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Drug and Pharmacies Regulation Act **Ontario Regulation 58/11** **General**	**Drug and Pharmacies Regulation Act, 1990** **O. Reg. 58/11**	In considering the current approach to the amendment of Ontario Regulation 58/11, the College chose to align the amendments to the requirements outlined in the Ontario Government's Regulatory Policy. The proposed regulations are high-level and outcomes-based, and set the standards and objectives that must be met by pharmacy operators. It is intended that this oversight will be supported by policies, standards and guidelines which will define specific expectations where necessary. It is intended that this model will provide flexibility in regulatory control and in turn encourage practice innovation without unduly diluting or complicating enforcement capabilities. The new regulations will rationalize the oversight of practice across various practice settings and codify the College's role in inspection/site visits as a mechanism for raising the practice standards over time as well as fulfilling the need to ensure minimum standards are being upheld. Council approved the proposed regulations in March 2015 for consultation and circulation to members for feedback.
Part 1 **Interpretation**	**Part I** **Interpretation**	
Interpretation **1.** (1) In this Regulation, "automated pharmacy system" means a mechanical system that performs operations or activities with respect to the storage and packaging of drugs or medications, and with respect to their dispensing or distribution directly to patients;	**Interpretation** 1. (1) In this Regulation, "automated pharmacy system" means a mechanical system that performs operations or activities with respect to the storage and packaging of drugs or medications, and with respect to their dispensing or distribution directly to patients;	The definitions have been updated as required to reflect the addition of hospital pharmacies.

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“computer system” means a system to electronically create, record, store, retrieve and process data and includes any hardware and software required to permit the computer to perform appropriately		
“controlled drug” means a substance set out in the Schedule to Part G of the *Food and Drug Regulations* under the *Food and Drugs Act* (Canada) and includes a substance that contains one or more controlled drugs and one or more medicinal ingredients in a recognized therapeutic dose that are not controlled drugs;	“controlled drug” means a substance set out in the Schedule to Part G of the Food and Drug Regulations under the Food and Drugs Act (Canada) and includes a substance that contains one or more controlled drugs and one or more medicinal ingredients in a recognized therapeutic dose that are not controlled drugs;	
“dispensary” means the area of a pharmacy where drugs are stored and prepared for dispensing and distribution and to which the public has no access, but does not include an automated pharmacy system;	“dispensary” means the area of a pharmacy, that is accredited as a community pharmacy, where drugs are stored and prepared for dispensing and distribution and to which the public has no access, but does not include an automated pharmacy system;	The phrase ‘accredited as a community pharmacy’ was added as only a community pharmacy contains a dispensary as defined in this regulation and to differentiate from the many areas in a hospital from which drugs are stored and to which the public has no access.
“document” includes a prescription, record and report;	“document” includes a prescription, record and report;	
“electronic document” means data that is created, recorded or stored on any medium in or by a computer system and that can be read or received by a person or a computer system;		The definitions of electronic document and signature are removed and addressed within the context of the standards of accreditation. A pharmacy is required to have an information management system that delivers the specified outcomes.
“electronic signature” means electronic information that a person creates or adopts in order to sign a document and that is in, attached to or associated with the document;		
“holder of the certificate” means the person to whom a certificate of accreditation has been issued;	“holder of the certificate” means the person to whom a certificate of accreditation has been issued;	
“Manual” means the manual published by the National Association of Pharmacy Regulatory Authorities entitled “Canada’s National Drug Scheduling System” and dated	“National Drug Schedules” means the National Drug Schedules that are part of the National Drug Scheduling	Updated to include current language at the Federal level.

