Ontario College of Pharmacists
Putting patients first since 1871

Agenda

ONTARIO COLLEGE OF PHARMACISTS

COUNCIL MEETING AGENDA

THURSDAY, AUGUST 22, 2019 – 10:00 A.M.

COUNCIL CHAMBERS, 483 HURON STREET, TORONTO

1. Noting Members Present

2. Declaration of Conflict

3. Approval of Agenda

4. For Decision

4.1 Briefing Note – Registrar – Approval of public consultation of proposed changes to regulation 202/94 VII.3 (controlled acts)

5. 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: AUGUST 2019

FOR DECISION	X	FOR INFORMATION

INITIATED BY: Nancy Lum-Wilson

TOPIC: Regulation amendments to enable expanded scope of practice for pharmacists

ISSUE: Approval to post the proposed amendments to *General Regulation 202/94* of the *Pharmacy Act*, Part VII.3 (Controlled Acts) for the purpose of public consultation.

PUBLIC INTEREST RATIONALE:
The Minister of Health has asked the College to submit regulations to enable an expanded scope of practice for pharmacists to help ease the burden on primary health care systems, particularly in areas with scarce resources, and thereby improve access to care for patients. In developing the regulatory changes needed to enable the new scope, the College needs to define the appropriate parameters that maximize the knowledge and skill of pharmacists while also ensuring the delivery of safe, high quality patient care.

BACKGROUND:
- On May 30, 2019, the College received a letter from the Minister of Health (Attachment 1) requesting that the Council of the College make regulations that would enable pharmacists to do the following:
    1. Administer the flu vaccine to children as young as two years old;
    2. Renew prescriptions in quantities of up to a 12-month supply;
    3. Administer certain substances by injection and/or inhalation for purposes that are in addition to patient education and demonstration; and
    4. Prescribe drugs for certain minor ailments.
- The Ministry has asked for the first three items to be submitted by November 30, 2019 and for the minor ailments regulation to be submitted by June 30, 2020.
- The Ministry also requested that the College work with Ministry staff to enable pharmacists to perform certain point of care tests (POCT) to support pharmacists' role in medication management and treatment of patients.
- The College has been working closely with the Ministry of Health in developing policy that will support these changes to scope, while ensuring that patient safety and quality care is not compromised.
- The College has also consulted with Ministry staff responsible for administration of the Universal Influenza Immunization Program (UIIP) and the *Laboratory and Specimen Collection Centre Licensing Act,* which will also require regulatory amendments in order to enable pharmacist administration to perform certain POCT.
- Over the last two months, the College has engaged and consulted broadly with stakeholders, including pharmacy associations and provincial pharmacy regulators, subject matter experts in pharmacy, medicine and public health, and with registrants through e-Connect and an online survey. The online survey gathered preliminary feedback from pharmacy professionals on the first three scope-related activities (see summary in Attachment 2). It was available for eight days and 373 responses were received during this time. The

feedback will inform the College's work to develop the regulatory amendments and tools needed to implement the scope changes.

- This briefing note addresses the regulation amendments to *General Regulation 202/94* to enable the first three scope-related activities, as well as additional changes needed to enable POCT. The proposed regulatory amendments to Part VII.3 (Controlled Acts) of the *General Regulation 202/94* of the *Pharmacy Act*, for the purpose of enabling the first three scope changes and POCT noted above, are outlined in Attachment 3.
- The rationale for each of these amendments is also presented in a clause-by-clause comparison chart in Attachment 4.

ANALYSIS:

- Enabling pharmacists to perform these acts aligns with the goals of the Premier's Council on Improving Healthcare and Ending Hallway Medicine.
- Expanding scope of practice will enable pharmacists, the health care professionals with the most extensive pharmacotherapeutics education, to optimize their therapeutic knowledge and experience and take on a greater role to improve health outcomes for patients.
- Over the past seven years, pharmacists have demonstrated their competency to safely and appropriately extend prescription renewals for up to six months. While pharmacists will continue to determine whether patients should first be assessed by their primary care provider, expanding this authority to renew for up to a year may enhance access to medication for some patients.
- Pharmacists, interns and pharmacy students who have injection training are currently permitted to administer certain vaccines to eligible patients who are five years of age or older. Based on consultations with public health experts, physicians, pharmacists and paediatric pain management experts, pharmacists will require an additional education program designed to equip them with the necessary techniques and strategies to manage behaviours in children as young as two when administering injections.
- Pharmacists have demonstrated their ability to safely and appropriately administer substances by injection and inhalation over the last seven years and have the competence required to extend this scope for purposes beyond patient education and demonstration.
- While Ministry policy continues to support reference to substances on a drug list, the College is working with Ministry staff to consider shifting the approach to a drug classification model based on the American Hospital Formulary Service (AHFS) categories. This would allow for continued currency of substances and the ability of pharmacists to administer the most appropriate substance based on individual patient needs. Given the potential that either of these models may be accepted, it is recommended that each model is included in the public consultation.
- In order to enable POCT, which requires amendments to the Ministry's regulation under the the *Laboratory and Specimen Collection Centre Licensing Act,* pharmacists will need to be able to pierce the dermis using a lancet type device for purposes beyond patient demonstration and self-monitoring of chronic diseases. POCT results and any subsequent prescription adaptations will also need to be communicated to the primary care provider, and documented in the patient record. These provisions are therefore included in the proposed amendments to the *Pharmacy Act's General Regulation 202/94.*

NEXT STEPS:

- Following approval of Council, the proposed regulations will be posted on the College's consultation page for the mandated 60 day period for public review. The Ministry of Health will concurrently post the proposed regulatory changes on the Public Registry for public consultation for a 45 day period.

- A consultation report, including a summary of feedback and any recommended changes to the proposed amendments, will be presented to Council for consideration at the special Council meeting on November 21, 2019, with the intent to submit the final regulation amendments to the Minister by November 30, 2019, as requested.
- The College has also initiated development of a plan, including a jurisdictional scan and stakeholder engagement, related to regulatory amendments needed to enable prescribing for minor ailments. Details will be presented to Council at the next meeting.

RECOMMENDATION: That Council approve the proposed amendments to *General Regulation 202/94* of the *Pharmacy Act*, Part VII.3 (Controlled Acts) for the purpose of public consultation in preparation for submission of regulatory amendments to the Minister of Health by November 30, 2019.

Ministry of Health and Long-Term Care

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Ontario

May 30, 2019

HLTC2968IT-2019-57

Ms. Laura Weyland
President
Ontario College of Pharmacists
483 Huron Street
Toronto ON M5R 2R4

Dear Ms. Weyland:

As was articulated in the 2019 Ontario Budget, we are committed to enabling health professions to use their education and training more effectively by expanding the scope of practice for certain regulated health professionals.

One way that we can achieve our vision, is to ensure that patients have streamlined care pathways that make connections easier in the system and that there is access to minor and routine care in the community. Recognizing the integral role that pharmacists play in helping us to achieve these commitments, I would like the Council of the Ontario College of Pharmacists (College) to make regulations that would enable pharmacists to do the following:

1. Administer the flu vaccine to children as young as two years old;
2. Renew prescriptions in quantities of up to a year's supply;
3. Administer certain substances by injection and/or inhalation for purposes that are in addition to patient education and demonstration; and
4. Prescribe drugs for certain minor ailments.

With respect to the first three items listed above, I would like the College to submit a regulation to the ministry for my review no later than November 30, 2019. With respect to prescribing for minor ailments, I would like the College to submit a regulation to the ministry for my review no later than June 30, 2020.

Additionally, in recognition of the need for pharmacists to have access to information to assist with medication management and the treatment of patients, I have asked ministry staff to work with the College to authorize pharmacists to perform certain point of care tests for certain chronic conditions. I have asked that this be implemented as soon as possible, once a broad consultation occurs.

Ms. Laura Weyland

To ensure that the work of the College considers all possible perspectives, I am expecting the College to actively consult with system partners in the development of its own regulations and that this work be undertaken as soon as possible. I understand that as a result of these consultations and through the College's own work, that there may be the need to place parameters on these new authorities. This may include the College requiring pharmacists to demonstrate that they are competent and can provide safe, high-quality care when performing these activities.

I would like to thank the College for its continued contributions to the healthcare system in Ontario, and I look forward to your continued partnership on these initiatives.

Sincerely,

Christine Elliott
Deputy Premier and Minister of Health and Long-Term Care

c: Helen Angus, Deputy Minister, Ministry of Health and Long-Term Care
Patrick Dicerni, Assistant Deputy Minister, Strategic Policy and Planning Division
Allison Henry, Director, Health Workforce Regulatory Oversight Branch
Nancy Lum-Wilson, Registrar and Chief Executive Officer, Ontario College of Pharmacists
Justin Bates, Chief Executive Officer, Neighbourhood Pharmacy Association of Canada
Bill Wilson, Interim Chief Executive Officer, Ontario Pharmacists Association

Summary: Expanded Scope Survey

Background

The College conducted a registrant-targeted online survey from July 11-18, 2019, which was promoted through e-Connect (also shared on social media) and the OCP website. There were 373 respondents.

The survey consisted of 15 questions with prompts to provide comments (e.g. "Please explain" or "If yes/no, please comment"). Some questions were not provided if the previous response negated them. Respondents could also skip questions.

Analysis of Survey Feedback

- The number of respondents (373 in eight days) is significantly higher in comparison to previous survey response rates, suggesting there is a high level of interest in expanded scope among pharmacy professionals.
- Many respondents indicated that they would feel more comfortable providing these additional patient care services if they had more training, access to medical notes and labs, the authority to order tests, etc.
- Some respondents saw risks associated with making certain changes (e.g. renewing prescriptions for up to a year's supply), including: lack of access to patient medication history and lab tests results, and patients failing to follow up with their primary care providers to determine whether bloodwork and/or an assessment by a physician is needed.
- Some respondents indicated that certain changes, such as renewing prescriptions for up to a year's supply, would have little impact on the issues pharmacists currently face.
- Many expressed a need for a funding model and work environment that supports expanded scope, such as additional staffing to accommodate new patient care services.
- Some changes to scope were seen to have an impact in reducing system costs and burdens in emergency departments and primary care (i.e. administering substances for injection/inhalation beyond training/education purposes).

Key Highlights

Renewing prescriptions up to a year's supply:

- Majority (79%) say the 6-month limit creates a barrier to providing patient care (such as patients who do not have a primary care provider or have difficulty accessing primary care).
- Majority (74%) say the change would not address the issues they currently face; 72% see risks around increasing the current six-month limit, including patients not following up with their primary care provider for an assessment and potential lab tests. Many felt that 6 months is enough time for a patient to follow up with their primary care provider.
- Many say they would feel more comfortable if they had access to lab results and could order tests.

Flu vaccine for children 2-5:

- Respondents were split on whether they have concerns vaccinating that age group.
- Concerns include difficulty in administering the injection to crying/upset/moving children; risk of severe reactions; the time required to administer the vaccine and lack of space and privacy for young patients.

- Respondents said additional training would be helpful, specifically guidance/education on injection technique, dosing schedule, pediatric care anatomy and physiology, how to administer an injection to a moving/crying/upset child, how to recognize the signs of a severe or allergic reaction and what to do in a medical emergency.

Administering substances for injection or inhalation beyond education and training purposes:

- Majority (81%) said it would increase access to patient care and 70% saw a role for pharmacists in administering these substances in a patient's home care setting.
    - Some respondents said that it would increase access for patients who are frail, elderly, housebound, disabled, live in remote and rural areas, and those who do not have a primary care provider.
    - Some respondents said it would help patients who are unable to administer these substances themselves, and if compliance is an issue.
- Concerns included role overlap with physicians/nurses and administration outside of pharmacists' role; too busy and not enough support to provide these services at a pharmacy.

Pharmacy Act, 1991
Loi de 1991 sur les pharmaciens

ONTARIO REGULATION 202/94
GENERAL

Consolidation Period: From December 15, 2016 to the e-Laws currency date.

Last amendment: 452/16.

Legislative History: 750/94, 539/95, 280/96, 121/97, 98/98, 642/98, 548/99, 270/04, 451/10, 59/11, 302/12, 154/13, 225/13, 452/16.

This Regulation is made in English only.

CONTENTS

PART I
INTERPRETATION

DEFINITIONS

1. In this Regulation,

"direct supervision" means supervision that is provided by a person who is physically present on the premises where the practice that is being supervised is being carried out;

"non-restricted registration" means the holding of a licence, permit, certificate or registration as a pharmacist from an authority responsible for the regulation of pharmacists in one of the states of the United States of America, or in another non-Canadian jurisdiction that has been approved by the Council, where that licence, permit, certificate or registration is not subject to any restrictions, terms, conditions or limitations, including terms, conditions or limitations that,

(a) relate to the holder's ability to practise independently,

(b) require the holder to practise under supervision or direction,

(c) require the holder to maintain a position or appointment as a condition of continued registration,

(d) require the holder to practise only in a part of the geographical area over which the authority has jurisdiction,

(e) restrict the holder to temporary or time-limited registration or practice,

(f) were imposed by that authority or any committee or panel of that authority as a result of a disciplinary, registration, fitness to practise or similar proceeding, or

(g) were placed on the holder's registration by agreement between the holder and that authority;

"pharmacy" has the same meaning as in subsection 1 (1) of the *Drug and Pharmacies Regulation Act*;

"remote dispensing location" has the same meaning as in subsection 1 (1) of the *Drug and Pharmacies Regulation Act*.

PART II
GENERAL PROVISIONS RE CERTIFICATES OF REGISTRATION

CLASSES OF CERTIFICATES OF REGISTRATION

2. (1) The following are prescribed as classes of certificates of registration:

1. Pharmacist.
2. Registered pharmacy student.
3. Intern.
4. Pharmacy technician.

(2) Every certificate of registration that was in existence immediately before December 3, 2010 is continued as the equivalent certificate of registration with the same status under this Regulation until such time as it otherwise ceases to be effective.

(3) Where an application for a certificate of registration had been made but not finally dealt with before December 3, 2010, the application shall be dealt with in accordance with this Regulation as amended by Ontario Regulation 451/10.

APPLICATION FOR CERTIFICATE OF REGISTRATION

3. A person may apply for a certificate of registration by submitting a completed application in the form provided by the Registrar together with any supporting documentation requested by the Registrar and the applicable fees.

REQUIREMENTS FOR ISSUANCE OF CERTIFICATE OF REGISTRATION, ANY CLASS

4. (1) The following are requirements for the issuance of a certificate of registration of any class:

1. The applicant must possess sufficient language proficiency, in either English or French, to be able to communicate and comprehend effectively, both orally and in writing.
2. The applicant must not have been found guilty of any offence in any jurisdiction.
3. The applicant must not be the subject of a current proceeding in respect of any offence in any jurisdiction.
4. The applicant must not have been the subject of a finding of professional misconduct, incompetence or incapacity or any like finding in Ontario or any other jurisdiction in relation to pharmacy or any other profession or occupation and must not be the subject of any current professional misconduct, incompetence, or incapacity proceeding or any like proceeding in Ontario or any other jurisdiction in relation to pharmacy or any other profession or occupation.
5. The applicant must be a Canadian citizen or permanent resident of Canada or must hold the appropriate authorization under the *Immigration and Refugee Protection Act* (Canada) to permit the applicant to engage in the practice of pharmacy in Ontario as a pharmacist, registered pharmacy student, intern or pharmacy technician in the manner permitted by the certificate of registration for which he or she has applied.
6. The applicant's past and present conduct must afford reasonable grounds for the belief that the applicant,
    i. will practise pharmacy with decency, honesty and integrity, and in accordance with the law,
    ii. does not suffer from any physical or mental condition or disorder that could affect his or her ability to practise pharmacy in a safe manner,
    iii. has sufficient knowledge, skill and judgment to competently engage in the practice of pharmacy authorized by the certificate of registration, and
    iv. will display an appropriately professional attitude.
7. The applicant must provide evidence satisfactory to the Registrar that the applicant will have professional liability insurance in the amount and in the form as required by the by-laws as of the anticipated date for the issuance of his or her certificate of registration.
8. The applicant must have paid any fees required under the by-laws for the issuance of the certificate of registration for which the applicant applied.

(2) The requirement under paragraph 8 of subsection (1) is non-exemptible.

(3) An applicant must meet all of the requirements for registration within one year following the filing his or her application, but this does not prevent the applicant from filing a new application.

(4) An applicant shall be deemed not to have satisfied the requirements for the issuance of a certificate of registration if the applicant makes a false or misleading statement or representation in his or her application or supporting documentation.

