be disproportionate or inappropriate. We disagree that approval should be required from the PSA on the basis this is an unnecessary restriction and could create a conflict of interest for the PSA in assuring the quality and robustness of the decisions and actions of the regulatory bodies.	To test	This consultation seeks views on whether the Privy Council's role in professional regulation should be reduced, with the regulatory bodies being given greater powers to set their own rules. **See: Autonomy and greater freedoms for the regulatory bodies section of consultation paper.** **Q16: Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?**

Annex B: Glossary

ABBREVIATIONS AND TERMS	EXPLANATION
Accredited registration/Assured voluntary registration	The Professional Standards Authority for Health and Care assesses and accreditd organisations that register health and social care practitioners who are not statutorily regulated.
Case Examiners	Case examiners make the decision at the end of the investigation stage of the fitness to practise procedures/process, on behalf of the Investigating Committee.
Consensual disposal	Consensual disposal can be used by the professional regulatory bodies, in appropriate cases. Consensual disposal is the conclusion of cases at the investigation stage of the fitness to practise procedures/process and is an alternative to referring the case forward for a fitness to practise panel hearing, whilst satisfactorily protecting the public.
Continuing Professional Development (CPD)	All professionals registered with a professional regulatory body are required to continue to develop their knowledge and skills while they are registered.
Continuing fitness to practise	Continuing Fitness to Practise (CFtP) procedures ensure that registrants remain fit to practice and that their knowledge and skills remain up to date.
Council	The Council is the governing body of the professional regulatory body.
Education and training	The professional regulatory bodies are responsible for assessing education and training programmes.
Equality Analysis	A process evaluating the impact of the proposed policy on the equality principles.
Fees	To be registered with a professional regulatory body, professionals must pay a fee.
Fitness to practise (FtP)	The skills, knowledge and character required of professionals to practise their profession safely and effectively.
Fitness to practise (FtP) procedures/process	Investigations into allegations made about professionals to their professional regulatory bodies are known as the 'fitness to practise' procedures.
General Chiropractic Council (GCC)	Professional regulatory body responsible for regulating chiropractors. http://www.gcc-uk.org/

General Dental Council (GDC)	Professional regulatory body responsible for dental professionals. https://www.gdc-uk.org/
General Medical Council (GMC)	Professional regulatory body responsible for regulating medical practitioners. http://www.gmc-uk.org/
General Optical Council (GOC)	Professional regulatory body responsible for regulating optometrists, dispensing opticians, student opticians and optical businesses. https://www.optical.org/
General Osteopathic Council (GOsC)	Professional regulatory body responsible for regulating osteopaths. http://www.osteopathy.org.uk/home/
General Pharmaceutical Society (GPhC)	Professional regulatory body responsible for regulating pharmacists, pharmacy technicians and pharmacy business premises in Great Britain. http://www.pharmacyregulation.org/
Health and Care Professions Council (HCPC)	Professional regulatory body responsible for regulating arts therapists, biomedical scientists, chiropodists/podiatrists, clinical scientists, dietitians, hearing aid dispensers, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, practitioner psychologists, prosthetists/orthotists, radiographers, social workers in England and speech and language therapists. http://hcpc-uk.co.uk/
Impact Assessment	A process evaluating the economic impact of the proposed policy.
Investigating Committee	Makes the decision at the end of the investigation stage of the fitness to practise procedures/process.
Law Commissions of England and Wales, Scotland and Northern Ireland	Independent bodies designed to keep the law under review and to recommend reform where it is needed.
Medical Practitioners Tribunal Service	The Medical Practitioners Tribunal Service is the adjudication service for United Kingdom doctors.
NHS Five Year Forward View	The plan for the next five years for the NHS.
Nursing and Midwifery Council (NMC)	Professional regulatory body responsible for regulating nurses and midwives. https://www.nmc.org.uk/