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September 25, 1998, as that manual is amended from time to time;	System published by the National Association of Pharmacy Regulatory Authorities, as those Schedules are amended from time to time;	
"medications" means drugs and other substances usually maintained in the dispensary including substances used in the compounding of drugs;	"medications" means drugs and other substances usually maintained in a pharmacy, including substances used in the compounding of drugs;	Broadened the definition to capture the drugs and other substances kept in the pharmacy, not just the dispensary
"narcotic drug" means a substance referred to in the Schedule to the *Narcotic Control Regulations* under the *Controlled Drugs and Substances Act* (Canada) or anything that contains any substance set out in that Schedule;	"narcotic drug" means a substance referred to in the Schedule to the Narcotic Control Regulations under the Controlled Drugs and Substances Act (Canada) or anything that contains any substance set out in that Schedule;	
	"owner" means any person or persons who own the pharmacy, and where the owner is or includes a corporation, includes each director of the corporation.	In the revised regulations, the definition of owner has been moved forward from **s.16** "Qualifications for Renewal" to the **Interpretation** section, and simplified.
	"Symbol" means the College's trademarked symbol in its unaltered form and any other trademarks that may be developed and adopted from time to time by the College;	The current regulation addresses this concept in **s. 26** "Point of care". Moved forward to the **Interpretation** section and the term 'symbol' is now used where relevant as it is a more generic term and allows for updating the actual trademark.
	"Prescription Drug List" means the list established under section 29.1 of the Food and Drugs Act (Canada), as amended from time to time;	Updated to include current language at the Federal level.
"sell" includes offer for sale, expose for sale, have in possession for sale, and distribute, whether or not the distribution is for consideration;	"sell" includes offer for sale, expose for sale, have in possession for sale, and distribute, whether or not the distribution is for consideration;	Definition did not change. It was considered that the term "sell" is also used in relation to hospital pharmacy where retail sales are not permitted but where unfunded cancer drugs may be offered to patients, at cost, in addition to a small fee for administration.
"signature" includes an electronic signature, and "signed" includes signed by an electronic signature;		

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“targeted substance” means, (a) a substance that is included in Schedule I of the *Benzodiazepines and Other Targeted Substances Regulation* under the *Controlled Drugs and Substances Act* (Canada), or (b) a product or compound that contains a substance that is included in Schedule I of the *Benzodiazepines and Other Targeted Substances Regulation* under the *Controlled Drugs and Substances Act* (Canada); “verbal prescription narcotic” means a substance, (a) that contains one narcotic drug, (b) that also contains, in a recognized therapeutic dose, two or more medicinal ingredients that are not narcotic drugs, (c) that is not intended for parenteral administration, and (d) that does not contain diacetylmorphine (heroin), hydrocodone, methadone, oxycodone or pentazocine. O. Reg. 58/11, s. 1 (1). (2) Where, in this Regulation, an obligation is placed on a pharmacy, or anything is described as being done by a pharmacy, operated by a pharmacy or held by a pharmacy, the reference extends, as the context requires, to apply to the holder of the certificate with respect to the pharmacy, the designated manager of the pharmacy, and the directors of the holder of the certificate if the holder of the certificate is a corporation. O. Reg. 58/11, s. 1 (2).	“targeted substance” means a targeted substance as defined in the *Benzodiazepines and Other Targeted Substances Regulation* under the *Controlled Drugs and Substances Act* (Canada); (2) In this Regulation, unless the context provides otherwise, reference to a “pharmacy” includes a hospital pharmacy.	All requirements generally indicated for a pharmacy are also indicated for a hospital pharmacy, unless otherwise specified.
“Remote dispensing location” **2.** For purposes of the Act and this Regulation, “remote dispensing location” means a premises where drugs are dispensed or sold by retail to the public and that is operated by, but is not at the same location as, a pharmacy whose certificate of accreditation permits its operation. O. Reg. 58/11,	**“Remote dispensing location”** 2 For purposes of the Act and this Regulation, “remote dispensing location” means: (a) in a pharmacy that is accredited as a community pharmacy, a place where drugs are dispensed or	Given the broad definition of hospital pharmacy in Bill 21, the College considered the necessity to define remote dispensing location (RDL) according to location.