TERMS, ETC., OF EVERY CERTIFICATE

5. Every certificate of registration is subject to the following terms, conditions and limitations:

1. The member shall provide to the Registrar the details of any of the following that relate to the member and that occur or arise after the registration of the member:
    i. a finding of guilt arising in any jurisdiction relating to any offence,
    ii. a charge arising in any jurisdiction relating to any offence,
    iii. a finding of professional misconduct, incompetence or incapacity or any like finding in any jurisdiction in relation to pharmacy or any other profession or occupation,
    iv. a proceeding for professional misconduct, incompetence or incapacity or any like proceeding in any jurisdiction in relation to pharmacy or any other profession or occupation.
2. The member shall not engage in the practice of pharmacy unless the member is a Canadian citizen or permanent resident of Canada or has authorization under the *Immigration and Refugee Protection Act* (Canada) permitting the member to engage in the practice of pharmacy in Ontario in the manner permitted by the certificate of registration.
3. The member shall immediately advise the Registrar in writing in the event the member ceases to be a Canadian citizen or permanent resident of Canada or to have authorization under the *Immigration and Refugee Protection Act* (Canada) permitting the member to engage in the practice of pharmacy in Ontario in the manner permitted by the certificate of registration.
4. If a member to whom paragraph 3 applies subsequently obtains Canadian citizenship or becomes a permanent resident of Canada or attains authorization under the *Immigration and Refugee Protection Act* (Canada) permitting the member to engage in the practice of pharmacy in Ontario permitted by the certificate of registration, the member shall immediately advise the Registrar in writing of that fact.
5. The member shall maintain professional liability insurance in the amount and in the form as required by the by-laws.

6. A member who fails to meet the condition in paragraph 5 shall immediately advise the Registrar in writing of that fact and immediately cease to engage in the practice of pharmacy until such time as the member obtains professional liability insurance as required in paragraph 5.

7. Where a member to whom paragraph 6 applies subsequently obtains professional liability insurance, the member shall notify the Registrar in writing of that fact and, if requested by the Registrar, shall provide details of that coverage.

PART III
REGISTRATION — PHARMACISTS

ADDITIONAL REQUIREMENTS

6. (1) The following are additional requirements for the issuance of a certificate of registration as a pharmacist:

1. The applicant must,

   i. have a minimum of a baccalaureate degree in pharmacy evidencing the successful completion of a program designed to educate and train persons to be practising pharmacists which was,

      A. awarded on or before December 31, 1993 by a constituent faculty of the Association of Faculties of Pharmacy of Canada, or

      B. awarded by a university as a result of successful completion of a program which was, at the time of the award, accredited by the Canadian Council for Accreditation of Pharmacy Programs or by another accrediting body approved by the Council for that purpose, or

   ii. have a university degree in pharmacy that does not meet the requirements of subparagraph i but that evidences the successful completion of a program designed to educate and train persons to be practising pharmacists, and,

      A. have successfully completed a program that, at the time the applicant commenced it, was approved by the Council as one whose graduates should possess knowledge, skill and judgment at least equal to those of current graduates of a program mentioned in sub-subparagraph i B, or

      B. have successfully completed the examination provided for in paragraph 4 on the applicant's first attempt and have successfully completed any further education or training or combination of education and training that was specified by a panel of the Registration Committee to evidence that the applicant possesses knowledge, skill and judgment at least equal to those of current graduates of a program mentioned in sub-subparagraph i B.

2. The applicant must have successfully completed an examination in pharmaceutical jurisprudence approved by the Council for applicants for a certificate of registration as a pharmacist.

3. Subject to subsection (5), the applicant must have successfully completed a structured practical training program approved by the Council, while holding a certificate of registration as an intern and while under the supervision of a preceptor approved by the Registration Committee.

4. The applicant must have successfully completed the qualifying examination of the Pharmacy Examining Board of Canada for pharmacists at a time when the examination was approved by the Council or have successfully completed another examination that has been approved by the Council for that purpose.

(2) With the approval of the Council, all or any part of a structured practical training program referred to in paragraph 3 of subsection (1) may be completed as part of a program referred to in paragraph 1 of subsection (1), even if the applicant did not hold a certificate of registration as an intern at the time.

(3) The requirement in paragraph 1 of subsection (1) must be met within two years before the date on which the applicant met all of the other requirements for the issuance of a certificate of registration as a pharmacist unless the applicant,

(a) satisfies the Registrar or a panel of the Registration Committee that the applicant has practised pharmacy within the scope of practice of the profession as set out in section 3 of the Act for at least 600 hours during the three years before the date on which the applicant met all of the other requirements for the issuance of a certificate of registration as a pharmacist in the course of providing patient care while practising as a pharmacist in Canada, the United States of America or another jurisdiction approved by the Council;

(b) undergoes a review of his or her practice conducted in a manner approved by the Registration Committee, meets any requirements regarding continuing education or remediation set by a panel of the Registration Committee within the time set by the panel, and pays the required fees; or

(c) successfully completes the examination referred to in paragraph 4 of subsection (1) within three years of the date on which he or she meets all of the other requirements for the issuance of a certificate of registration as a pharmacist.

(4) The requirement in paragraph 2 of subsection (1) shall not be considered to be met unless the applicant is issued a certificate of registration as a pharmacist within three years of meeting that requirement.

(5) An applicant is deemed to have met the requirement in paragraph 3 of subsection (1) if, at the time of application, the applicant,

(a) has successfully completed a structured practical training program which is, in the opinion of the Registration Committee at least equivalent to the program mentioned in paragraph 3 of subsection (1); or

(b) has other education, training or experience that is, in the opinion of a panel of the Registration Committee at least equivalent to the program mentioned in paragraph 3 of subsection (1).

(6) The requirement in paragraph 3 of subsection (1) shall not be considered to have been met unless the applicant is issued a certificate of registration as a pharmacist within two years of meeting the requirement or within such greater time as is specified by a panel of the Registration Committee.

(7) Subject to subsection (8), the requirement in paragraph 4 of subsection (1) is not considered to have been met unless the applicant,

(a) successfully completed the examination within three attempts; or

(b) successfully completed the examination on the applicant's fourth attempt having first successfully completed the further education or training or combination of education and training required by the examining body responsible for the administration of the examination or, if no further education or training was required by that body, the further education or training or combination of education and training, if any, specified by a panel of the Registration Committee.

(8) Where, by virtue of subsection (7), an applicant is not considered to have met the requirement in paragraph 4 of subsection (1), the applicant may not attempt the examination again until the applicant obtains a new degree mentioned in subparagraph 1 i of subsection (1).

(9) An applicant is only eligible to take the examination referred to in paragraph 2 of subsection (1) three times in any 24-month period.

(10) The requirements in paragraphs 1, 3 and 4 of subsection (1) are deemed to have been met by an applicant,

(a) who previously held a certificate of registration as a pharmacist in Ontario; and

(b) who,

(i) satisfies the Registrar or a panel of the Registration Committee that the applicant has practised pharmacy within the scope of practice of the profession as set out in section 3 of the Act for at least 600 hours during the three years before the date on which the applicant met all of the other requirements for the issuance of a certificate of registration as a pharmacist in the course of providing patient care while practising as a pharmacist in Canada, the United States of America or another jurisdiction approved by the Council, or

(ii) undergoes a review of his or her practice conducted in a manner approved by the Registration Committee, meets any requirements regarding continuing education or remediation set by a panel of the Registration Committee within the time set by the panel, and pays the required fees.

(11) An applicant who has a university degree in pharmacy mentioned in subparagraph 1 ii of subsection (1), and who successfully completes any further education or training or combination of education and training specified by a panel of the Registration Committee shall be deemed to have met the requirement in paragraph 1 of subsection (1) if the applicant,

(a) was registered as an intern on December 3, 2010; or

(b) becomes registered as an intern after December 3, 2010 but before December 3, 2011.

(12) Subject to subsections (2), (5), (10) and (11) and sections 7 and 8, the requirements in subsection (1) are non-exemptible.

(13) A reference in this section or section 7 to "all of the other requirements for the issuance of a certificate of registration" includes, without being limited to, a requirement set out in subsection 4 (1) or subsection (1) of this section.

MOBILITY FROM OUTSIDE CANADA

7. An applicant is deemed to have met the requirements in paragraph 1 of subsection 6 (1) if the applicant meets all the following non-exemptible requirements:

1. The applicant must,

i. hold a non-restricted registration in at least one jurisdiction at the time of application and have held that registration continuously for at least two years, and

ii. satisfy the Registrar or a panel of the Registration Committee that the applicant engaged in the full scope of practice as a pharmacist in that jurisdiction for at least 600 hours.

2. The applicant must,

i. satisfy the Registrar or a panel of the Registration Committee that the applicant has practised pharmacy within the scope of practice of the profession as set out in section 3 of the Act for at least 600 hours during the three years before the date on which the applicant met all of the other requirements for the issuance of a certificate of registration as a pharmacist in the course of providing patient care while practising as a pharmacist in one or more of the jurisdictions where he or she held the non-restricted registration,

ii. undergo a review of his or her practice conducted in a manner approved by the Registration Committee, meet any requirements regarding continuing education or remediation set by a panel of the Registration Committee within the time set by the panel, and pay the required fees, or

iii. successfully complete the examination referred to in paragraph 4 of subsection 6 (1) within three years of the date on which he or she meets all of the other requirements for the issuance of a certificate of registration as a pharmacist.

MOBILITY WITHIN CANADA

8. (1) Where section 22.18 of the Health Professions Procedural Code applies to an applicant the requirements of paragraphs 1, 3 and 4 of subsection 6 (1) are deemed to have been met by the applicant if he or she provides, for each jurisdiction where the applicant holds an out-of-province certificate, a certificate, letter or other evidence satisfactory to the Registrar or a panel of the Registration Committee confirming that the applicant is in good standing as a pharmacist in that jurisdiction.

(2) Without in any way limiting the generality of subsection (1), "good standing" shall include the fact that,

(a) the applicant is not the subject of any discipline or fitness to practise order or of any proceeding or ongoing investigation or of any interim order or agreement as a result of a complaint, investigation or proceeding; and

(b) the applicant has complied with the continuing competency and quality assurance requirements of the regulatory authority that issued the applicant that out-of-province certificate as a pharmacist.

(3) An applicant referred to in subsection (1) is deemed to have met the requirements of paragraph 1 of subsection 4 (1) where the requirements for the issuance of the applicant's out-of-province certificate included language proficiency requirements equivalent to those required by that paragraph.

(4) Despite subsection (1), an applicant is not deemed to have met a requirement if that requirement is described in subsection 22.18 (3) of the Health Professions Procedural Code.

TERMS, CONDITIONS AND LIMITATIONS, PART B PHARMACIST

9. (1) Every certificate of registration of a pharmacist listed in Part B of the register is subject to the following terms, conditions and limitations:

1. The member shall not provide any care to a patient, whether direct or indirect.
2. The member shall not dispense, sell or compound drugs.
3. The member shall not supervise that part of the pharmacy where drugs are kept.
4. The member shall not be the designated manager of a pharmacy within the meaning of the *Drug and Pharmacies Regulation Act*.
5. The member shall not supervise the practice of pharmacy of an intern, registered pharmacy student or pharmacy technician.
6. The member shall, when working in a pharmacy or any other environment where patient care is being provided, clearly identify him or herself as a non-practising pharmacist.

(2) With the prior written approval of the Registrar, and despite paragraphs 1 and 2 of subsection (1), a pharmacist listed in Part B of the register may dispense, sell or compound a drug and provide care to a patient under the direct supervision of a pharmacist who is registered in Part A of the register where the sole purpose is to assist the member in preparing to meet the requirements specified in subsection 46 (3) to transfer a member holding a certificate of registration as a pharmacist who is registered in Part B of the register to Part A of the register.

(3) Where a member wishes to seek the approval of the Registrar under subsection (2), the member shall provide to the Registrar, in writing, the name of the pharmacist or pharmacists who will be providing the required supervision, the name and address of the pharmacy or pharmacies at which the member proposes to practise under that supervision and the proposed date upon which the member wishes to commence practice.

(4) Any approval provided by the Registrar under subsection (2) must specify,

(a) the name of the pharmacist or pharmacists who will be required to supervise the member;

(b) the name and address of the pharmacy or pharmacies where the member will be practising; and

(c) the term of the approval, which must not exceed six months.

(5) Where the Registrar is satisfied that it is appropriate to do so the Registrar may extend the term of the approval provided under subsection (2) but in no case may the combined term exceed one year unless a panel of the Quality Assurance Committee approves of a further extension.

PART IV
REGISTRATION — REGISTERED PHARMACY STUDENTS

ADDITIONAL REQUIREMENT

10. (1) It is an additional requirement for the issuance of a certificate of registration as a registered pharmacy student that the applicant must,

(a) have been accepted as a student in a university program referred to in subparagraph 1 i of subsection 6 (1) or in an approved program referred to in sub-subparagraph 1 ii A of that subsection;

(b) be engaged in attaining any education or training referred to in sub-subparagraph 1 ii B of subsection 6 (1); or

(c) be engaged in attaining any education or training specified by a panel of the Registration Committee as a condition for the issuance of another certificate of registration, other than a certificate of registration as a pharmacy technician.

(2) Subject to section 11, the requirement in subsection (1) is non-exemptible.

MOBILITY WITHIN CANADA

11. (1) Where section 22.18 of the Health Professions Procedural Code applies to an applicant the requirements of subsection 10 (1) are deemed to have been met by the applicant if he or she provides, for each jurisdiction where the applicant holds an out-of-province certificate, a certificate, letter or other evidence satisfactory to the Registrar or a panel of the Registration Committee confirming that the applicant is in good standing as a pharmacy student in that jurisdiction.

(2) Without in any way limiting the generality of subsection (1), "good standing" shall include the fact that,

(a) the applicant is not the subject of any discipline or fitness to practise order or of any proceeding or ongoing investigation or of any interim order or agreement as a result of a complaint, investigation or proceeding; and

(b) the applicant has complied with the continuing competency and quality assurance requirements of the regulatory authority that issued the applicant that out-of-province certificate as a registered pharmacy student.

(3) An applicant referred to in subsection (1) is deemed to have met the requirements of paragraph 1 of subsection 4 (1) where the requirements for the issuance of the applicant's out-of-province certificate included language proficiency requirements equivalent to those required by that paragraph.

(4) Despite subsection (1), an applicant is not deemed to have met a requirement if that requirement is described in subsection 22.18 (3) of the Health Professions Procedural Code.

TERMS, CONDITIONS AND LIMITATIONS

12. (1) Every certificate of registration as a registered pharmacy student is subject to the following terms, conditions and limitations:

1. The member,
    i. in the case of a member to whom subsection 11 (1) does not apply, shall only engage in the practice of pharmacy while enrolled in and actively participating in a program provided for in subsection 10 (1) or while actively engaged in any education or training specified in that subsection, and
    ii. in the case of a member to whom subsection 11 (1) applies, shall only engage in the practice of pharmacy while enrolled in and actively participating in an educational program that is a requirement for the issuance of an applicable out-of-province certificate authorizing practice as an intern or pharmacist.
2. The member may only engage in the practice of pharmacy,
    i. while under the direct supervision of a member who holds a certificate of registration as a pharmacist, or
    ii. where a program or any education or training provided for in subsection 10 (1) includes a clinical component in a premises that is not a pharmacy but at which drugs may be prescribed or dispensed, while under the direct supervision of a member of a College within the meaning of the *Regulated Health Professions Act, 1991* who has been approved for this purpose by the faculty that provides the program, education or training.
3. Despite subparagraph 2 ii, the member shall not dispense, compound or sell a drug unless under the direct supervision of a member holding a certificate of registration as a pharmacist.
4. Despite subparagraph 2 ii, the member may not supervise that part of the pharmacy where drugs are kept.
5. The member may neither delegate a controlled act nor accept the delegation of a controlled act.

(2) A certificate of registration as a registered pharmacy student automatically expires when the member is issued a certificate of registration as a pharmacist or an intern.

(3) A certificate of registration as a registered pharmacy student automatically expires,

(a) in the case of a member engaged in a program referred to in subparagraph 1 i of subsection 6 (1), when the member is refused readmission to the program, ceases to be enrolled in the program or ceases to actively participate in the program;

(b) in the case of a member engaged in an approved program referred to in sub-subparagraph 1 ii A of subsection 6 (1), two years after registration as a registered pharmacy student unless that period of time is extended by a panel of the Registration Committee;

(c) in the case of a member engaged in attaining any education or training or combination of education and training referred to in sub-subparagraph 1 ii B of subsection 6 (1) or in attaining any education or training or combination of education and training required by a panel of the Registration Committee as a condition for the issuance of another class of certificate of registration, on the date specified by the panel in its decision or, if no date was specified, one year from that decision, unless extended by a panel of the Registration Committee; and

(d) in the case of a member whose application for a certificate of registration as a registered pharmacy student was considered under subsection 11 (1), on the date on which the member ceases to hold an out-of-province certificate that is equivalent to a certificate of registration as a registered pharmacy student.

PART V
REGISTRATION — INTERNS

ADDITIONAL REQUIREMENTS

13. (1) The following are additional requirements for the issuance of a certificate of registration as an intern:

1. The applicant must,

   i. have a minimum of a baccalaureate degree in pharmacy evidencing the successful completion of a program designed to educate and train persons to be practising pharmacists which was,

      A. awarded on or before December 31, 1993 by a constituent faculty of the Association of Faculties of Pharmacy of Canada, or

      B. awarded by a university as a result of successful completion of a program which was, at the time of the award, accredited by the Canadian Council for Accreditation of Pharmacy Programs or by another accrediting body approved by the Council for that purpose, or

   ii. have a university degree in pharmacy that does not meet the requirements of subparagraph i but that evidences the successful completion of a program designed to educate and train persons to be practising pharmacists, and,

      A. have successfully completed a program that, at the time the applicant commenced it, was approved by the Council as one whose graduates should possess knowledge, skill and judgment at least equal to those of current graduates of a program mentioned in sub-subparagraph i B, or

      B. have successfully completed the examination provided for in paragraph 4 of subsection 6 (1) on the applicant's first attempt and have successfully completed any further education or training or combination of education and training that was specified by a panel of the Registration Committee to evidence that the applicant possesses knowledge, skill and judgment at least equal to those of current graduates of a program mentioned in sub-subparagraph i B.