Office of the Health Professions Adjudicator	OHPA was originally set up to take over Fitness to Practice hearings from the General Medical Council from 1 April 2011 and those from the General Optical Council at a later date. However it was closed before it became operational. It was abolished in 2012.
Pharmaceutical Society of Northern Ireland (PSNI)	Professional regulatory body responsible for regulating pharmacists and pharmacy business premises in Northern Ireland, and has a professional leadership function for its registrants. http://www.psni.org.uk/
Privy Council	The Privy Council is the mechanism through which agreement is reached on items of government business which fall to Ministers as Privy Counsellors rather than as Departmental Ministers. The Privy Council currently has a role in various aspects of statutory professional regulation.
Professional regulatory bodies	The organisations responsible for protecting the public by: Setting the standards of behaviour, competence and education that health professionals must meet; Dealing with concerns from patients, the public and others about health professionals who are unfit to practise because of poor health, misconduct or poor performance; Keeping registers of health professionals who are fit to practise in the United Kingdom; The regulators can remove professionals from their registers and prevent them from practising if they consider this to be in the best interests of the public.
Professional Standards Authority for Health and Social Care (PSA)	Established in 2002 to promote greater consistency and responsiveness from the health regulators. It conducts annual performance reviews, promotes good practice, provides specific advice to government when commissioned to do so and undertakes special investigations as required. It also has the power to challenge fitness to practise decisions that it regards as insufficient to protect the public. https://www.professionalstandards.org.uk/contact-us
Registration	Those professionals practising a statutorily regulated profession must apply to join the appropriate organisation's register. The professional regulatory bodies are responsible for: • allowing access to the register for those professionals who meet the standards • continuing registration for those professionals who meet the standards • removing those individuals who no longer meet the standards It is a criminal offence for an individual to practice a statutorily

	regulated profession without being listed on the appropriate register.
Revalidation	Revalidation is a system of ongoing checks to encourage reflective practice and make sure practitioners are competent and up to date. It is also designed to help identify good practice and address poor practice behaviours before it results in patient harm.
Right-touch regulation	*Right-touch regulation* has been developed by the Professional Standards Authority for Health and Social Care and is aimed at making sure the level of regulation is proportionate to the level of risk to the public. (*Right-touch Regulation, PSA, 2015.)*
Self-regulation	Where professionals themselves are responsible for policing their own conduct, performance and behaviour.
Shared regulation	Encompassing both the public and professionals in the oversight of regulation.
Standards	The professional standards that professionals must uphold in order to be registered to practise a statutorily regulated profession in the United Kingdom.
Statutory professional regulation	The framework around which professional groups which are regulated by statute are required to register with the appropriate regulatory body and to meet the standards of practise set by those organisations. It is a criminal offence for an individual to practice a statutorily regulated profession without being listed on the appropriate register.
System regulation	This involves regulation of the quality and safety of care delivered by providers and regulation of the market in healthcare services.
Undertakings	Undertakings are an agreement between a professional regulatory body and a registered professional about their future practice. Undertakings are used, in appropriate cases, during the fitness to practise procedures/ process and are a form of consensual disposal.
Unitary Board	Board structure which comprises both non-executive and executive directors.
'Upstream'	The early intervention activities which the government proposes the professional regulatory bodies should take support professionals at an earlier stage to reduce the need for action at the fitness to practise stage.

9. References

[1] https://www. england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf

[2] http://www.gov.scot/Publications/2016/02/8699

[3] https://www.health-ni.gov.uk/sites/default/files/publications/health/health-and-wellbeing-2026-delivering-together.pdf

[4] http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted

[5] https://www.chseo.org.uk/downloads/report4-costefficiency.pdf

[6] Professions regulated following the Scotland Act 1998: operating department practitioners and practitioner psychologists, regulated by the Health and Care Professions Council; dental nurses, dental technicians, clinical dental technicians and orthodontic therapists, regulated by the General Dental Council and pharmacy technicians, regulated by the General Pharmaceutical Council.