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s. 2.	sold by retail to the public under the supervision of a pharmacist who is not physically present; and (b) in a pharmacy that is accredited as a hospital pharmacy, a place where drugs are dispensed or supplied to patients of the hospital under the supervision of a pharmacist who is not physically present.	In the context of the Act (**s.119**) 'supply' includes selling or giving drugs to a patient, including an outpatient. Also permits a RDL in a satellite location. A hospital that wishes to sell drugs by retail to the general public is required to apply for a certificate of accreditation as a community pharmacy.
PART II **DRUG SCHEDULES**	**PART II** **DRUG SCHEDULES**	The revision to **Part II** addresses all provisions dealing with drugs, including drug schedules, the location of scheduled drugs in the pharmacy, and transferring prescriptions.
Schedules and special cases **3.** (1) Schedules I, II, III and U are established for the purposes of the Act. O. Reg. 58/11, s. 3 (1). (2) The following substances are prescribed as being included in Schedule I for the purposes of the Act: 1. The substances listed in Schedule I of the Manual. 2. The substances listed in Parts I and II of Schedule F to the *Food and Drug Regulations* under the *Food and Drugs Act* (Canada). 3. The substances listed in Schedules I, II, III, IV, V, VI, VII and VIII of the *Controlled Drugs and Substances Act* (Canada). O. Reg. 58/11, s. 3 (2). (3) The substances listed in Schedule II of the Manual are prescribed as being included in Schedule II for the purposes of the Act. O. Reg. 58/11, s. 3 (3). (4) The substances listed in Schedule III of the Manual are prescribed as being included in Schedule III for the purposes of	**Drug schedules** **3.** (1) Schedules I, II, III and U are established for the purposes of the Act. (2) The following substances are prescribed as being included in Schedule I for the purposes of the Act: 1. The substances listed in Schedule I of the National Drug Schedules. 2. The substances listed in the Prescription Drug List. 3. The substances listed in the Schedules to the *Controlled Drugs and Substances Act* (Canada). (3) The substances listed in Schedule II of the National Drug Schedules are prescribed as being included in Schedule II for the purposes of the Act. (4) The substances listed in Schedule III of the National Drug Schedules are prescribed as being included in Schedule III for	The College has the authority to establish drug schedules: DPRA **s. 161. (1) (a)** The proposed changes update provisions to align to federal legislation regarding the National Drug Schedules and Prescription Drug List. Changes to the Food and Drugs Act (*FDA)* were included as part of Bill C-38 (*Jobs, Growth and Long-term Prosperity Act*), that gave the federal Minister of Health the power to establish a list that sets out prescription drugs or classes of prescription drugs and to provide that the list may be incorporated by reference to be made part of the regulations. Updates to the *FDA* regulations were required to bring these changes into force. Effective December 19, 2013, Schedule F to the *FDA* regulations was repealed and replaced by a list of prescription drugs called the Prescription Drug List (PDL). Therefore, all drugs previously listed in Schedule F (F1 and F2) are now on the PDL. The intent of the federal amendments is to replace the previous