2. Subject to subsections (3) and (4), the applicant must have successfully completed a structured practical training program approved by the Council while holding a certificate of registration as a registered pharmacy student and while under the direct supervision of a preceptor approved by the Registration Committee.

(2) Subject to subsections (3) and (4) and section 14, the requirements in subsection (1) are non-exemptible.

(3) With the approval of the Council, all or any part of a structured practical training program referred to in paragraph 2 of subsection (1) may be completed as part of a program referred to in paragraph 1 of subsection (1), even if the applicant did not hold a certificate of registration as a registered pharmacy student at the time.

(4) An applicant shall be deemed to have met the requirement in paragraph 2 of subsection (1) if, at the time of application, the applicant holds a non-restricted registration as a pharmacist, has held that registration for at least two years and the applicant,

(a) satisfies the Registrar or a panel of the Registration Committee that the applicant engaged in the full scope of practice as a pharmacist in that jurisdiction for at least 600 hours;

(b) successfully completed a structured practical training program which is, in the opinion of a panel of the Registration Committee at least equivalent to a program mentioned in paragraph 2 of subsection (1), or has other education, training or experience that, in the opinion of a panel of the Registration Committee is at least equivalent to the program mentioned in paragraph 2 of subsection (1); or

(c) successfully completed the education and obtained the additional training or experience that a panel of the Registration Committee has specified.

(5) The requirement of paragraph 2 of subsection (1) shall not be considered to have been met unless the applicant is issued a certificate of registration as an intern within one year of meeting that requirement or within such greater time as is specified by a panel of the Registration Committee.

(6) An applicant who has a university degree in pharmacy mentioned in subparagraph 1 ii of subsection (1), and who successfully completes any further education or training or combination of education and training specified by a panel of the Registration Committee shall be deemed to have met the requirement in paragraph 1 of subsection (1) if the applicant,

(a) was registered as a registered pharmacy student on December 3, 2010; or

(b) becomes registered as a registered pharmacy student after December 3, 2010 but before December 3, 2011.

MOBILITY WITHIN CANADA

14. (1) Where section 22.18 of the Health Professions Procedural Code applies to an applicant the requirements of subsection 13 (1) are deemed to have been met by the applicant if he or she provides, for each jurisdiction where the applicant holds an out-of-province certificate, a certificate, letter or other evidence satisfactory to the Registrar or a panel of the Registration Committee confirming that the applicant is in good standing as an intern in that jurisdiction.

(2) Without in any way limiting the generality of subsection (1), "good standing" shall include the fact that,

(a) the applicant is not the subject of any discipline or fitness to practise order or of any proceeding or ongoing investigation or of any interim order or agreement as a result of a complaint, investigation or proceeding; and

(b) the applicant has complied with the continuing competency and quality assurance requirements of the regulatory authority that issued the applicant that out-of-province certificate as an intern.

(3) An applicant referred to in subsection (1) is deemed to meet the requirements of paragraph 1 of subsection 4 (1) where the requirements for the issuance of the applicant's out-of-province certificate included language proficiency requirements equivalent to those required by that paragraph.

(4) Despite subsection (1), an applicant is not deemed to have met a requirement if that requirement is described in subsection 22.18 (3) of the Health Professions Procedural Code.

TERMS, CONDITIONS AND LIMITATIONS

15. (1) Every certificate of registration as an intern is subject to the following terms, conditions and limitations:

1. The member shall only engage in the practice of pharmacy,
   i. when practising in a pharmacy to which the *Drug and Pharmacies Regulation Act* applies, while under the direct supervision of a member holding a certificate of registration as a pharmacist, or
   ii. in all other cases, while under the supervision of a member holding a certificate of registration as a pharmacist.
2. The member shall not supervise that part of the pharmacy where drugs are kept.
3. The member shall not delegate a controlled act.

(2) A certificate of registration as an intern automatically expires,

(a) when the member is issued a certificate of registration as a pharmacist; or

(b) one year from the date on which it was issued unless a panel of the Registration Committee specifies otherwise.

PART VI
REGISTRATION — PHARMACY TECHNICIANS

ADDITIONAL REQUIREMENTS

16. (1) The following are additional requirements for the issuance of a certificate of registration as a pharmacy technician:

1. The applicant must,
   i. have successfully completed a pharmacy technician program designed to educate and train persons to be pharmacy technicians which was, at the time the applicant graduated, accredited by the Canadian Council for Accreditation of Pharmacy Programs or such other accrediting body approved by the Council for that purpose,
   ii. have successfully completed a pharmacy technician program designed to educate and train persons to be pharmacy technicians other than one referred to in subparagraph i or have a university degree or university diploma in pharmacy and, in either case,
      A. must have successfully completed a program that, at the time the applicant commenced was approved by the Council as one whose graduates should possess knowledge, skill and judgment at least equivalent to a current graduate of a program referred to in subparagraph i, or

B. must have successfully completed the examination referred to in paragraph 4 on the applicant's first attempt, and have successfully completed any further education or training or combination of education and training that was specified by a panel of the Registration Committee to evidence that the applicant possesses knowledge, skill and judgment at least equivalent to a current graduate of a program referred to in subparagraph i,

iii. have successfully completed a program before January 1, 2015 that, at the time the applicant commenced was approved by the Council as one whose graduates should possess knowledge, skill and judgment at least equivalent to a current graduate of a program referred to in subparagraph i, or

iv. have met the requirements of paragraph 1 of subsection 6 (1).

2. The applicant must have successfully completed an examination in pharmaceutical jurisprudence approved by the Council for applicants for a certificate of registration as a pharmacy technician.

3. The applicant must have successfully completed a structured practical training program approved by the Council and must have done so under the direct supervision of a preceptor approved by the Registration Committee.

4. The applicant must have successfully completed the qualifying examination of the Pharmacy Examining Board of Canada for pharmacy technicians or successfully completed another examination that has been approved by the Council for that purpose.

(2) With the approval of the Council, all or any part of a structured practical training program referred to in paragraph 3 of subsection (1) may be completed as part of a program referred to in subparagraph 1i of subsection (1) or sub-subparagraph 1 ii A of subsection (1).

(3) The requirement in paragraph 1 of subsection (1) must be met within two years before the date on which the applicant met all of the other requirements for the issuance of a certificate of registration as a pharmacy technician unless the applicant,

(a) satisfies the Registrar or a panel of the Registration Committee that the applicant has practised pharmacy within the scope of practice of the profession as set out in section 3 of the Act under the supervision or direction of a pharmacist for at least 600 hours during the three years before the date on which the applicant met all the other requirements for the issuance of a certificate of registration as a pharmacy technician and did so while practising as a pharmacy technician in Canada or in another jurisdiction approved by the Council;

(b) meets any requirements regarding any further education or training or a combination of education or training, if any, set by a panel of the Registration Committee within the time set by the panel; or

(c) successfully completes the examination referred to in paragraph 4 of subsection (1) within three years of the date on which he or she meets all of the other requirements for the issuance of a certificate of registration as a pharmacy technician.

(4) The requirement of paragraph 2 of subsection (1) shall not be considered to have been met unless the applicant is issued a certificate of registration as a pharmacy technician within three years of meeting that requirement.

(5) An applicant is only eligible to take the examination referred to in paragraph 2 of subsection (1) three times in any 24-month period.

(6) The requirement in paragraph 3 of subsection (1) shall not be considered to have been met unless the applicant,

(a) is issued a certificate of registration as a pharmacy technician within two years of meeting that requirement;

(b) satisfies the Registrar or a panel of the Registration Committee that the applicant has practised pharmacy within the scope of practice of the profession as set out in section 3 of the Act under the supervision or direction of a pharmacist for at least 600 hours during the three years before the date on which the applicant met all the other requirements for the issuance of a certificate of registration as a pharmacy technician and did so while practising as a pharmacy technician in Canada or in another jurisdiction approved by the Council; or

(c) meets any requirements regarding any further education or training or a combination of education or training, if any, set by a panel of the Registration Committee within the time set by the panel.

(7) Subject to subsection (8), paragraph 4 of subsection (1) is not considered to have been met unless the applicant,

(a) successfully completed the examination within three attempts; or

(b) successfully completed the examination on the applicant's fourth attempt having first successfully completed the further education or training or combination of education and training required by the examining body responsible for the administration of the examination or, if no further education or training was required by that body, the further education or training or combination of education and training, if any, that was specified by a panel of the Registration Committee.

(8) Where, by virtue of subsection (7), an applicant is not considered to have met the requirement in paragraph 4 of subsection (1), the applicant may not attempt the examination again until the applicant successfully completes a new program mentioned in subparagraph 1 i of subsection (1).

(9) An applicant shall be deemed not to have met the requirement of subparagraph 1 iii of subsection (1) unless, before January 1, 2012 and before commencing the program referred to in that subparagraph, the applicant successfully completed,

(a) the College's Pharmacy Technician Certification Examination;

(b) the Pharmacy Technician Evaluating Examination of the Pharmacy Examining Board of Canada; or

(c) another examination approved by the Council.

(10) Subject to subsection (2) and section 17, the requirements in subsection (1) are non-exemptible.

(11) A reference in this section to "all of the other requirements for the issuance of a certificate of registration" includes, without being limited to, a requirement set out in subsection 4 (1) or subsection (1) of this section.

MOBILITY WITHIN CANADA

17. (1) Where section 22.18 of the Health Professions Procedural Code applies to an applicant the requirements of paragraphs 1, 3 and 4 of subsection 16 (1) are deemed to have been met by the applicant if he or she provides, for each jurisdiction where the applicant holds an out-of-province certificate, a certificate, letter or other evidence satisfactory to the Registrar or a panel of the Registration Committee confirming that the applicant is in good standing as a pharmacy technician in that jurisdiction.

(2) Without in any way limiting the generality of subsection (1), "good standing" shall include the fact that,

(a) the applicant is not the subject of any discipline or fitness to practise order or of any proceeding or ongoing investigation or of any interim order or agreement as a result of a complaint, investigation or proceeding; and

(b) the applicant has complied with the continuing competency and quality assurance requirements of the regulatory authority in that issued the applicant that out-of-province certificate as a pharmacy technician.

(3) An applicant referred to in subsection (1) is deemed to meet the requirements of paragraph 1 of subsection 4 (1) where the requirements for the issuance of the applicant's out-of-province certificate included language proficiency requirements equivalent to those required by that paragraph.

(4) Despite subsection (1), an applicant is not deemed to have met a requirement if that requirement is described in subsection 22.18 (3) of the Health Professions Procedural Code.

TERMS, CONDITIONS AND LIMITATIONS

18. Every certificate of registration as a pharmacy technician is subject to the following terms, conditions and limitations:

1. The member shall only engage in the practice of pharmacy,
   i. when practising in a pharmacy to which the *Drug and Pharmacies Regulation Act* applies, other than a remote dispensing location, while under the direct supervision of a member holding a certificate of registration as a pharmacist, or
   ii. in all other cases, while under the supervision or direction of a member holding a certificate of registration as a pharmacist.
2. When practising in a pharmacy to which the *Drug and Pharmacies Regulation Act* applies the member shall not supervise that part of a pharmacy where drugs are kept.
3. The member shall not delegate a controlled act.
4. The member shall not provide information or education relating to drug use, either to or for a patient, where the provision of the information requires therapeutic knowledge, clinical analysis or clinical assessment.

PART VII
SUSPENSIONS, RESIGNATIONS, REINSTATEMENTS, ETC.

ADMINISTRATIVE SUSPENSIONS

19. (1) If a member fails to provide information about the member in the manner and in the form as required under the by-laws, the Registrar may give the member notice of intention to suspend the member and may suspend the member's certificate of registration for failure to provide the information 60 days after notice is given.

(2) Where the Registrar suspends a member's certificate of registration under subsection (1), the Registrar shall lift the suspension upon being satisfied that the required information has been filed with the College and that any fees required for the lifting of that suspension has been paid.

20. (1) If, pursuant to the by-laws, the College requests evidence that the member holds professional liability insurance in the amount and in the form as required by the by-laws and the member fails to provide that evidence within 14 days of having been requested to do so, the Registrar shall immediately give the member notice of intention to suspend the member and may suspend the member's certificate of registration for failure to provide the evidence 30 days after notice is given.

(2) Where the Registrar suspends the member's certificate of registration under subsection (1), the Registrar shall lift that suspension upon being satisfied that the member holds professional liability insurance in the amount and in the form required by the by-laws and that any fee required for the lifting of that suspension has been paid.

21. Where the Registrar suspends a member's certificate of registration under section 24 of the Health Professions Procedural Code for failure to pay a fee, the Registrar shall lift the suspension upon being satisfied that the member,

(a) has paid all amounts owed to the College;

(b) holds professional liability insurance in the amount and in the form required by the by-laws; and

(c) pays any fees required for the lifting of that suspension.

DEEMED RESIGNATIONS

22. (1) A member shall be deemed to have resigned where,

(a) the member's certificate of registration was suspended for failure to pay a fee that the member was required to pay in accordance with the regulations or by-laws and that suspension continued for 120 days; or

(b) the member's certificate of registration was suspended pursuant to subsection 19 (1) or subsection 20 (1) and the suspension continued for 60 days.

(2) The resignation is effective,

(a) in the case of a resignation under clause (1) (a), on the 121st day following the commencement of that suspension;

(b) in the case of a suspension under clause (1) (b), on the 61st day following the commencement of the suspension.

RETURN OF CERTIFICATE, ETC.

23. A member who resigns, or whose certificate of registration is suspended or revoked shall, if so requested, immediately return to the College,

(a) his or her certificate of registration; and

(b) any card or other form of identification issued to him or her by the College for the purpose of identifying him or her as a member of the College.

REINSTATEMENT

24. (1) A former member who held a certificate of registration as a pharmacist or pharmacy technician and who resigned as a member of the College may apply for the reinstatement of his or her certificate of registration by submitting a completed application to the Registrar in the form provided by the Registrar.

(2) Subject to subsections (3), (4) and (6), the Registrar may reinstate the former member's certificate of registration if,

(a) the former member has paid,

(i) the required reinstatement fee,

(ii) the annual fee for the year in which the certificate of registration is to be reinstated, if not previously paid,

(iii) the annual fee for the year in which the former member resigned or was deemed to have resigned, if not previously paid unless the Registrar is satisfied that the former member did not engage in the practice of pharmacy in Ontario during that year, and

(iv) any other money owed by the former member to the College at the date the application for reinstatement is submitted, including, without being limited to, any penalty fees that were due at the time that he or she ceased to be a member and any costs or expenses ordered to be paid under section 53.1 of the Health Professions Procedural Code, any costs awarded to the College by a Court and any amount owing to the College under a by-law or former regulation made under the Act;

(b) the application for reinstatement was submitted to the Registrar within three years of the date on which the former member resigned or in the case of a former member who was deemed to have resigned under subsection 22 (1), three years from the date on which the former member was suspended where that suspension resulted in a deemed resignation; and

(c) the application meets the requirement set out in paragraph 7 of subsection 4 (1) with necessary modifications.

(3) A former member is ineligible for reinstatement under subsection (2) if he or she,

(a) is the subject of a proceeding for professional misconduct, incompetence or incapacity in Ontario or any like proceeding in any other jurisdiction in relation to the practice of pharmacy or another profession, or was the subject of such a proceeding, other than a proceeding that was completed on its merits;

(b) was, at the time he or she ceased to be a member or at any time since, the subject of a proceeding in respect of,

(i) any criminal offence in any jurisdiction,

(ii) any offence relating to the use, possession or sale of drugs in any jurisdiction,

(iii) any offence arising in any jurisdiction relating to the practice of pharmacy or any other profession or occupation, or

(iv) any offence under the *Controlled Drugs and Substances Act* (Canada);

(c) was, after he or she ceased to be a member, found guilty of,

(i) any criminal offence in any jurisdiction,

(ii) any offence relating to the use, possession or sale of drugs in any jurisdiction,

(iii) any offence arising in any jurisdiction relating to the practice of pharmacy or any other profession or occupation, or

(iv) any offence under the *Controlled Drugs and Substances Act* (Canada);

(d) is the subject of an inquiry or investigation by the Registrar, a committee, a panel of a committee or a board of inquiry of the College, or was the subject of such an inquiry or investigation, that was not completed on its merits or which resulted in the member's resignation;

(e) was, at the time he or she ceased to be a member, the subject of an outstanding order or requirement of a committee, a panel of a committee, or a board of inquiry of the College;

(f) was, at the time he or she ceased to be a member, in breach of an order or requirement of a committee, a panel of a committee, or a board of inquiry of the College;

(g) was, at the time he or she ceased to be a member, in violation of a decision of a panel of the Inquiries, Complaints and Reports Committee or of any predecessor committee, including a decision requiring the member to attend to be cautioned;

(h) was, at the time he or she ceased to be a member, in breach of any written agreement with or undertaking provided to the College; or

(i) had, at the time he or she ceased to be a member, terms, conditions or limitations on his or her certificate of registration, other than those applicable to all members of the class of certificate of registration he or she previously held.