[7] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228847/7013.pdf

[8] http://www.professionalstandards.org.uk/publications/detail/regulation-rethought

[9] http://www.lawcom.gov.uk/wp-content/uploads/2015/03/lc345_regulation_of_healthcare_professionals.pdf

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[11] http://www.professionalstandards.org.uk/publications/detail/right-touch-assurance-a-methodology-for-assessing-and-assuring-occupational-risk-of-harm

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[16] http://www.gmc-uk.org/guidance/good_medical_practice.asp

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[18] http://www.legislation.gov.uk/ukpga/2002/17/part/2/crossheading/the-council-for-the-regulation-of-health-care-professionals

[19] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228847/7013.pdf

[20] http://www.gmc-uk.org/guidance/good_medical_practice.asp

[21] https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf

[22] Professional Standards Authority estimated that these begin to be realised in a registrant base of between 100k and 200k individuals: http://www.professionalstandards.org.uk/docs/default-source/publications/special-review-report/cost-effectiveness-and-efficiency-review-health-professional-regulators-2012.pdf

[23] https://www.gov.uk/government/publications/striking-the-balance-upholding-the-7-principles-in-regulation

[24] http://www.lawcom.gov.uk/wp-content/uploads/2015/03/lc345_regulation_of_healthcare_professionals.pdf

[25] https://www.gov.uk/government/publications/regulation-of-health-and-social-care-professionals-response

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Memo

TO:	**Nancy Lum-Wilson, CEO and Registrar**
DATE:	**November 8, 2017**
CC:	
FROM:	**Todd Leach, Manager, Communications**
RE:	**2017 Regional (District) Meetings**

This fall, the College hosted a series of regional meetings (formerly referred to as district meetings) in four communities across the province. Meetings were held in Toronto (October 10), Ottawa (October 12), London (October 26) and Sudbury (November 1). College registrants were invited to attend any one of the meetings in person; although registration was required, there was no cost associated with registering for the regional meetings. Additionally, in an effort to provide flexible options for those who were not able to attend any of the four dates in person, members were given the option to register for one of two live webcasts (Toronto and London).

This year's regional meetings were the first member-facing meetings hosted by the College in over two years and the first opportunity for the College's new CEO and Registrar to engage with members through a regional meeting program. The program theme was "Patients First – Our Shared Goal" and was delivered by the CEO and Registrar, the Deputy Registrar and Director of Quality. Council members who were present were introduced at each of the meetings.

The program featured a 60-minute presentation followed by approximately 30-45 minutes of Q&A with those in attendance and those joining the meeting via webcast (where available). The presentation focused on the following topics: the College's Evolving Role, Patient Safety and Medication Safety, Legislative Updates, Practice Assessments and the Opioid Strategy.

A total of 1,112 members (including both pharmacists and pharmacy technicians) registered to attend either an in-person or webcast meeting; of those, 707 were confirmed to have attended in person or logged in to a webcast. More than one-third of those who registered either for an in person or webcast meeting did not attend. The breakdown by city/town is as follows:

City/Town	Registered	Webcast Registered	Attended	Webcast Attended
Toronto	319	249	135	171
Ottawa	156	-	85	-
London	122	180	95	141
Sudbury	86	-	80	-
Totals	**683**	**429**	**395**	**312**
Grand Total	**1,112**		**707**	

Access to consistent data on the performance of previous regional/district meetings is limited. A target satisfaction rate of at least 80% was assigned prior to the regional meeting implementation. Brief surveys have been sent to all meeting registrants following each meeting to identify overall satisfaction, what worked well, what could be improved, whether the meetings met expectations and potential future topics for the College to consider in future engagement and communication activities.

The surveys will close on November 20; the current response rate is 23%. Preliminary analysis of survey responses received to date indicate the following:

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Memo

In Person Attendees:

- 86% strongly agreed or agreed that, overall, the regional meetings were a worthwhile event
- 91% strongly agreed or agreed that they have a better understanding of College priorities and initiatives
- 93% strongly agreed or agreed that the meeting information was well organized and easy to follow
- 83% strongly agreed or agreed that the information was useful for member practice
- 94% strongly agreed or agreed that the meeting objectives were clear
- 87% strongly agreed or agreed that they would attend a future regional meeting

Webcast Attendees:

- 86% strongly agreed or agreed that, overall, the regional meetings were a worthwhile event
- 85% strongly agreed or agreed that they have a better understanding of College priorities and initiatives
- 93% strongly agreed or agreed that the meeting information was well organized and easy to follow
- 83% strongly agreed or agreed that the information was useful to member practice
- 90% strongly agreed or agreed that the meeting objectives were clear
- 86% strongly agreed or agreed that they would attend a future regional meeting
- 95% strongly agreed or agreed it was easy to sign up for the webcast
- 90% strongly agreed or agreed that it was easy to join in and participate via webcast

A final report will be prepared once the survey is closed. The report will include a breakdown of role (e.g. pharmacist, pharmacy technician, etc.) as well as an analysis of open-ended comments provided by respondents. Recommendations on future member engagement programming will be made at that time.

An archived webcast plus questions and answers from the regional meetings will be posted on the College website by late November.

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Memo

Date: **November 14, 2017**

To: **Council**

From: **Laura Weyland, Vice President, Chair - Strategic Planning Process**

RE: **2018 Strategic Planning Session**

As outlined in the Council Governance Manual, the position of Vice President is to chair the strategic planning process. Accordingly, I am pleased to advise that a planning group, consisting of staff and council, have been busy strategizing on an approach for our planning session in March 2018.

A team of facilitators were selected from amongst several that had been referred to the College over the past several months. They were specifically chosen for their background with broader health system delivery organizations as the changing environment within which the College operates warranted looking outside of the health regulatory arena. Over the next month or two, many of you will be contacted by co-facilitators, Georgina Veldhorst and/or Vania Sakelaris to share your thoughts and ideas with respect to the upcoming planning retreat.

A preliminary outline of pre-planning activities, including proposed approaches to soliciting input from internal and external stakeholders, has been developed. The planning group will be meeting with Georgina and Vania several times between now and the March retreat to consider how the feedback collected should be incorporated into the planning session.

To promote fresh thinking and encourage social interaction, the retreat will be held offsite as opposed to on College premises. We have secured the White Oaks Inn and Conference Centre in Niagara-on-the-Lake. The Council meeting and planning retreat will be held from noon, Sunday, March 25th to approximately noon, Tuesday, March 27th.

I will continue to update you as details of the pre-planning activities and retreat are finalized.

Attached: Facilitator Biographies
White Oaks Information

APPENDIX

A) PROFILES

Georgina Veldhorst is a seasoned and respected facilitator with more than 30 years' experience in the health care system as a clinician, senior executive and consultant. Since 2007, she has focused on supporting organizations plan and implement their transformations and increase their organizational effectiveness. She has exceptional facilitation skills and has extensive training and experience analyzing and managing the people dynamics slowing or limiting transformation. She is especially noted for her ability to provide guidance and support to executives, while ensuring alignment of internal and external stakeholders.

Clients describe her approach as relaxed but deep and thorough, which creates a respectful environment that achieves buy-in and commitment. Georgina's assignments have included guiding and supporting public sector and non-profit organizations navigate through complex and contentious situations with internal and external stakeholders. She has also worked with clients in Africa and Asia.

For this project, she brings experience in Strategic Planning and stakeholder engagement including:

- Health Quality Ontario - development of a Strategy to engage and involve citizens, patients and caregivers in the decision-making processes of Health Quality Ontario.
- Centre for Addictions and Mental Health – development of a 20 year service plan which included consultations with persons with lived experience across the province.
- Ministry of Children and Youth Services - developed a change management strategy and road map for the Systems Transitions Team and provided training and coaching to build their capacity for managing system transformation challenges.
- Save the Children (SC) International – designed and facilitated a process for SC United Kingdom, SC Canada, SC Denmark, SC Finland and SC Japan to develop and come to consensus on one common Country Strategic Plan for Kenya in preparation for 6 organizations merging into one.
- Bluewater Health – co-designed and facilitated development of a Strategic Plan and supported management of contentious Issues.
- United Nations AIDS Kenya – co-designed and facilitated Joint Programme and Joint Team Review and priority setting process with key UN technical experts and host government stakeholders.