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the Act. O. Reg. 58/11, s. 3 (4). (5) The substances listed in the Unscheduled Category of the Manual are prescribed as being included in Schedule U for the purposes of the Act. O. Reg. 58/11, s. 3 (5). (6) The substances listed in Schedules A and B to this Regulation are not drugs for the purposes of the Act. O. Reg. 58/11, s. 3 (6). (7) Despite clause (f) of the definition of "drug" in subsection 1 (1) of the Act, any substance that is a natural health product containing pseudoephedrine or its salts, or ephedrine or its salts, or any combination of any of them, is a drug for the purposes of the Act. O. Reg. 58/11, s. 3 (7).	the purposes of the Act. (5) The substances listed in the Unscheduled Category of the National Drug Schedules are prescribed as being included in Schedule U for the purposes of the Act. (6) The substances listed in Schedules A and B to this Regulation are not drugs for the purposes of the Act. (7) Despite clause (f) of the definition of "drug" in subsection 1 (1) of the Act, any substance that is a natural health product containing pseudoephedrine or its salts, or ephedrine or its salts, or any combination of any of them, is a drug for the purposes of the Act.	regulatory process with a more efficient administrative process without compromising the established scientific review and consultation. Federal oversight of the Prescription Drug List is through C.R.C., c.870. **C.01.040.3, C.01.040.4 and C.01.040.5** (*Food and Drug Regulations*) Retains pseudoephedrine and ephedrine within the definition of 'drug' to protect against diversion and illicit use.
Schedule I, conditions on sale **4.** The following conditions apply to the sale in a pharmacy of a drug referred to in Schedule I: 1. Subject to paragraph 2, a pharmacist must be physically present in the pharmacy. 2. Where the drug is sold in a remote dispensing location, a pharmacist must be physically present either in the remote dispensing location or in the pharmacy that operates the remote dispensing location. 3. There must be a prescription for the drug. 4. The sale of the drug must be approved by a pharmacist. 5. Subject to paragraph 6, the drug shall only be available for sale from the dispensary. 6. Where the drug is sold in a remote dispensing location, the drug shall only be available for sale from the dispensary or from an automated pharmacy system. O. Reg. 58/11, s. 4; O.	**Location of Schedule I, II and III drugs** 4 In a pharmacy accredited as a community pharmacy, (a) Schedule I drugs shall only be available for sale from, 1. the dispensary, or 2. where sold in a remote dispensing location, the dispensary or an automated pharmacy system,	A drug can only be sold on prescription by a person authorized to do so (C.R.C., c. 870. **C.01.041. (1)**) (*Food and Drug Regulations*). For all Scheduled drugs: if a hospital wishes to offer drugs for sale by retail, the hospital would need to apply for a certificate of accreditation as a community pharmacy. The public interest is protected by ensuring that substances are categorized and located in the community pharmacy according to the risk they pose. The proposed regulations provide oversight for the operation of a pharmacy. They are high-level and outcomes-based, and set the standards and objectives that must be met by pharmacy operators. Statements that refer to clinical decision-making, such as approving a drug for sale, have been removed. Member practice is guided through the *Pharmacy Act and Regulations*, and professional ethics, standards of practice,

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Reg. 301/12, s. 1.		policies and guidelines. Any additional guidance required for members will be addressed through those documents.
	(b) Schedule II drugs shall only be available for sale from, (i) the dispensary or other area in the pharmacy to which the public does not have access and which does not permit self-selection of drugs by patients, or (ii) where sold in a remote dispensing location, the dispensary or an automated pharmacy system,	The wording on self-selection is from the NAPRA document *Supplemental Standards of Practice for Schedule II and III Drugs*. The standards clarify that schedule II drugs require professional intervention from the pharmacist at point of sale, and possibly referral to another practitioner.
	(c) Schedule III drugs shall only be available for sale from, (i) the dispensary or an area in the pharmacy that allows for self-selection of drugs by patients and where a member is available for consultation, or (ii) where sold in a remote dispensing location, an area in the remote dispensing location to which the public does not have access.	Removed the reference to “10 meters from the dispensary” as the availability of a member for consultation is the relevant outcome. The reference to ‘pharmacist or intern’ was changed to ‘member’, which will also permit this requirement to be fulfilled by a student under appropriate supervision, in accordance with the *Pharmacy Act*.
Schedule II, conditions on sale **5.** The following conditions apply to the sale in a pharmacy of a drug referred to in Schedule II: 1. Subject to paragraph 2, a pharmacist must be physically present in the pharmacy. 2. Where the drug is sold in a remote dispensing location, a pharmacist must be physically present either in the remote dispensing location or in the pharmacy that operates the remote dispensing location. 3. The sale of the drug must be approved by a pharmacist.		Addressed above within the context of the location of scheduled drugs in a community pharmacy.