(4) A former member must meet all of the requirements set out in subsection (2) within one year of submitting his or her application for reinstatement.

(5) Nothing in this section prevents a former member from making any number of applications for reinstatement or from making an application for a new certificate of registration.

(6) A former member who is seeking reinstatement of a certificate of registration as a pharmacist and who is otherwise eligible for the reinstatement shall be reinstated into Part B of the register unless the former member satisfies the Registrar that,

(a) the former member did not resign at a time when the member had been selected for but had not successfully completed a practice review under the College's Quality Assurance Program; and

(b) the member had performed at least 600 hours of patient care in Canada, the United States of America or another jurisdiction approved by the Council during the period of three years commencing immediately before the date of the member's resignation.

REINSTATEMENT, PURSUANT TO ORDER

25. If a former member's certificate of registration is ordered to be reinstated by a panel of the Discipline Committee or of the Fitness to Practise Committee, the Registrar shall reinstate the certificate of registration upon payment of,

(a) the required reinstatement fee; and

(b) the annual fee for the year in which the certificate of registration is to be reinstated, if not previously paid.

PART VII.1
NOTICES OF MEETINGS AND HEARINGS

NOTICE OF MEETINGS

26. (1) The Registrar shall ensure that notice of every Council meeting that is required to be open to the public under the Act is given in accordance with this section.

(2) The notice must be published at least 14 days before the date of the meeting in a daily newspaper of general circulation throughout Ontario.

(3) The notice must be in English and French.

(4) The notice must contain the following information:

1. The date, time and place of the meeting.
2. A statement of the purpose of the meeting.

(5) The Registrar shall provide the information contained in the notice to every person who requests it by telephone.

NOTICE OF HEARINGS

27. (1) The Registrar shall ensure that the information concerning an impending hearing by a panel of the Discipline Committee to deal with allegations of professional misconduct or incompetence made against a member is given, in accordance with this section, to a person who requests the information.

(2) The information shall be given,

(a) at least 14 days before the date of the hearing, if the request is received 14 days before the date of the hearing; or

(b) as soon as possible after the request is made, if the request is received after that time but before the date of the hearing.

(3) The information given shall be as follows:

1. The name of the member against whom the allegations have been made.
2. The member's principal place of practice.
3. The date, time and place of the hearing.
4. A statement of the purpose of the hearing.

(4) The Registrar shall provide the information in French to a person who requests that the information be provided in French, wherever reasonably possible.

PART VII.2
ADVERTISING

ADVERTISING

28. (1) In this section,

"advertisement" includes an announcement, directory listing or other form of communication similar to an advertisement;

"drug services" means one or more of the compounding, dispensing or sale by retail of drugs or the provision of information or advice with respect to drugs.

(2) A member shall not, through any medium, publish, display, distribute or use, or permit, directly or indirectly, the publication, display, distribution or use through any medium of, an advertisement relating to drug services that,

(a) is false, misleading or deceptive, whether as a result of the inclusion of information or the omission of information;

(b) is not readily comprehensible to the persons to whom it is directed;

(c) is not dignified and in good taste;

(d) contains anything that cannot be verified;

(e) contains testimonials, comparative statements or endorsements;

(f) contains a reference to a member's area of practice or to a procedure or treatment available from a member practising in the pharmacy, unless the advertisement discloses whether or not the member has an area of expertise and, if the member does have such an area of expertise, the particular expertise;

(g) contains references to a particular brand of equipment used to assist in providing drug services;

(h) contains information that is not relevant to the choice of a pharmacist; or

(i) contains any representations as to the safety or effectiveness or an indication for use of any drug referred to in Schedule I established by the regulations under the *Drug and Pharmacies Regulation Act*.

(j) REVOKED: O. Reg. 59/11, s. 1 (4).

(3) An advertisement by a member that includes price information relating to drugs referred to in Schedule I established by the regulations under the Drug and Pharmacies Regulation Act shall include the price information for at least 15 different drugs, 10 of which each belong to a different one of the following drug classifications:

1. Anti-infective agents.
2. Antineoplastic agents.

3. Autonomic agents.
4. Blood formation and coagulation drugs.
5. Cardiovascular drugs.
6. Central nervous system drugs.
7. Diagnostic agents.
8. Electrolytic, caloric and water balance drugs.
9. Cough preparations.
10. Eye, ear, nose and throat preparations.
11. Gastrointestinal drugs.
12. Gold compounds.
13. Heavy metal antagonists.
14. Hormones and substitutes.
15. Oxytocics.
16. Skin and mucous membrane preparations.
17. Spasmolytics.
18. Unclassified therapeutic agents.
19. Vitamins.

(4) Where an advertisement by a member includes price information relating to drugs referred to in Schedule I established by the regulations under the *Drug and Pharmacies Regulation Act*, the advertisement shall include at a minimum the following information with respect to each drug:

1. The quantity of the drug being advertised at the advertised price.
2. The total cost for the drug to the purchaser including any dispensing fee.
3. The time period during which the advertised price will be available.

(5) An advertisement by a member that includes price information relating to drugs referred to in Schedule I established by the regulations under the *Drug and Pharmacies Regulation Act* shall include, in addition to the price information referred to in subsection (4), the following information with respect to each advertised drug:

1. The strength of the drug.
2. The brand name of the drug.
3. The dosage form of the drug.

(6) Where an advertisement by a member includes price information relating to drugs referred to in Schedule I established by the regulations under the *Drug and Pharmacies Regulation Act*, equal prominence shall be given to each drug and, for each of those drugs, equal prominence shall be given to all the information required under subsections (4) and (5).

(7), (8) REVOKED: O. Reg. 59/11, s. 1 (6).

PROFESSIONAL MISCONDUCT RE ADVERTISING

29. It is professional misconduct for the purposes of clause 51 (1) (c) of the Health Professions Procedural Code for a member who advertises price information with respect to a drug referred to in Schedule I established by the regulations under the *Drug and Pharmacies Regulation Act* to charge any purchaser, including the executive officer under the *Ontario Drug Benefit Act* more for the drug than the member has advertised, pursuant to paragraph 2 of subsection 28 (4), as the total cost for the drug to the purchaser including any dispensing fee.

CLARIFICATION RE APPLICATION OF PART

30. Nothing in this Part prohibits a member from publishing, displaying, distributing or using, or permitting directly or indirectly the publication, display, distribution or use of, an advertisement that relates solely to the co-payment or dispensing fee charged by the member for supplying a drug that is a listed drug product under the *Ontario Drug Benefit Act* to an eligible person under that Act.

PART VII.3
CONTROLLED ACTS

INTERPRETATION

31. In this Part,

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

(a) the dose of the prescribed drug,

(b) the dosage form of the prescribed drug,

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

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

but does not include therapeutic substitution;

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

"point of care test" means a diagnostic test performed on a patient sample at the site of patient care;

"prescriber" means a person who is authorized under the laws of a province or territory of Canada to give a prescription within the scope of his or her practice of a health profession;

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

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

"therapeutic substitution" means the substitution of a drug that contains chemically different active ingredients that are considered to be therapeutically equivalent.

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

(2) Where the provisions of this Part are inconsistent with the provisions of the *Narcotics Safety and Awareness Act, 2010*, the provisions of that Act shall prevail and the provisions of this Part, to the extent they are inconsistent with that Act, shall not apply.

CONTROLLED ACTS

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

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

1. Administering a substance specified in Schedule 1 by injection to a patient through a route other than direct intravenous, intravenous push, intravenous bolus, intrathecal, intraarticular, intracardiac, intraspinal, intraocular, and intracavernous.
2. Administering a substance specified in Schedule 2 by inhalation to a patient.

(2) A Part A pharmacist, an intern or a registered pharmacy student is authorized to perform an act provided for in subsections (1), (4) and (5), subject to the terms, conditions and limitations imposed on his or her certificate of registration.

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

1. The member must receive an informed consent from the patient or his or her authorized agent before performing the act.
2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient.
3. The member shall ensure that appropriate infection control procedures are in place.
4. The member must possess sufficient knowledge, skill and judgment respecting the substance to be administered, and sufficient understanding of the condition of the patient, to be able to administer the substance safely.
5. The member must consider whether administering a substance by injection or inhalation to the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome after administration and any other relevant circumstances.
6. The member must maintain a patient record that includes,

i. the name and address of the patient,

ii. the name and address of the member,

iii. the date the act was performed,

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

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

vi. confirmation that an informed consent was given by the patient or his or her authorized agent.

7. Where the act is performed for a purpose other than patient education and demonstration, the member must notify the patient's primary care provider (if any) within a reasonable time that the member performed the act and provide details respecting the act.

(4) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) is authorized to administer influenza vaccine by injection to a patient who is two years of age or older, if the member,

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

(b) meets all the requirements in paragraphs 1 to 6 of subsection (3).

(5) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) is authorized to administer a vaccine from one of the vaccines specified in Schedule 3 by injection to a patient who is five years of age or older, if the member,

(a) meets all the requirements in paragraphs 1 to 6 of subsection (3); and

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

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

1. Varenicline Tartrate.

2. Bupropion Hydrochloride.

(2) A drug mentioned in subsection (1) may only be prescribed by a member for the sole purpose of smoking cessation.

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

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

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

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

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

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

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

(f) complies with the additional requirements under sections 37 and 38.

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

1. Adapting a patient's prescription.

2. Renewing a patient's prescription for the purpose of continuity of care.

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

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

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

1. The member must either possess the patient's prescription to be adapted or renewed or,
    i. receive a copy of the prescription directly from the pharmacy where the prescription was dispensed to the patient,
    ii. be satisfied based on verbal confirmation from a pharmacist at the pharmacy where the prescription was dispensed to the patient as to the existence and details of the prescription, or
    iii. have access to the medical record that contains information about the prescription.
2. If the member is renewing a prescription, he or she must not prescribe a quantity of the drug that exceeds the lesser of,
    i. the quantity that was originally prescribed, including any refills that were authorized by the prescriber, and
    ii. a twelve months' supply.
3. The member must, within a reasonable time, notify the prescriber identified on the prescription adapted or renewed by the member, as well as the patient's primary care provider if the member knows that the patient has such a care provider other than the prescriber, providing details about the patient's prescription, when the member,
    i. renews a patient's prescription, or
    ii. adapts a patient's prescription, if, in the member's opinion,
        A. adapting the prescription is clinically significant in relation to the patient, or
        B. the notification is necessary to support the patient's care.
4. At the time that the member adapts or renews the patient's prescription, the member must advise the patient or his or her authorized agent,
    i. that he or she is entitled to the prescription, and
    ii. that he or she may take the prescription to a pharmacy of his or her choosing for dispensing.
5. The member must comply with the additional requirements under sections 37 and 38.

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

1. The name and address of the patient for whom the drug is prescribed.
2. The name, strength (where applicable) and quantity of the prescribed drug.
3. Directions for the use of the drug, including its dose, frequency, route of administration and any special instructions.
4. The name, address, telephone number and College registration number of the member issuing the prescription.
5. The date the prescription was issued by the member.
6. If applicable, reference to the prescription that the member adapted or renewed, including the name and contact details of the original prescriber.
7. The number of refills that the member authorized, if applicable.
8. Any other information required by law.

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

1. Reference to, or a copy of, the patient's prescription that the member renewed or adapted, including the name and contact information of the prescriber.
2. A copy of the prescription that the member gave to the patient or his or her authorized agent under clause 35 (4) (c) or that the member gave to the patient or his or her authorized agent to take to a pharmacy of their choosing under paragraph 4 of subsection 36 (4).
3. A record of the results of laboratory or other tests that the member considered in making the decision to act under section 35 or 36.
4. The date on which the member notified the following persons, as applicable, and the method by which the notification occurred:
    i. The patient's primary care provider notified under clause 35 (4) (e) or paragraph 3 of subsection 36 (4).
    ii. The patient's prescriber notified under paragraph 3 of subsection 36 (4).

39. (1) For the purposes of paragraph 5 of subsection 4 (1) of the Act, and subject to subsection (3), a member referred to in subsection (2) who meets all the requirements in subsection (4) is authorized to perform the act of piercing a patient's dermis with a lancet-type device to obtain blood.

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

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

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

(b) the pharmacy technician is under the direction of a Part A pharmacist at the time when the pharmacy technician performs the act; and

(c) where the act is performed to administer a point of care test, a Part A pharmacist interprets the results of the test and makes the professional decision arising from the results of the test.

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

1. The member must receive an informed consent from the patient or his or her authorized agent before performing the act.
2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient.
3. The member shall ensure that appropriate infection control procedures are in place.
4. The member must possess the knowledge, skill and judgment respecting the performance of the act and understand the condition of the patient, to perform it safely and effectively.
5. The member must consider whether performing the act on the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome and any other relevant circumstances.
6. The member must maintain a patient record that includes,
    i. the name and address of the patient,
    ii. the name and address of the member,
    iii. the date the act was performed,
    iv. the circumstances relating to the act and any adverse reaction experienced by the patient,
    v. where the member performed the act to administer a point of care test, the results of the test,
    vi. the professional decision arising from the results of the point of care test and the rationale for the decision, and
    vii. confirmation that an informed consent was given by the patient or his or her authorized agent.
7. Where the act is performed for a purpose other than patient education and demonstration, the member must notify the patient's primary care provider (if any) within a reasonable time that the member performed the act and provide details respecting the act.

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

PART VIII
QUALITY ASSURANCE

GENERAL

41. In this Part,

"assessor" means an assessor appointed under section 81 of the Health Professions Procedural Code;

"Committee" means the Quality Assurance Committee.

42. The Committee shall administer the quality assurance program, which shall include the following components:

1. Maintenance of a portfolio of continuous learning.
2. Maintenance of a two-part register for pharmacist members.
3. Practice review and remediation.
4. Remediation of behaviour and remarks of a sexual nature.

CONTINUOUS LEARNING PORTFOLIO

43. (1) A pharmacist shall maintain a portfolio of continuous learning activities in accordance with guidelines on such activities published by the College and distributed to the members.

(2) A pharmacist shall submit the portfolio to the College on request.

TWO-PART REGISTER FOR PHARMACISTS

44. (1) The part of the College's register that lists pharmacists shall have a Part A (patient care) and a Part B (no patient care).

(2) Every pharmacist shall be listed in either Part A or Part B.

45. (1) Upon being issued a certificate of registration as a pharmacist for the first time, the member shall ask to be listed in Part A or Part B of the register by completing and submitting the form provided by the Registrar.

(2) Every year at the time of paying the annual membership fee, a pharmacist shall ask for a renewal of his or her listing in Part A or Part B or for a transfer to the other Part.

(3) A member who asks for a renewal of a listing in Part A after the third anniversary of being issued a certificate of registration as a pharmacist for the first time shall not be listed in that Part unless he or she has dispensed, sold or compounded drugs, provided non-prescription drugs, health care aids and devices or information related to drug use for at least 600 hours during the preceding three years in the course of providing patient care while practising the profession in Canada.

46. (1) A pharmacist may ask for a transfer from Part A of the register to Part B or from Part B to Part A at any time.

(2) If a member listed in Part A asks for a transfer to Part B, the member shall be transferred to Part B.

(3) If a member listed in Part B asks for a transfer to Part A, the member shall be transferred to Part A if he or she,

(a) undergoes a practice review in accordance with section 47; and

(b) satisfies the educational and practice requirements that may be specified by the Quality Assurance Committee.

(4) If the Registrar proposes to reject a request for a transfer to Part A, the request shall be referred to a panel of the Quality Assurance Committee.

(5) The member shall be given a reasonable opportunity to make written submissions to the panel before it makes a decision.

(6) A member whose request to be listed in Part A is rejected by the panel may appeal to another panel of the Quality Assurance Committee.

(7) No member of a panel that rejects a request to be listed in Part A shall sit on a panel hearing an appeal of that decision.

(8) On an appeal, the member shall be given a reasonable opportunity to make written submissions to the panel before it makes a decision.

PRACTICE REVIEW AND REMEDIATION

47. (1) Each year the College shall select at random the names of pharmacists required to undergo a practice review.

(2) A pharmacist listed in Part A is required to undergo a practice review if his or her name is selected at random or the member is referred to the Committee by the Complaints Committee or Executive Committee.

(3) If a pharmacist listed in Part A fails to undergo a required practice review, the Committee may transfer the pharmacist to Part B after giving him or her a reasonable opportunity to make written submissions.

(4) A pharmacist listed in Part B is required to undergo a practice review if he or she is referred to the Committee by the Complaints Committee or Executive Committee or if the pharmacist has asked to be listed in Part A under subsection 46 (3).

(5) The Committee shall appoint an assessor to conduct a practice review.

(6) The assessor shall prepare a written report on the review and submit it to the Committee.

(7) After considering the report, the Committee may decide,

(a) that no further action is required;

(b) that the pharmacist is required to undertake the remediation specified by the Committee to correct any deficiency in his or knowledge, skills or judgment identified by the review; or

(c) that the pharmacist is to be listed in Part A where the review took place pursuant to a request to be listed in Part A.