Vania Sakelaris runs a management consulting practice providing advisory, coaching and training services with a focus in the health, social services and education industries building on over 20 years as a seasoned executive. Her track record as a strategic, respected and collaborative leader includes effective government relations, and sound knowledge of public policy. She has highly developed communication and presentation skills.

VAS & ASSOCIATES

Vania is well versed in the development and execution of strategies, and in the translation of strategic priorities into tangible and achievable programs. Her portfolio has included accountability for system level design, transformation and health care service capacity planning. Vania is effective at building partnerships, facilitating executive level discussions and influencing, negotiating and advancing innovative, integrated solutions.

Prior to establishing her consulting practice, Vania's extensive career has included progressive leadership roles within provincial government and crown agencies, and within community based organizations in the for-profit and not-for-profit sectors. Vania has also worked as a college instructor with a focus on policy and has lectured on health system strategy through Ivey Business School's Executive Education Program. She provides executive level coaching and is an active volunteer, participating on various community based boards.

Vania's relevant experience includes:

- leadership for stakeholder engagement to support the development of strategic plans in collaboration with a variety of stakeholders including private and public-sector funders, various levels of government, boards, service users and providers;
- leadership for the implementation of strategic plans and the advancement of strategic directions at the provincial, regional and organizational level;
- understanding of the relevance of strategic alignment, positioning and messaging, and the critical importance of tailoring corporate communications for internal and external stakeholders

VAS & ASSOCIATES

WHITE OAKS AT A GLANCE

LOCATION:

The Niagara Region has evolved to be an international travel destination and is distinguished as a world centre of viticulture. White Oaks is located centrally in the heart of wine country on 13 manicured acres in beautiful Niagara-on-the-Lake. The Resort is within 15 minutes from the Shaw Festival Theatre(s), the Old Town of NOTL, Fallsview Casino, Casino Niagara and Niagara Falls.

ADDRESS:

253 Taylor Road SS4,
Niagara-on-the-Lake, Ontario, Canada L0S 1J0
Phone: (905)688-2550 North America: 800-263-5766
E-Mail: reservations@whiteoaksresort.com

GUEST ROOMS:

* Chosen by "Canada Select" as Ontario's first Five Star Hotel Resort
* Four Diamond designation from Canadian Automobile Association/ American Automobile Association - CAA/AAA
* First recipient of the Christopher Newton "Niagara Visionary Award"
* Non Smoking Facility (All Conference and Guestrooms)
* 220 Rooms in total, including 126 Superior Guestrooms (double/king) and 61 Tower Guestrooms (Queen/King)
* Four White Oaks Suites with fireplace (sleeps five comfortably)
* Seven Platinum Rooms located on our secured level Seventh Floor (Queen/King)
* PLUS 22 Luxury Suites all boasting gas fireplaces and deep soaking tubs.
* Pillow top mattresses covered with luxurious duvets and pillows
* Bedding linens are 100% Egyptian Cotton Linen with 200 thread count
* Two oversized Robes in every guestroom
* Evening Turndown Service upon request
* Room Service
* Magnifying Make-Up Mirrors
* Hair Dryers, Iron and Ironing Boards
* Wi-Fi available in all rooms and throughout property
* Bedside USB charging ports
* Three telephones in every guestroom (one with speaker phone) and voicemail
* Alarm Clock/CD/Radios
* Professionally Designed Work Stations
* In-Room Coffee Makers with complimentary coffee/tea
* Personal Cooling Units
* LG 37 Inch 1080p LCD HDTV in every guestroom
* 8" LCD Televisions in bathrooms (all suites have 15" LCD Screens)
* Complimentary In-Room Laptop Safes
* Indoor Pool with Complimentary Towel Service
* Lodgenet movie system
* Each guestroom has its own efficient heat and air-conditioning controls
* Rooms available for the Physically Challenged Guest
* Dry Cleaning Service available Monday to Friday
* Convenient hairstyling at Nine Zero Five Salon in lobby

WHITE OAKS RESORT & SPA
Niagara-on-the-Lake