(8) If the Committee proposes to require a pharmacist to undertake remediation under clause (7) (b), it shall not do so unless,

(a) the pharmacist has been given a report of the results of the review;

(b) the pharmacist has been given written notice of the Committee's intention to require him or her to undertake remediation;

(c) the pharmacist has been given at least 14 days from receipt of the notice to make written submissions to the Committee; and

(d) the Committee has considered any such submissions.

(9) After the pharmacist undertakes the specified remediation, the Committee may require him or her to undergo another practice review by an assessor, and subsections (6), (7) and (8) apply to that review.

48. (1) If the Committee requires a pharmacist to undertake remediation under section 47 and the pharmacist either fails to do so or fails to successfully complete the remediation, the Committee may direct the Registrar to impose terms, conditions or limitations on the pharmacist's certificate of registration for a specified period not exceeding six months.

(2) If the Committee proposes to make a direction under subsection (1), it shall not do so unless,

(a) the pharmacist has been given written notice of its intention;

(b) the pharmacist has been given at least 14 days from receipt of the notice to make written submissions to the Committee or to request an appearance before the Committee in order to make oral submissions; and

(c) the Committee has considered any such submissions.

(3) A pharmacist who requests an appearance under clause (2) (b) shall be given a reasonable opportunity to appear but the Committee may dispose of the matter if he or she has been given a reasonable opportunity to appear and does not.

(4) If the period specified under subsection (1) expires and the pharmacist still has not undertaken or successfully completed the remediation, the Committee may report him or her to the Executive Committee and provide it with such information as it considers appropriate, except information that may not be disclosed under section 83 of the Health Professions Procedural Code.

(5) If the Registrar imposes terms, conditions or limitations on a pharmacist's certificate of registration for a specified period pursuant to a direction given by the Committee under subsection (1), the Committee may direct the Registrar to remove the terms, conditions or limitations before the end of the specified period if the Committee is satisfied that they are no longer needed.

(6) After directing the imposition of terms, conditions or limitations on a pharmacist's certificate of registration for a specified period not exceeding six months under subsection (1), the Committee may direct the imposition of terms, conditions or limitation on the pharmacist's certificate of registration for a second specified period not exceeding six months under subsection (1) but, after having done so, the Committee shall not direct the imposition of terms, conditions or limitations on the pharmacist's certificate of registration for any further specified period.

(7) If the Committee directs a second imposition of terms, conditions or limitations on the pharmacist's certificate, subsections (2), (3), (4) and (5) apply with respect to the second imposition.

REMEDIATION OF BEHAVIOUR AND REMARKS OF A SEXUAL NATURE

49. (1) This section applies to matters referred to the Committee by,

(a) a panel of the Complaints Committee under subsection 26 (3) of the Health Professions Procedural Code; and

(b) the Executive Committee under section 79.1 of the Code.

(2) The chair of the Committee shall establish a panel from among the members of the Committee for the purpose of considering a matter referred to in subsection (1).

(3) The chair of the Committee shall appoint a mediator to attempt to resolve the matter.

(4) If the mediator is unable to resolve the matter within 90 days after being appointed, the mediator shall report the failure to the chair without delay and provide the chair with a written report on the mediation.

(5) The chair shall give the member complained against a copy of the mediator's report and a notice advising him or her of the right to make written submissions to the panel.

(6) The member shall be given at least 14 days after receipt of the mediator's report and recommendations to make written submissions to the panel or to request an appearance before the panel to make oral submissions, or to do both.

(7) A member who requests an appearance shall be given a reasonable opportunity to make an appearance, but the panel may dispose of the matter without such appearance if the member has been given a reasonable opportunity to appear.

(8) If the mediation concerns a matter referred by the Complaints Committee, the chair shall give the complainant a copy of the mediator's report.

(9) A mediator's proposed resolution of a matter referred to the Committee by the Complaints Committee must be acceptable to the complainant, the member complained against and the panel.

(10) A mediator's proposed resolution of a matter referred to the Committee by the Executive Committee must be acceptable to the member complained against and the panel.

(11) After considering the mediator's report and any written or oral submissions, the panel may require the member to undergo an assessment for the purpose of establishing if he or she requires education with respect to sexual abuse.

(12) The assessment shall be carried out by an assessor appointed by the Committee.

(13) The assessor shall provide a written report to the panel and shall make such recommendations as the assessor considers appropriate about the member's need for education with respect to sexual abuse.

(14) A copy of the report and recommendations, and a notice informing him or her of the right to make submissions in accordance with subsections (6) and (7), shall be provided to the member.

(15) After considering the assessor's report and recommendations and the member's submissions, if any, the panel may require the member to attend or participate in a sexual abuse education program.

(16) If the panel proposes to take action under subsection (15), the member has the right to make submissions in accordance with subsections (6) and (7).

50. (1) If a member refuses to undergo an assessment under subsection 49 (11) or to attend or participate in a program under subsection 49 (15), the panel may direct the Registrar to impose terms, conditions or limitations on the member's certificate of registration for a specified period not exceeding six months.

(2) If the panel proposes to take action under subsection (1), the member has the right to make submissions in accordance with subsections 49 (6) and (7).

(3) If the panel is satisfied that the terms, conditions and limitations imposed on a member's certificate or registration are no longer needed, it shall direct the Registrar to remove them before the end of the specified period.

(4) If, at the end of the specified period, the member continues to refuse to undergo the required assessment or to attend or participate in the program, the panel shall refer the matter to the Executive Committee.

PANEL REQUIREMENTS

51. (1) The Committee may sit as a panel to consider a report on a practice review or any matter arising out of a practice review, a matter relating to the imposition of terms, conditions or limitations on a member's registration under section 48 or a matter under section 49.

(2) A panel shall have at least three members appointed by the chair of the Committee from among the Committee members; at least one member of the panel shall be a member appointed to the Committee by the Lieutenant Governor in Council.

(3) Three members of a panel constitute a quorum.

PART IX
INSPECTION OF DRUG PREPARATION PREMISES

TEMPORAL APPLICATION

52. This Part applies to the College and members as of the day that it comes into force, except that,

(a) sections 54, 55, 56, 59 and 60 apply as of 90 days from the day that this Part comes into force; and

(b) the requirements in subsection 57 (1) and section 58 apply as of 30 days from the day that this Part comes into force.

INTERPRETATION

53. (1) In this Part,

"designated member" means,

(a) the member designated for a drug preparation premises in accordance with section 58, or

(b) where only one member engages in or supervises drug preparation activities at or in connection with a drug preparation premises, that member;

"drug" means a substance or a preparation containing a substance referred to in clauses (a) to (d) of the definition of "drug" in subsection 1 (1) of the *Drug and Pharmacies Regulation Act*, but does not include,

(a) a substance or preparation referred to in those clauses that is manufactured, sold or represented for use in animals or fowl, or

(b) a substance or preparation referred to in clause (e), (f), (g), (h) or (i) of that definition;

"drug preparation activities" means reconstituting, diluting or otherwise preparing a drug or combining, admixing or mixing together two or more substances, at least one of which is a drug, to create a final product for the purposes of the sale or provision to another person, other than pursuant to or in anticipation of a prescription;

"drug preparation premises" means any place where a member engages in drug preparation activities, or where drug preparation activities take place that a member supervises, but does not include,

(a) a pharmacy in respect of which a valid certificate of accreditation has been issued under the *Drug and Pharmacies Regulation Act*,

(b) a premises in respect of which a valid establishment licence has been issued under the *Food and Drugs Act* (Canada), or

(c) a hospital or a health or custodial institution approved or licensed under any general or special Act;

"inspector" means a person appointed by the College to carry out an inspection on behalf of the College;

"supervise" means to supervise either directly or indirectly.

(2) Anything that may be done by the College under this Part may be done by the Council or by a committee established under clause 94 (1) (i) of the Health Professions Procedural Code.

INSPECTION

54. (1) All drug preparation premises are subject to inspection by the College in accordance with this Part.

(2) In carrying out an inspection of a drug preparation premises under subsection (1), the College may also require any or all of the following:

1. Inspection, examination or testing regarding any equipment, instrument, materials or any other thing that may be used in the drug preparation premises.
2. Examination and copying of books, accounts, reports, records or similar documents that are, in the opinion of the College, relevant to the member's practice with respect to the drug preparation activities at or in connection with the drug preparation premises.
3. Inquiries or questions to be answered by the member that are relevant to the member's practice with respect to the drug preparation activities at or in connection with the drug preparation premises.
4. Direct observation of a member in his or her practice with respect to drug preparation activities at or in connection with the drug preparation premises.

55. An inspector may, on the production of information identifying him or her as an inspector, enter and have access to any drug preparation premises at reasonable times and may inspect the drug preparation premises and do any of the things mentioned in subsection 54 (2) on behalf of the College.

56. (1) It is the duty of every member engaging in or supervising drug preparation activities at or in connection with drug preparation premises that are subject to an inspection to,

(a) submit to an inspection of the drug preparation premises in accordance with this Part;

(b) promptly answer a question or comply with a requirement of the inspector that is relevant to an inspection under this Part; and

(c) co-operate fully with the College and the inspector who is conducting an inspection of a drug preparation premises in accordance with this Part.

(2) A member shall not engage in or supervise drug preparation activities at or in connection with a drug preparation premises where an inspector has been denied entry or access.

57. (1) No member shall commence engaging in or supervising drug preparation activities at or in connection with drug preparation premises unless the member has previously given notice in writing to the College in accordance with subsection (5) of the member's intention to do so.

(2) Where a member has provided notice in writing to the College in accordance with subsection (1) and the drug preparation premises have not passed an inspection or passed an inspection with conditions within the previous five years, the College shall ensure that an inspection of the drug preparation premises is performed within 60 days from the day that the College receives the member's notice or 150 days from the day this Part comes into force, whichever is later.

(3) A member who engages in or supervises drug preparation activities at or in connection with a drug preparation premises as of the day that is 30 days from the day this Part comes into force shall give notice in writing to the College in accordance with subsection (5) within 90 days from the day this Part comes into force.

(4) The College shall ensure that an inspection of the drug preparation premises with respect to which a member gives notice under subsection (3) is performed within 150 days from the day this Part comes into force.

(5) The notice required in subsections (1) and (3) shall include the following information, submitted in the form and manner required by the College:

1. The full name of the member giving the notice and the full name of the individual or corporation who is the owner or occupier of the drug preparation premises, if he or she is not the member who is required to give notice under this section.
2. The full address of the drug preparation premises.

3. The date when the member first began engaging in or supervising drug preparation activities at or in connection with the drug preparation premises or the proposed date when the member intends to begin engaging in or supervising drug preparation activities at or in connection with the drug preparation premises.
4. Any other information the College requires that is relevant to an inspection of the drug preparation premises conducted under this Part.

58. Where two or more members engage in or supervise drug preparation activities at or in connection with a drug preparation premises, the members shall designate a member as the designated member for the drug preparation premises, and shall immediately notify the College of the designated member's identity.

59. All drug preparation premises are subject to an inspection by the College once every five years after the initial inspection of the premises or more often if, in the opinion of the College, it is necessary or advisable to do so.

60. (1) After an inspection of a drug preparation premises, the College shall determine, in accordance with the accepted standards of practice, whether the drug preparation premises pass, pass with conditions or fail.

(2) In determining whether drug preparation premises pass, pass with conditions or fail an inspection, the College may consider,

(a) the inspection results provided to the College by the inspector;

(b) information provided by one or more members engaging in or supervising drug preparation activities at or in connection with the drug preparation premises respecting the inspection, including the answers given by them in response to inquiries or questions asked by the inspector;

(c) the information contained in a notice given by a member under subsection 57 (1) or (3);

(d) any submissions made by the member or members engaging in or supervising drug preparation activities at or in connection with the drug preparation premises that are relevant to the inspection; and

(e) any other information that is directly relevant to the inspection of the drug preparation premises conducted under this Part.

(3) The College shall deliver a report, in writing and in accordance with section 39 of the *Regulated Health Professions Act, 1991*, to the individual or corporation that is the owner or occupier of the drug preparation premises and to the designated member for the drug preparation premises, within a reasonable time after the inspection is completed.

(4) Any report made by the College respecting an inspection of drug preparation premises where a member is engaging in or in respect of which the member is supervising drug preparation activities shall make a finding that the drug preparation premises passed, passed with conditions or failed the inspection and shall provide reasons where the drug preparation premises passed with conditions or failed the inspection.

(5) Any report made by the College that finds that drug preparation premises failed an inspection or passed with conditions is effective on the day that it is received, in accordance with section 39 of the *Regulated Health Professions Act, 1991*, by the designated member for the drug preparation premises.

(6) The designated member who receives a report made by the College that finds that a drug preparation premises failed an inspection or passed with conditions shall promptly provide copies of the report to all members engaging in or supervising drug preparation activities at or in connection with the drug preparation premises.

(7) A member shall not engage in or supervise drug preparation activities at or in connection with a drug preparation premises that fail an inspection until,

(a) the College delivers a report indicating that the drug preparation premises passed a subsequent inspection, or passed with conditions; or

(b) after considering submissions under subsection (9), the College substitutes a finding that the drug preparation premises pass or pass with conditions.

(8) A member shall not engage in or supervise drug preparation activities at or in connection with drug preparation premises that pass an inspection with conditions except in accordance with the conditions set out in the report until,

(a) the College delivers a report indicating that the drug preparation premises passed a subsequent inspection; or

(b) after considering submissions under subsection (9), the College substitutes a finding that the drug preparation premises pass.

(9) A member may make submissions in writing to the College within 14 days from the date on which a report made by the College that finds that the drug preparation premises passed with conditions or failed the inspection becomes effective in accordance with subsection (5).

(10) The College may or may not elect to reinspect the drug preparation premises after receiving a member's submissions, but no more than 60 days after a member provides his or her submissions, the College shall do one or more of the following:

1. Confirm its finding that the drug preparation premises failed the inspection or passed with conditions.

2. Make a report and find that the drug preparation premises passed with conditions.

3. Make a report and find that the drug preparation premises passed the inspection.

(11) Drug preparation premises that fail an inspection or pass with conditions may be subject to one or more further inspections within a reasonable time after the College delivers its report, at the request of a member, any other person to whom the College gave the report, or at any time at the discretion of the College.

(12) Where, as a result of an inspection carried out under this Part, a report made by the College finds that a member's knowledge, skill or judgment is unsatisfactory, the College may direct the Registrar to refer the report to the Quality Assurance Committee.

(13) Where, as a result of an inspection carried out under this Part, a report made by the College finds that a member may have committed an act of professional misconduct or may be incompetent or incapacitated, the College may direct the Registrar to refer the report to the Inquiries, Complaints and Reports Committee.

PART X
FUNDING FOR THERAPY AND COUNSELLING

61. In this Part,

"member" includes a former member.

62. (1) The alternative requirements that must be satisfied in order for a person to be eligible for funding under clause 85.7 (4) (b) of the Health Professions Procedural Code are prescribed in this section.

(2) A person is eligible for funding for therapy or counselling if,

(a) there is an admission made by a member in a statement to the College or in an agreement with the College that he or she sexually abused the person while the person was a patient of the member;

(b) a member has been found guilty under the *Criminal Code* (Canada) of sexually assaulting the person while the person was a patient of the member;

(c) there is a statement, contained in the written reasons of a committee of the College given after a hearing, that the person, while a patient, was sexually abused by a member; or

(d) there is sufficient evidence presented to the Patient Relations Committee to support a reasonable belief that the person, while a patient, was sexually abused by a member.

(3) For the purposes of clause (2) (d), and without limiting the generality of that clause, the following kinds of evidence may support a reasonable belief that a person, while a patient, was sexually abused by a member:

1. Evidence of reports made with respect to the member under subsection 85.1 (1) or 85.2 (1) of the Health Professions Procedural Code.

2. Evidence that corroborates the person's allegations of sexual abuse by the member.

(4) A person is not eligible under subsection (2) unless, at the time the sexual abuse occurred, the person was a patient of the member and the member was practising in Ontario.

(5) Despite subsections (2), (3) and (4), a person is eligible for funding for therapy or counselling under this Part only if,

(a) the person submits an application for funding to the Patient Relations Committee in the form provided by the College and, in the application, the person names the member who is alleged to have sexually abused the person;

(b) the person adheres to the procedures followed by the Patient Relations Committee when determining whether the person has satisfied the requirements for eligibility for funding; and

(c) the person provides such other information as is required by the Patient Relations Committee.

(6) A decision by the Patient Relations Committee that a person is eligible for funding for therapy or counselling does not constitute a finding against the member and shall not be considered by any other committee of the College dealing with the member.

TABLES 1, 2 REVOKED: O. Reg. 452/16, s. 2.

SCHEDULE 1
INJECTED SUBSTANCES

(Arranged by American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification)

1. 8:00 Anti-infective Agents
    i. 8:12 Antibacterials
        A. 8:12.02 Aminoglycosides

1. Amikacin
2. Gentamicin

B. 8:12.06.04 First Generation Cephalosporins
1. Cefazolin

C. 8:12.06.12 Third Generation Cephalosporins
1. Cefotaxime
2. Ceftazidime
3. Ceftriaxone

D. 8:12.06.16 Fourth Generation Cephalosporins
1. Cefepime

E. 8:12.07.08 Carbapenems
1. Ertapenem

F. 8:12.07.12 Cephamycins
1. Cefoxitin

G. 8:12.16.04 Natural Penicillins
1. Penicillin G

H. 8:12.16.08 Aminopenicillins
1. Ampicillin

I. 8:12.16.12 Pencillinase-Resistant Penicillins
1. Cloxacillin

J. 8: 12.28.20 Lincomycins
1. Clindamycin

K. 8:12.28.28 Polymyxins
1. Colistin

ii. 8:18 Antivirals

A. 8:18.08.04 HIV Entry and Fusion Inhibitors
1. Enfuvirtide

B. 8:18.20 Interferons
1. Interferon Alfa-2b
2. Peginterferon alfa-2a
3. Peginterferon Beta-1a

2. 10:00 Antineoplastic Agents
1. Goserelin
2. Leuprolide
3. Methotrexate
4. Fulvestrant
5. Triptorelin acetate
6. Rituximab

3. 12:00 Autonomic Drugs

i. 12:08.08 Antimuscarinic Antispasmodics
1. Atropine

ii. 12:12 Sympathomimetic (Adrenergic) Agents

A. 12:12.12 Alpha- and Beta-Adrenergic Agonists
1. Scopolamine
2. Hyoscine
3. Glycopyrrolate
4. Epinephrine

iii. 12:16 Sympatholytic (Adrenergic Blocking) Agents
1. Dihydroergotamine

4. 20:00 Blood Formation and Coagulation

i. . 20:12 Coagulants and Anticoagulants

A. 20:12.04 Anticoagulants
1. Dalteparin
2. Danaparoid
3. Enoxaparin
4. Fondaparinux
5. Heparin
6. Nadroparin
7. Tinzaparin

ii. 20:16 Hematopoietic Agents
1. Ancestim
2. Darbepoetin alfa
3. Epoetin alfa
4. Filgrastim
5. Pegfilgrastim
6. Romiplostim

iii. 20:28.92 Antihemorrhagic Agents, Miscellaneous
1. Emicizumab

5. 24:00 Cardiovascular Drugs

i. 24:06.24 Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors
1. Alirocumab
2. Evolocumab

6. 28:00 Central Nervous System Agents

i. 28:08 Analgesics and Antipyretics

A. 28:08.08 Opiate Agonists
1. Codeine
2. Hydromorphone
3. Morphine

B. 28:08.12 Opiate Partial Agonists
1. Nalbuphine
2. Pentazocine

ii. 28:10 Opiate Antagonists
1. Naloxone

iii. 28:16 Psychotherapeutic Agents

A. 28:16.08 Antipsychotics
1. Haloperidol
2. Methotrimeprazine
3. Aripiprazole
4. Flupentixol
5. Methotrimeprazine
6. Paliperidone
7. Risperidone
8. Zuclopenthixol
9. Fluphenazine
10. Olanzapine

iv. 28:24.08 Benzodiazepines
1. Lorazepam
2. Diazepam
3. Midazolam

v. 28:32 Antimigraine Agents
A. 28:32:12 Calcitonin-Gene-Related Peptide (CGRP) Antagonists
1. Erenumab
B. 28:32.28 Selective Serotonin Agonists
1. Sumatriptan

vi. 28.36 Antiparkinsonian Agents
A. 28:36.20.08 Nonergot-derivative Dopamine Receptor Agonists
1. Apomorphine
B. 28:36.08 Anticholinergic Agents
1. Benztropine

vii. 28:92 Miscellaneous Central Nervous System Agents
1. Inotersen

7. 40:00 Electrolytic, Caloric, and Water Balance
i. 40:12 Replacement Preparations
1. Normal saline

8. 44:00 Enzymes
1. Asfotase Alfa

9. 48:00 Respiratory Tract Agents
i. 48:92 Respiratory Tract Agents, Miscellaneous
1. Omalizumab
2. Benralizumab

10. 56:00 Gastrointestinal Drugs
i. 56:22 Antiemetics
A. 56:22.08 Antihistamines
1. Dimenhydrinate

ii. 56:32 Prokinetic Agents
1. Metoclopropamide

iii. 56:92 GI Drugs, Miscellaneous
1. Certolizumab Pegol
2. Methylnaltrexone

11. 64:00 Heavy Metal Antagonists
1. Deferoxamine

12. 68:00 Hormones and Synthetic Substitutes

i. 68:04 Adrenals
1. Betamethasone
2. Tetracosactide
3. Hydrocortisone
4. Dexamethasone
5. Prednisolone
6. Methylprednisolone

ii. 68:08 Androgens
1. Testosterone

iii. 68:18 Gonadotropins
1. Follitropin-alpha
2. Follitropin-beta
3. Follitropin-delta
4. Gonadotropin-chorionic
5. Gonadotropin-chorionic-alfa
6. Gonadotropin-human
7. Lutropin-alfa
8. Menotropins

iv. 68:20 Antidiabetic Agents
1. Exenatide
2. Insulins
3. Liraglutide
4. Dulaglutide
5. Lixisenatide
6. Semaglutide

v. 68:22 Antihypoglycemic Agents
A. 68:22:12 Glycogenolytic Agents
1. Glucagon

vi. 68:24 Parathyroid
1. Calcitonin Salmon
2. Teriparatide

vii. 68:28 Pituitary
1. Desmopressin
2. Vasopressin

viii. 68:29:04 Somatostatin Agonists
1. Pasireotide

ix. 68:30 Somatotropin Agonists and Antagonists
A. 68:30.04 Somatotropin Agonists
1. Somatropin
2. Tesamorelin
B. 68:30.08 Somatotropin Antagonists
1. Pegvisomant
x. 68:32 Progestins
1. Medroxyprogesterone
2. Progesterone
xi. 68:36:04 Thyroid Agents
1. Levothyroxine

13. 72:00 Local Anesthetics
1. Lidocaine
2. Prilocaine
3. Articaine
4. Bupivacaine
5. Mepivacaine

14. 84:92 Misc. Skin and Mucous Membrane Agents
1. Brodalumab
2. Dupilumab
3, Guselkumab
4. Ixekizumab
5. Risankizumab
6. Secukinumab

15. 88:00 Vitamins
i. 88:08 Vitamin B Complex
1. Cyanocobalamin
2. Folic Acid
3. Pyridoxine
4. Thiamine
ii. 88:12 Vitamin C
1. Ascorbic Acid
iii. 88:24 Vitamin K Activity
1. Vitamin K

16. 92:00 Miscellaneous Therapeutic Agents
i. 92:20 Biologic Response Modifiers
1. Denosumab
2. Glatiramer
3. Interferon-Beta-1A
4. Interferon-Beta-1B
ii. 92:32 Complement Inhibitors
1. Icatibant

2. Lanadelumab

iii. 92:36 Disease-modifying Antirheumatic Drugs

1. Abatacept
2. Adalimumab
3. Anakinra
4. Etanercept
5. Golimumab
6. Ustekinumab
7. Sarilumab
8. Tocilizumab

iv. 92:40 Gonadotropin- releasing Hormone Antagonists

1. Cetrorelix
2. Ganirelix

v. 92:44 Immunosuppressive Agents

1. Belimumab
2. Mepolizumab

vi. 92:92 Other Miscellaneous Therapeutic Agents

7. Octreotide
8. Lanreotide

17. Miscellaneous

1. Sterile Water for Injection (Diluent)

SCHEDULE 2
INHALED SUBSTANCES

(Arranged by American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification)

1. 8:00 Anti-infective Agents
   i. 8:18 Antivirals
      A. 8:18.28 Neuraminidase Inhibitors
         1. Zanamivir
   ii. 8:12 Antibacterials
      A. 8:12.07.16 Monobactams
         1. Tobramycin
         2. Aztreonam
      B. 8:12.18 Quinolones
         1. Levofloxacin
2. 12:00 Autonomic Drugs
   i. 12:08 Anticholinergic Agents
      A. 12:08.08 Antimuscarinics/Antispasmodics
         1. Ipratropium
         2. Tiotropium
         3. Umeclidinium

4. Aclidinium

ii. 12:12 Sympathomimetic (Adrenergic) Agents

A. 12:12.08.12 Selective Beta2- Adrenergic Agonists

1. Formoterol
2. Salbutamol
3. Salmeterol
4. Terbutaline
5. Vilanterol
6. Indacaterol
7. Olodaterol

iii. 12:16 Sympatholytic (Adrenergic Blocking) Agents

A. 12:16.04.04 Non-Selective alpha-Adrenergic Blocking Agents

1. Dihyroergotamine

iv. 12:92 Autonomic Drugs, Miscellaneous

1. Nicotine

3. 28:00 Central Nervous System Agents

i. 28:08 Analgesics and Antipyretics

A. 28:08.12 Opiate Partial Agonists

1. Butorphanol

ii. 28:32 Antimigraine Agents

A. 28:32.28 Selective Serotonin Agonists

1. Sumatriptan
2. Zolmitriptan

4. 40:00 Electrolytic, Caloric, and Water Balance

i. 40:12 Replacement Preparations

1. Sodium chloride

5. 48:00 Respiratory Tract Agents

i. 48:12.08 Anticholinergic Agents

1. Glycopyrronium

ii. 48:24 Mucolytic Agents

1. Dornase alfa

6. 52:00 Eye, Ear, Nose and Throat (EENT) Preparations

i. 52:02 Antiallergic Agents

1. Sodium Cromoglycate
2. Levocabastine

ii. 52:08 Anti-inflammatory Agents

A. 52:08.08 Corticosteroids

1. Beclomethasone
2. Budesonide
3. Ciclesonide
4. Flunisolide
5. Fluticasone

6. Mometasone
7. Triamcinolone

iii. 52:32 Vasoconstrictors

1. Oxymetazoline
2. Phenylephrine
3. Xylometazoline

7. 68:00 Hormones and Synthetic Substitutes

i. 68:18 Gonadotropins

1. Buserelin
2. Nafarelin

ii. 68:24 Parathyroid

1. Calcitonin Salmon

iii. 68:28 Pituitary

1. Desmopressin
2. Vasopressin

8. 92:00 Miscellaneous Therapeutic Agents

i. 92:12 Antidotes

1. Acetylcysteine

SCHEDULE 1
INJECTED SUBSTANCES

(Arranged by American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification)

1. 8:00 Anti-infective Agents
   i. 8:12 Antibacterials
   ii. 8:18 Antivirals

2. 10:00 Antineoplastic Agents

3. 12:00 Autonomic Drugs
   i. 12:08 Antimuscarinic Antispasmodics
   ii. 12:12 Sympathomimetic (Adrenergic) Agents
   iii. 12:16 Sympatholytic (Adrenergic Blocking) Agents

4. 20:00 Blood Formation and Coagulation
   i. 20:12 Coagulants and Anticoagulants
   ii. 20:16 Hematopoietic Agents
   iii. 20:28.92 Antihemorrhagic Agents, Miscellaneous

5. 24:00 Cardiovascular Drugs
   i. 24:06.24 Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors

6. 28:00 Central Nervous System Agents

i. 28:08 Analgesics and Antipyretics
ii. 28:10 Opiate Antagonists
iii. 28:16 Psychotherapeutic Agents
iv. 28:24 Bezodiazepines
v. 28:32 Antimigraine Agents
vi. 28.36 Antiparkinsonian Agents
vii. 28:92 Miscellaneous Central Nervous System Agents

7. 40:00 Electrolytic, Caloric, and Water Balance
    i. 40:12 Replacement Preparations

8. 44:00 Enzymes

9. 48:00 Respiratory Tract Agents
    i. 48:92 Respiratory Tract Agents, Miscellaneous

10. 56:00 Gastrointestinal Drugs
    i. 56:22 Antiemetics
    ii. 56:32 Prokinetic Agents
    iii. 56:92 GI Drugs, Miscellaneous

11. 64:00 Heavy Metal Antagonists

12. 68:00 Hormones and Synthetic Substitutes
    i. 68:04 Adrenals
    ii. 68:08 Androgens
    iii. 68:18 Gonadotropins
    iv. 68:20 Antidiabetic Agents
    v. 68:22 Antihypoglycemic Agents
    vi. 68:24 Parathyroid
    vii. 68:28 Pituitary
    viii. 68:29:04 Somatostatin Agonists
    ix. 68:30 Somatotropin Agonists and Antagonists
    x. 68:32 Progestins
        1. Medroxyprogesterone
        2. Progesterone
    xi. 68:36:04 Thyroid Agents

13. 72:00 Local Anesthetics

14. 84:92 Misc. Skin and Mucous Membrane Agents

15. 88:00 Vitamins
    i. 88:08 Vitamin B Complex
    ii. 88:12 Vitamin C
    iii. 88:24 Vitamin K Activity

16. 92:00 Miscellaneous Therapeutic Agents
    i. 92:20 Biologic Response Modifiers
    ii. 92:32 Complement Inhibitors
    iii. 92:36 Disease-modifying Antirheumatic Drugs
    iv. 92:40 Gonadotropin- releasing Hormone Antagonists
    v. 92:44 Immunosuppressive Agents
    vi. 92:92 Other Miscellaneous Therapeutic Agents

17. Miscellaneous

SCHEDULE 2
INHALED SUBSTANCES

(Arranged by American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification)

1. 8:00 Anti-infective Agents
    i. 8:18 Antivirals
    ii. 8:12 Antibacterials

2. 12:00 Autonomic Drugs
    i. 12:08 Anticholinergic Agents
    ii. 12:12 Sympathomimetic (Adrenergic) Agents
    iii. 12:16 Sympatholytic (Adrenergic Blocking) Agents
    iv. 12:92 Autonomic Drugs, Miscellaneous

3. 28:00 Central Nervous System Agents
    i. 28:08 Analgesics and Antipyretics
    ii. 28:32 Antimigraine Agents

4. 40:00 Electrolytic, Caloric, and Water Balance
    i. 40:12 Replacement Preparations

5. 48:00 Respiratory Tract Agents
    i. 48:12.08 Anticholinergic Agents
    ii. 48:24 Mucolytic Agents

6. 52:00 Eye, Ear, Nose and Throat (EENT) Preparations
    i. 52:02 Antiallergic Agents
    ii. 52:08 Anti-inflammatory Agents

iii. 52:32 Vasoconstrictors

7. 68:00 Hormones and Synthetic Substitutes
   i. 68:18 Gonadotropins
   ii. 68:28 Pituitary

8. 92:00 Miscellaneous Therapeutic Agents
   i. 92:12 Antidotes
      1. Acetylcysteine

.

SCHEDULE 3
VACCINES

1. Bacille Calmette-Guerin (BCG) Vaccines
2. Haemophilus Influenzae type b (Hib) Vaccines
3. Meningococcal Vaccines
4. Pneumococcal Vaccines
5. Typhoid Vaccines
6. Combined Typhoid and Hepatitis A Vaccines
7. Hepatitis A Vaccines
8. Hepatitis B Vaccines
9. Hepatitis A and B combined Vaccines
10. Herpes Zoster Vaccines
11. Human Papillomavirus (HPV) Vaccines
12. Japanese Encephalitis Vaccines
13. Rabies Vaccines
14. Varicella Vaccines
15. Yellow Fever Vaccines

DRAFT General Regulation 202/94
Clause by Clause Comparison of Amended Sections

ATTACHMENT 4

Existing Clause	Proposed New Clause	Rationale
VII.3 (CONTROLLED ACTS)		
31. In this Part, “adapt” means to change a patient’s prescription respecting, (a) the dose of the prescribed drug, (b) the dosage form of the prescribed drug, (c) the directions for use of the prescribed drug, or 16 (d) the route of administration for taking the prescribed drug, but does not include therapeutic substitution; “Part A pharmacist” means a member who holds a certificate of registration as a pharmacist and who is listed in Part A of the register; “prescriber” means a person who is authorized under the laws of a province or territory of Canada to give a prescription within the scope of his or her practice of a health profession; “prescription” means a direction from a prescriber directing the dispensing of a drug or mixture of drugs for a specific patient; “renew” means to provide a patient with a prescription that repeats a prescription previously provided to that patient; “therapeutic substitution” means the substitution of a drug that contains chemically different active ingredients that are considered to be therapeutically equivalent.	**31.** In this Part, “adapt” means to change a patient’s prescription respecting, (a) the dose of the prescribed drug, (b) the dosage form of the prescribed drug, (c) the directions for use of the prescribed drug, or 16 (d) the route of administration for taking the prescribed drug, but does not include therapeutic substitution; “Part A pharmacist” means a member who holds a certificate of registration as a pharmacist and who is listed in Part A of the register; “point of care test” means a diagnostic test performed on a patient sample at the site of patient care; “prescriber” means a person who is authorized under the laws of a province or territory of Canada to give a prescription within the scope of his or her practice of a health profession; “prescription” means a direction from a prescriber directing the dispensing of a drug or mixture of drugs for a specific patient; “renew” means to provide a patient with a prescription that repeats a prescription previously provided to that patient; “therapeutic substitution” means the substitution of a drug that contains chemically different active ingredients that are considered to be therapeutically equivalent.	To add a definition of “point of care test”.
34. (1) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) who meets all the requirements in subsection (3) is authorized to perform the following acts: 1. Administering a substance specified in Schedule 1 by injection to a patient. 2. Administering a substance specified in Schedule 2 by inhalation to a patient.	34. (1) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) who meets all the requirements in subsection (3) is authorized to perform the following acts: 1. Administering a substance specified in Schedule 1 by injection to a patient through a route other than direct intravenous, intravenous push, intravenous bolus, intrathecal, intraarticular, intracardiac, intraspinal, intraocular, and intracavernous. 2. Administering a substance specified in Schedule 2 by inhalation to a patient.	The current regulation restricts administration of substances by injection and inhalation for the purposes of patient education and demonstration, which inherently limits the route of administration. The new regulation removes the restriction on the purpose of administration, resulting in the need to specify which routes of administration are beyond the scope of practice of a pharmacist.

Existing Clause	Proposed New Clause	Rationale
[…] (3) A member may only perform an act provided for in subsection (1) if he or she complies with the following: 1. The member may only perform the act for the purpose of patient education and demonstration, and before performing the act, i. must explain that purpose to the patient or his or her authorized agent, and ii. must receive an informed consent from the patient or his or her authorized agent. 2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient. 3. The member shall ensure that appropriate infection control procedures are in place. 4. The member must possess sufficient knowledge, skill and judgment respecting the substance to be administered, and sufficient understanding of the condition of the patient, to be able to administer the substance safely. 5. The member must consider whether administering a substance by injection or inhalation to the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome after administration and any other relevant circumstances. 6. The member must maintain a patient record that includes, i. the name and address of the patient, ii. the name and address of the member, iii. the date the act was performed, iv. the name, strength (where applicable) and quantity of the substance that the member administered to the patient, v. the circumstances relating to the administration of the substance to the patient and any adverse reaction experienced by the patient, and vi. confirmation that an informed consent was given by the patient or his or her authorized agent.	[…] (3) A member may only perform an act provided for in subsection (1) if he or she complies with the following: 1. The member ~~may only perform the act for the purpose of patient education and demonstration, and before performing the act,~~ ~~i. must explain that purpose to the patient or his or her authorized agent, and~~ ~~ii.~~ must receive an informed consent from the patient or his or her authorized agent before performing the act. 2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient. 3. The member shall ensure that appropriate infection control procedures are in place. 4. The member must possess sufficient knowledge, skill and judgment respecting the substance to be administered, and sufficient understanding of the condition of the patient, to be able to administer the substance safely. 5. The member must consider whether administering a substance by injection or inhalation to the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome after administration and any other relevant circumstances. 6. The member must maintain a patient record that includes, i. the name and address of the patient, ii. the name and address of the member, iii. the date the act was performed, iv. the name, strength (where applicable) and quantity of the substance that the member administered to the patient, v. the circumstances relating to the administration of the substance to the patient and any adverse reaction experienced by the patient, and vi. confirmation that an informed consent was given by the patient or his or her authorized agent. 7. Where the act is performed for a purpose other than patient education and demonstration, the member must notify the	The removal in section 34(3)1. allows for the administration of substances by injection and inhalation beyond the purposes of patient education and demonstration (i.e. for therapeutic purposes). Numbering is adjusted as necessary. Communication of services that are provided for patient care or therapeutic purposes are necessary to support continuity and co-ordination of care among the health team.

Existing Clause	Proposed New Clause	Rationale
	patient's primary care provider (if any) within a reasonable time that the member performed the act and provide details respecting the act.	
34. (4) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) is authorized to administer influenza vaccine by injection to a patient who is five years of age or older, if the member, (a) administers the vaccine in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website; (b) receives an informed consent from the patient or his or her authorized agent; and (c) meets all the requirements in paragraphs 2 to 6 of subsection (3). (5) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) is authorized to administer a vaccine from one of the vaccines specified in Schedule 3 by injection to a patient who is five years of age or older, if the member, (a) receives an informed consent from the patient or his or her authorized agent; (b) meets all the requirements in paragraphs 2 to 6 of subsection (3); and (c) notifies the patient's primary care provider (if any) within a reasonable time that the member administered a vaccine to the patient and provides details respecting the administration.	34. (4) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) is authorized to administer influenza vaccine by injection to a patient who is ~~five~~ two years of age or older, if the member, (a) administers the vaccine in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website; and ~~(b) receives an informed consent from the patient or his or her authorized agent; and~~ (~~c~~b) meets all the requirements ~~2~~ 1 to 6 of subsection (3). (5) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a member referred to in subsection (2) is authorized to administer a vaccine from one of the vaccines specified in Schedule 3 by injection to a patient who is five years of age or older, if the member, (a) ~~receives an informed consent from the patient or his or her authorized agent; (b~~) meets all the requirements in paragraphs ~~2~~1 to 6 of subsection (3); and (~~c~~b) notifies the patient's primary care provider (if any) within a reasonable time that the member administered a vaccine to the patient and provides details respecting the administration.	The change in age allows for the administration of the influenza vaccination by injection to a patient who is two years of age or older. Numbering is adjusted as necessary. Removal of the requirement to provide informed consent in (4) a and (5) a is to remove repetition in the drafting. The requirement for informed consent is referenced in paragraph 1 of subsection (3).
36. (1) For the purposes of paragraph 4 of subsection 4 (1) of the Act, a member referred to in subsection (3) who complies with the other provisions of this section is authorized to perform the following acts: 1. Adapting a patient's prescription. 2. Renewing a patient's prescription for the purpose of continuity of care. […]	36. (1) For the purposes of paragraph 4 of subsection 4 (1) of the Act, a member referred to in subsection (3) who complies with the other provisions of this section is authorized to perform the following acts: 1. Adapting a patient's prescription. 2. Renewing a patient's prescription for the purpose of continuity of care. […]	

Existing Clause	Proposed New Clause	Rationale
(4) A member may only perform an act provided for in subsection (1) if he or she complies with the following: […] 2. If the member is renewing a prescription, he or she must not prescribe a quantity of the drug that exceeds the lesser of, i. the quantity that was originally prescribed, including any refills that were authorized by the prescriber, and ii. a six months'supply.	(4) A member may only perform an act provided for in subsection (1) if he or she complies with the following: […] 2. If the member is renewing a prescription, he or she must not prescribe a quantity of the drug that exceeds the lesser of, i. the quantity that was originally prescribed, including any refills that were authorized by the prescriber, and ii. a ~~six~~ twelve months' supply.	Changing a "six months' supply" to a "twelve months' supply" allows pharmacists to renew prescriptions for up to 12 months, enabling greater access and continuity of care to patients, and potentially reducing some of the burden on the system, particularly for patients without access to a primay care physician (e.g. unnecessary visits to the emergency room department).
39. (1) For the purposes of paragraph 5 of subsection 4 (1) of the Act, a member referred to in subsection (2) who meets all the requirements in subsection (4) is authorized to perform the act of piercing a patient's dermis with a lancet-type device to obtain blood. (2) A member who is a Part A pharmacist, an intern, a registered pharmacy student or a pharmacy technician is authorized to perform the act provided for in subsection (1), subject to the terms, conditions and limitations imposed on his or her certificate of registration. (3) A pharmacy technician shall not perform the act provided for in subsection (1) unless, (a) a Part A pharmacist is physically present on the premises at the time when the pharmacy technician performs the act; and (b) the pharmacy technician is under the direction of a Part A pharmacist at the time when the pharmacy technician performs the act.	39. (1) For the purposes of paragraph 5 of subsection 4 (1) of the Act, and subject to subsection (3), a member referred to in subsection (2) who meets all the requirements in subsection (4) is authorized to perform the act of piercing a patient's dermis with a lancet-type device to obtain blood. (2) A member who is a Part A pharmacist, an intern, a registered pharmacy student or a pharmacy technician is authorized to perform the act provided for in subsection (1), subject to the terms, conditions and limitations imposed on his or her certificate of registration. (3) A pharmacy technician shall not perform the act provided for in subsection (1) unless, (a) a Part A pharmacist is physically present on the premises at the time when the pharmacy technician performs the act; ~~and~~ (b) the pharmacy technician is under the direction of a Part A pharmacist at the time when the pharmacy technician performs the act, and (c) where the act is performed to administer a point of care test, a Part A pharmacist interprets the results of the test and makes the professional decision arising from the results of the test.	The current regulation restricts the act of piercing the dermis to purposes related to patient education and self monitoring of a chronic disease. Removal of this restriction allows for members perform the act of piercing below the dermis for other purposes, such as point of care testing. This is an enabling change in the event that point of care testing is permitted in the future as a result of amendments to the Ministry's regulations under the Laboratory Speciman Collection and Centre Licensing Act. Numbering is adjusted as necessary. Consistent with the scope of practice of pharmacy technicians, this addition enables performamce of the act of piercing the dermis for additional purposes, but restricts pharmacy technicians from interpreting the results and making a therapeutic decision to act on the results.
(4) A member may only perform the act provided for in subsection (1) if he or she complies with the following: 1. The member may only perform the act for the purpose of demonstrating the appropriate use of lancet-type devices for the patient's self care and education or for the patient's self monitoring of his or her chronic disease, and before performing the act, i. shall explain that purpose to the patient or his or her authorized agent, and	(4) A member may only perform the act provided for in subsection (1) if he or she complies with the following: 1. ~~The member may only perform the act for the purpose of demonstrating the appropriate use of lancet-type devices for the patient's self care and education or for the patient's self monitoring of his or her chronic disease, and before performing the act,~~ i. ~~shall explain that purpose to the patient or his or her authorized agent, and ii. shall~~ The	As noted above, removal of the specific purpose for performing the act of piercing the dermis, enables additional purposes such as point of care testing.

Existing Clause	Proposed New Clause	Rationale
ii. shall receive an informed consent from the patient or his or her authorized agent. 2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient. 3. The member shall ensure that appropriate infection control procedures are in place. 4. The member must possess the knowledge, skill and judgment respecting the performance of the act and understand the condition of the patient, to perform it safely and effectively. 5. The member must consider whether performing the act on the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome and any other relevant circumstances. 6. The member must maintain a patient record that includes, i. the name and address of the patient and the member, ii. the date the act was performed, and iii. confirmation that an informed consent was given by the patient or his or her authorized agent.	member must receive an informed consent from the patient or his or her authorized agent before performing the act. 2. The member shall ensure that he or she only performs the act in an environment that is clean, safe, private and comfortable for the patient. 3. The member shall ensure that appropriate infection control procedures are in place. 4. The member must possess the knowledge, skill and judgment respecting the performance of the act and understand the condition of the patient, to perform it safely and effectively. 5. The member must consider whether performing the act on the patient is appropriate, given the known risks and benefits to the patient and the safeguards and resources available to safely manage the outcome and any other relevant circumstances. 6. The member must maintain a patient record that includes, i. the name and address of the patient ~~and the member,~~ , ii. the ~~date~~name and address of the member, iii. the date the act was performed, ~~and~~ ~~iii.~~ iv. the circumstances relating to the act and any adverse reaction experienced by the patient, v. where the member performed the act to administer a point of care test, the results of the test, vi. the professional decision arising from the results of the point of care test and the rationale forthe decision, and vii. confirmation that an informed consent was given by the patient or his or her authorized agent. 7. Where the act is performed for a purpose other than patient education and demonstration, the member must notify the patient's primary care provider (if any) within a reasonable time that the member performed the act and provide details respecting the act.	Communication of services that are provided for patient care or therapeutic purposes are necessary to support continuity and co-ordination of care among the health team. These requirements are consistent with the other patient care documentation requirments, and include the requirements specific to point of care testing.

DRAFT General Regulation 202/94
Clause by Clause Comparison

Existing Clause	Proposed New Clause (List)	Proposed New Clause (Categories)
SCHEDULE 1 INJECTED SUBSTANCES (Arranged by American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification) 1. 8:00 Anti-infective Agents i. 8:18 Antivirals A. 8:18.08.04 HIV Entry and Fusion Inhibitors 1. Enfuvirtide B. 8:18.20 Interferons 1. Interferon Alfa-2b 2. Peginterferon alfa-2a 3. Peginterferon alfa-2b 2. 10:00 Antineoplastic Agents 1. Goserelin 2. Leuprolide 3. Methotrexate 3. 12:00 Autonomic Drugs i. 12:12 Sympathomimetic (Adrenergic) Agents A. 12:12.12 Alpha- and Beta-Adrenergic Agonists 1. Scopolamine 2. Hyoscine 3. Glycopyrrolate 4. Epinephrine 4. 20:00 Blood Formation and Coagulation	SCHEDULE 1 INJECTED SUBSTANCES (Arranged by American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification) 1. 8:00 Anti-infective Agents i. 8:12 Antibacterials A. 8:12.02 Aminoglycosides 1. Amikacin 2. Gentamicin B. 8:12.06.04 First Generation Cephalosporins 1. Cefazolin C. 8:12.06.12 Third Generation Cephalosporins 1. Cefotaxime 2. Ceftazidime 3. Ceftriaxone D. 8:12.06.16 Fourth Generation Cephalosporins 1. Cefepime E. 8:12.07.08 Carbapenems 1. Ertapenem	SCHEDULE 1 INJECTED SUBSTANCES (Arranged by American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification) 1. 8:00 Anti-infective Agents i. 8:12 Antibacterials ii. 8:18 Antivirals 2. 10:00 Antineoplastic Agents 3. 12:00 Autonomic Drugs i. 12:08 Antimuscarinic Antispasmodics ii. 12:12 Sympathomimetic (Adrenergic) Agents iii. 12:16 Sympatholytic (Adrenergic Blocking) Agents 4. 20:00 Blood Formation and Coagulation i. ~~20:04 Antianemia Drugs~~ i. . 20:12 Coagulants and Anticoagulants ii. 20:16 Hematopoietic Agents

i. 20:04 Antianemia Drugs
A. 20:04.04 Iron Preparations

1. Iron
ii. 20:12 Coagulants and Anticoagulants
A. 20:12.04 Anticoagulants
1. Dalteparin
2. Danaparoid
3. Enoxaparin
4. Fondaparinux
5. Heparin
6. Nadroparin
7. Tinazaparin
iii. 20:16 Hematopoietic Agents
1. Ancestim
2. Darbepoetin alfa
3. Epoetin alfa
4. Filgrastim
5. Pegfilgrastim
6. Romiplostim

5. 28:00 Central Nervous System Agents
i. 28:08 Analgesics and Antipyretics
A. 28:08.08 Opiate Agonists
1. Codeine
2. Hydromorphone
3. Meperidine
4. Morphine
B. 28:08.12 Opiate Partial Agonists
1. Nalbuphine
2. Pentazocine
ii. 28:16 Psychotherapeutic Agents
A. 28:16.08 Antipsychotics
1. Haloperidol

F. 8:12.07.12 Cephamycins
1. Cefoxitin
G. 8:12.16.04 Natural Penicillins
1. Penicillin G
H. 8:12.16.08 Aminopenicillins
1. Ampicillin
I. 8:12.16.12 Pencillinase-Resistant Penicillins
1. Cloxacillin
J. 8: 12.28.20 Lincomycins
1. Clindamycin
K. 8:12.28.28 Polymyxins
1. Colistin

ii. 8:18 Antivirals
A. 8:18.08.04 HIV Entry and Fusion Inhibitors
1. Enfuvirtide
B. 8:18.20 Interferons
1. Interferon Alfa-2b
2. Peginterferon alfa-2a
~~3. Peginterferon alfa-2b~~
3. Peginterferon Beta-1a

2. 10:00 Antineoplastic Agents
1. Goserelin
2. Leuprolide
3. Methotrexate
4. Fulvestrant

iii. 20:28.92 Antihemorrhagic Agents, Miscellaneous

5. 24:00 Cardiovascular Drugs
i. 24:06.24 Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors

6. 28:00 Central Nervous System Agents
i. 28:08 Analgesics and Antipyretics

ii. 28:10 Opiate Antagonists

iii. 28:16 Psychotherapeutic Agents

iv. 28:24 Bezodiazepines

v. 28:32 Antimigraine Agents
vi. 28.36 Antiparkinsonian Agents
vii. 28:92 Miscellaneous Central Nervous System Agents

7. 40:00 Electrolytic, Caloric, and Water Balance
i. 40:12 Replacement Preparations

8. 44:00 Enzymes

9. 48:00 Respiratory Tract Agents

2. Methotrimeprazine
iii. 28:32 Antimigraine Agents
A. 28:32.28 Selective Serotonin Agonists
1. Sumatriptan
6. 40:00 Electrolytic, Caloric, and Water Balance
i. 40:12 Replacement Preparations
1. Normal saline
7. 48:00 Respiratory Tract Agents
i. 48:92 Respiratory Tract Agents, Miscellaneous
1. Omalizumab
8. 56:00 Gastrointestinal Drugs
i. 56:22 Antiemetics
A. 56:22.08 Antihistamines
1. Dimenhydrinate
2. Prochlorperazine
ii. 56:32 Prokinetic Agents
1. Metoclopropamide
iii. 56:92 GI Drugs, Miscellaneous
1. Certolizumab Pegol
2. Methylnaltrexone
9. 64:00 Heavy Metal Antagonists
1. Deferoxamine

10. 68:00 Hormones and Synthetic Substitutes
i. 68:18 Gonadotropins
1. Follitropin-alpha
2. Follitropin-beta
3. Gonadotropin-chorionic
4. Gonadotropin-chorionic-alfa
5. Gonadotropin-human
6. Lutropin-alfa
7. Menotropins
8. Urofollitropin
ii. 68:20 Antidiabetic Agents

5. Triptorelin acetate
6. Rituximab

3. 12:00 Autonomic Drugs
i. 12:08.08 Antimuscarinic Antispasmodics
1. Atropine
ii. 12:12 Sympathomimetic (Adrenergic) Agents
A. 12:12.12 Alpha- and Beta-Adrenergic Agonists
1. Scopolamine
2. Hyoscine
3. Glycopyrrolate
4. Epinephrine
iii. 12:16 Sympatholytic (Adrenergic Blocking) Agents
1. Dihydroergotamine
4. 20:00 Blood Formation and Coagulation
i. ~~20:04 Antianemia Drugs~~
~~A. 20:04.04 Iron Preparations~~
~~1. Iron~~
i. . 20:12 Coagulants and Anticoagulants
A. 20:12.04 Anticoagulants
1. Dalteparin
2. Danaparoid
3. Enoxaparin
4. Fondaparinux
5. Heparin
6. Nadroparin
7. Tinzaparin

i. 48:92 Respiratory Tract Agents, Miscellaneous

10. 56:00 Gastrointestinal Drugs
i. 56:22 Antiemetics
ii. 56:32 Prokinetic Agents
iii. 56:92 GI Drugs, Miscellaneous
11. 64:00 Heavy Metal Antagonists
12. 68:00 Hormones and Synthetic Substitutes
i. 68:04 Adrenals
ii. 68:08 Androgens
iii. 68:18 Gonadotropins
iv. 68:20 Antidiabetic Agents
v. 68:22 Antihypoglycemic Agents
vi. 68:24 Parathyroid
vii. 68:28 Pituitary
viii. 68:29:04 Somatostatin Agonists

1. Exenatide
2. Insulins
3. Liraglutide

iii. 68:22 Antihypoglycemic Agents
A. 68:22:12 Glycogenolytic Agents
1. Glucagon

iv. 68:24 Parathyroid
1. Calcitonin Salmon
2. Teriparatide

v. 68:28 Pituitary
1. Desmopressin
2. Vasopressin

vi. 68:30 Somatotropin Agonists and Antagonists
A. 68:30.04 Somatotropin Agonists
1. Somatropin
B. 68:30.08 Somatotropin Antagonists
1. Pegvisomant

vii. 68:32 Progestins
1. Medroxyprogesterone

11. 88:00 Vitamins
i. 88:08 Vitamin B Complex
1. Cyanocobalamin
2. Folic Acid
3. Methylcobalamin
4. Pyridoxine
5. Thiamine

ii. 88:12 Vitamin C
1. Ascorbic Acid

iii. 88:24 Vitamin K Activity
1. Vitamin K

12. 92:00 Miscellaneous Therapeutic Agents
i. 92:12 Antidotes

ii. 20:16 Hematopoietic Agents
1. Ancestim
2. Darbepoetin alfa
3. Epoetin alfa
4. Filgrastim
5. Pegfilgrastim
6. Romiplostim

iii. 20:28.92 Antihemorrhagic Agents, Miscellaneous
1. Emicizumab

5. 24:00 Cardiovascular Drugs
i. 24:06.24 Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors
1. Alirocumab
2. Evolocumab

6. 28:00 Central Nervous System Agents
i. 28:08 Analgesics and Antipyretics
A. 28:08.08 Opiate Agonists
1. Codeine
2. Hydromorphone
3. ~~Meperidine~~
4. Morphine

B. 28:08.12 Opiate Partial Agonists
1. Nalbuphine
2. Pentazocine

ii. 28:10 Opiate Antagonists
1. Naloxone

iii. 28:16 Psychotherapeutic Agents

ix. 68:30 Somatotropin Agonists and Antagonists

x. 68:32 Progestins
3. Medroxyprogesterone
4. Progesterone

xi. 68:36:04 Thyroid Agents

13. 72:00 Local Anesthetics

14. 84:92 Misc. Skin and Mucous Membrane Agents

15. 88:00 Vitamins
i. 88:08 Vitamin B Complex

ii. 88:12 Vitamin C

iii. 88:24 Vitamin K Activity

16. 92:00 Miscellaneous Therapeutic Agents
~~i. 92:12 Antidotes~~

i. 92:20 Biologic Response Modifiers

ii. 92:32 Complement Inhibitors

iii. 92:36 Disease-modifying Antirheumatic Drugs

1. Leucovorin ii. 92:20 Biologic Response Modifiers 1. Denosumab 2. Glatiramer 3. Interferon-Beta-1A 4. Interferon-Beta-1B 5. Natalizumab iii. 92:36 Disease-modifying Antirheumatic Drugs 1. Abatacept 2. Adalimumab 3. Anakinra 4. Etanercept 5. Gold Sodium Thiomalate 6. Golimumab 7. Ustekinumab iv. 92:40 Gonadotropin- releasing Hormone Antagonists 1. Cetrorelix 2. Ganirelix v. 92:92 Other Miscellaneous Therapeutic Agents 1. Octreotide 13. Miscellaneous 1. Sterile Water for Injection (Diluent)	A. 28:16.08 Antipsychotics 1. Haloperidol 2. Methotrimeprazine 3. Aripiprazole 4. Flupentixol 5. Methotrimeprazine 6. Paliperidone 7. Risperidone 8. Zuclopenthixol 9. Fluphenazine 10. Olanzapine iv. 28:24.08 Benzodiazepines 1. Lorazepam 2. Diazepam 3. Midazolam v. 28:32 Antimigraine Agents A. 28:32:12 Calcitonin-Gene-Related Peptide (CGRP) Antagonists 1. Erenumab B. 28:32.28 Selective Serotonin Agonists 1. Sumatriptan vi. 28.36 Antiparkinsonian Agents A. 28:36.20.08 Nonergot-derivative Dopamine Receptor Agonists 1. Apomorphine	iv. 92:40 Gonadotropin- releasing Hormone Antagonists v. 92:44 Immunosuppressive Agents vi. 92:92 Other Miscellaneous Therapeutic Agents 17. Miscellaneous

	B. 28:36.08 Anticholinergic Agents 1. Benztropine vii. 28:92 Miscellaneous Central Nervous System Agents 1. Inotersen 7. 40:00 Electrolytic, Caloric, and Water Balance i. 40:12 Replacement Preparations 1. Normal saline 8. 44:00 Enzymes 1. Asfotase Alfa 9. 48:00 Respiratory Tract Agents i. 48:92 Respiratory Tract Agents, Miscellaneous 1. Omalizumab 2. Benralizumab 10. 56:00 Gastrointestinal Drugs i. 56:22 Antiemetics A. 56:22.08 Antihistamines 1. Dimenhydrinate ~~2. Prochlorperazine~~ ii. 56:32 Prokinetic Agents 1. Metoclopropamide iii. 56:92 GI Drugs, Miscellaneous 1. Certolizumab Pegol 2. Methylnaltrexone 11. 64:00 Heavy Metal Antagonists 1. Deferoxamine 12. 68:00 Hormones and Synthetic Substitutes i. 68:04 Adrenals	

	1. Betamethasone 2. Tetracosactide 3. Hydrocortisone 4. Dexamethasone 5. Prednisolone 6. Methylprednisolone ii. 68:08 Androgens 1. Testosterone iii. 68:18 Gonadotropins 1. Follitropin-alpha 2. Follitropin-beta 3. Follitropin-delta 4. Gonadotropin-chorionic 5. Gonadotropin-chorionic-alfa 6. Gonadotropin-human 7. Lutropin-alfa 8. Menotropins 9. ~~Urofollitropin~~ iv. 68:20 Antidiabetic Agents 1. Exenatide 2. Insulins 3. Liraglutide 4. Dulaglutide 5. Lixisenatide 6. Semaglutide v. 68:22 Antihypoglycemic Agents A. 68:22:12 Glycogenolytic Agents 1. Glucagon	

	vi. 68:24 Parathyroid 1. Calcitonin Salmon 2. Teriparatide vii. 68:28 Pituitary 1. Desmopressin 2. Vasopressin viii. 68:29:04 Somatostatin Agonists 1. Pasireotide ix. 68:30 Somatotropin Agonists and Antagonists A. 68:30.04 Somatotropin Agonists 1. Somatropin 2. Tesamorelin B. 68:30.08 Somatotropin Antagonists 1. Pegvisomant x. 68:32 Progestins 1. Medroxyprogesterone 2. Progesterone xi. 68:36:04 Thyroid Agents 1. Levothyroxine 13. 72:00 Local Anesthetics 1. Lidocaine 2. Prilocaine 3. Articaine 4. Bupivacaine 5. Mepivacaine	

	14. 84:92 Misc. Skin and Mucous Membrane Agents 1. Brodalumab 2. Dupilumab 3, Guselkumab 4. Ixekizumab 5. Risankizumab 6. Secukinumab 15. 88:00 Vitamins i. 88:08 Vitamin B Complex 1. Cyanocobalamin 2. Folic Acid ~~3. Methylcobalamin~~ 4. Pyridoxine 5. Thiamine ii. 88:12 Vitamin C 1. Ascorbic Acid iii. 88:24 Vitamin K Activity 1. Vitamin K 16. 92:00 Miscellaneous Therapeutic Agents ~~i. 92:12 Antidotes~~ 1. ~~Leucovorin~~ i. 92:20 Biologic Response Modifiers 1. Denosumab 2. Glatiramer 3. Interferon-Beta-1A 4. Interferon-Beta-1B ~~5. Natalizumab~~ ii. 92:32 Complement Inhibitors	

	1. Icatibant 2. Lanadelumab iii. 92:36 Disease-modifying Antirheumatic Drugs 1. Abatacept 2. Adalimumab 3. Anakinra 4. Etanercept ~~5. Gold Sodium Thiomalate~~ 6. Golimumab 7. Ustekinumab 8. Sarilumab 9. Tocilizumab iv. 92:40 Gonadotropin- releasing Hormone Antagonists 1. Cetrorelix 2. Ganirelix v. 92:44 Immunosuppressive Agents 1. Belimumab 2. Mepolizumab vi. 92:92 Other Miscellaneous Therapeutic Agents 7. Octreotide 8. Lanreotide 17. Miscellaneous 1. Sterile Water for Injection (Diluent)	

DRAFT General Regulation 202/94
Clause by Clause Comparison

Existing Clause	Proposed New Clause (List)	Proposed New Clause (Categories)
SCHEDULE II INHALED SUBSTANCES		
SCHEDULE 2 INHALED SUBSTANCES (Arranged by American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification) 1. 8:00 Anti-infective Agents i. 8:18 Antivirals A. 8:18.28 Neuraminidase Inhibitors 1. Zanamivir ii. 8:12 Antibacterials A. 8:12.07.16 Monobactams 1. Tobramycin 2. Aztreonam 2. 12:00 Autonomic Drugs i. 12:08 Anticholinergic Agents A. 12:12.08 Antimuscarinics/Antispasmodics 1. Ipratropium 2. Tiotropium ii. 12:12 Sympathomimetic (Adrenergic) Agents A. 12:12.08.12 Selective Beta2- Adrenergic Agonists 1. Fenoterol	SCHEDULE 2 INHALED SUBSTANCES (Arranged by American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification) 1.8:00 Anti-infective Agents i. 8:18 Antivirals A. 8:18.28 Neuraminidase Inhibitors 1. Zanamivir ii. 8:12 Antibacterials A. 8:12.07.16 Monobactams 1. Tobramycin 2. Aztreonam B. 8:12.18 Quinolones 1. Levofloxacin 2. 12:00 Autonomic Drugs i. 12:08 Anticholinergic Agents A. 12:08.08 Antimuscarinics/Antispasmodics 1. Ipratropium 2. Tiotropium 3. Umeclidinium 4. Aclidinium	SCHEDULE 2 INHALED SUBSTANCES (Arranged by American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification) 1. 8:00 Anti-infective Agents i. 8:18 Antivirals ii. 8:12 Antibacterials 2. 12:00 Autonomic Drugs i. 12:08 Anticholinergic Agents ii. 12:12 Sympathomimetic (Adrenergic) Agents iii. 12:16 Sympatholytic (Adrenergic Blocking) Agents iv. 12:92 Autonomic Drugs, Miscellaneous 3. 28:00 Central Nervous System Agents i. 28:08 Analgesics and Antipyretics

2. Formoterol 3. Salbutamol 4. Salmeterol 5. Terbutaline iii. 12:16 Sympatholytic (Adrenergic Blocking) Agents A. 12:16.04.04 Non-Selective alpha-Adrenergic Blocking Agents 1. Dihyroergotamine iv. 12:92 Autonomic Drugs, Miscellaneous 1. Nicotine 3. 28:00 Central Nervous System Agents i. 28:08 Analgesics and Antipyretics A. 28:08.12 Opiate Partial Agonists 1. Butorphanol ii. 28:32 Antimigraine Agents A. 28:32.28 Selective Serotonin Agonists 1. Sumatriptan 2. Zolmitriptan 4. 40:00 Electrolytic, Caloric, and Water Balance i. 40:12 Replacement Preparations 1. Sodium chloride 5. 48:00 Respiratory Tract Agents i. 48:24 Mucolytic Agents 1. Dornase alfa 6. 52:00 Eye, Ear, Nose and Throat (EENT) Preparations i. 52:02 Antiallergic Agents 1. Sodium Cromoglycate	ii. 12:12 Sympathomimetic (Adrenergic) Agents A. 12:12.08.12 Selective Beta2-Adrenergic Agonists ~~1. Fenoterol~~ 2. Formoterol 3. Salbutamol 4. Salmeterol 5. Terbutaline 6. Vilanterol 7. Indacaterol 8. Olodaterol iii. 12:16 Sympatholytic (Adrenergic Blocking) Agents A. 12:16.04.04 Non-Selective alpha-Adrenergic Blocking Agents 1. Dihyroergotamine iv. 12:92 Autonomic Drugs, Miscellaneous 1. Nicotine 3. 28:00 Central Nervous System Agents i. 28:08 Analgesics and Antipyretics A. 28:08.12 Opiate Partial Agonists 1. Butorphanol ii. 28:32 Antimigraine Agents A. 28:32.28 Selective Serotonin Agonists 1. Sumatriptan 2. Zolmitriptan	ii. 28:32 Antimigraine Agents 4. 40:00 Electrolytic, Caloric, and Water Balance i. 40:12 Replacement Preparations 5. 48:00 Respiratory Tract Agents i. 48:12.08 Anticholinergic Agents ii. 48:24 Mucolytic Agents 6. 52:00 Eye, Ear, Nose and Throat (EENT) Preparations i. 52:02 Antiallergic Agents ii. 52:08 Anti-inflammatory Agents iii. 52:32 Vasoconstrictors 7. 68:00 Hormones and Synthetic Substitutes i. 68:18 Gonadotropins ~~ii. 68:24 Parathyroid~~ ii. 68:28 Pituitary 8. 92:00 Miscellaneous Therapeutic Agents i. 92:12 Antidotes 1. Acetylcysteine

2. Levocabastine ii. 52:08 Anti-inflammatory Agents A. 52:08.08 Corticosteroids 1. Beclomethasone 2. Budesonide 3. Ciclesonide 4. Flunisolide 5. Fluticasone 6. Mometasone 7. Triamcinolone iii. 52:32 Vasoconstrictors 1. Oxymetazoline 2. Phenylephrine 3. Xylometazoline 7. 68:00 Hormones and Synthetic Substitutes i. 68:18 Gonadotropins 1. Buserelin 2. Nafarelin ii. 68:24 Parathyroid 1. Calcitonin Salmon iii. 68:28 Pituitary 1. Desmopressin 2. Vasopressin 8. 92:00 Miscellaneous Therapeutic Agents i. 92:12 Antidotes 1. Acetylcysteine	4. 40:00 Electrolytic, Caloric, and Water Balance i. 40:12 Replacement Preparations 1. Sodium chloride 5. 48:00 Respiratory Tract Agents i. 48:12.08 Anticholinergic Agents 1. Glycopyrronium ii. 48:24 Mucolytic Agents 1. Dornase alfa 6. 52:00 Eye, Ear, Nose and Throat (EENT) Preparations i. 52:02 Antiallergic Agents 1. Sodium Cromoglycate 2. Levocabastine ii. 52:08 Anti-inflammatory Agents A. 52:08.08 Corticosteroids 1. Beclomethasone 2. Budesonide 3. Ciclesonide 4. Flunisolide 5. Fluticasone 6. Mometasone 7. Triamcinolone iii. 52:32 Vasoconstrictors 1. Oxymetazoline 2. Phenylephrine 3. Xylometazoline 7. 68:00 Hormones and Synthetic Substitutes i. 68:18 Gonadotropins	.

	1. Buserelin 2. Nafarelin ii. 68:24 Parathyroid 1. Calcitonin Salmon iii. 68:28 Pituitary 1. Desmopressin 2. Vasopressin 8. 92:00 Miscellaneous Therapeutic Agents i. 92:12 Antidotes 1. Acetylcysteine .	