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4. Subject to paragraph 5, the drug shall only be available for sale from the dispensary. 5. Where the drug is sold in a remote dispensing location, the drug shall only be available for sale from the dispensary or from an automated pharmacy system. O. Reg. 58/11, s. 5.		
Schedule III, conditions on sale **6.** The following conditions apply to the sale in a pharmacy of a drug referred to in Schedule III: 1. Subject to paragraph 2, a pharmacist must be physically present in the pharmacy. 2. Where the drug is sold in a remote dispensing location, a pharmacist must be physically present either in the remote dispensing location or in the pharmacy that operates the remote dispensing location. 3. A pharmacist or intern must be available for consultation with the patient. 4. Subject to paragraph 5, the drug shall only be available for sale in the pharmacy from the dispensary or from an area within 10 metres of the dispensary. 5. Where the drug is sold in a remote dispensing location, the drug shall only be available for sale from an automated pharmacy system, or from an area in the remote dispensing location to which the public does not have access. O. Reg. 58/11, s. 6.		Addressed above within the context of the location of scheduled drugs in a community pharmacy.
	Transferring prescriptions **5.** Subject to compliance with any other applicable federal or provincial laws, a prescription shall be transferred from a pharmacy that is accredited as a community pharmacy on the request of the patient or a person acting on behalf of the patient.	The provisions regarding prescription transfers have been moved forward from **Part VI**. In keeping with Ontario Regulatory Policy, the proposed language addresses the objective that must be met. The details regarding prescription transfers have been removed from the regulations to avoid duplication. The rules regarding prescription transfers are outlined in Federal legislation, which has recently been updated to include pharmacy technicians and

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		are outlined in a Fact Sheet on Prescription Transfers that provides greater detail and clarity. The Fact Sheet brings together references from Federal and Provincial legislation to present an up-to-date summary of the framework governing transfers, including the record-keeping required by both the transferring and receiving pharmacy. The Fact Sheet also addresses the conditions under which a prescription transfer is not permitted. Additional advice concerning misconceptions and best practices is also provided. By presenting the details in a College-drafted document, changes and updates regarding the expectations on pharmacies can be made very quickly to address changes in the governing legislation.
PART III **CERTIFICATES OF ACCREDITATION: ISSUANCE AND RENEWAL**	**PART III** **CERTIFICATES OF ACCREDITATION: ISSUANCE AND RENEWAL**	Two different types of documents will be created to support issuance and renewal: 1) policy documents, which define how the regulator will approach a situation; and 2) process documents, which contain the steps that must be taken to achieve a specific goal. It is intended that policies will be circulated for input by members and approved by Council, while process documents will address the administrative processes undertaken by staff members.
Definition **7.** In this Part, "applicant" means each proposed owner of the pharmacy and, where any proposed owner is, (a) a corporation, other than a non-profit corporation referred to in subsection 142 (5) of the Act, includes each officer and director of the corporation and each shareholder of the	**Definition** 6 In this Part, "applicant" means each proposed owner of the pharmacy.	The model for the issuance and renewal of certificates of accreditation has not changed. The Registrar and Accreditation Committee continue to have the authority to refuse to issue and/or renew certificates for a variety of reasons, including where there is reason to believe, based on past or continuing

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corporation who is a member, if that member owns, directly or indirectly, five per cent or more of the voting shares of the corporation, (b) a non-profit corporation as referred to in subsection 142 (5) of the Act, includes each officer and director of that corporation. O. Reg. 58/11, s. 7.		pharmacy performance, that the pharmacy will not be operated in accordance with the required laws.
	Classes of accreditation 7 a.The following classes of accreditation are hereby established: (a) community pharmacy; and (b) hospital pharmacy. b. A pharmacy that holds a certificate of accreditation to operate a pharmacy as of the date this Regulation comes into force is deemed to be accredited as a community pharmacy.	The Regulations will address community and hospital pharmacies as separate classes. Most provisions will apply to both classes; however, when necessary it will be stated when a provision is relevant to one class or another. The College does not anticipate the establishment of specific sub-classes of accreditation within broad classes; however, specialty practices such as sterile compounding or methadone dispensing will be managed through the requirement to meet standards, or through policy.
Qualifications for the issuance of a certificate of accreditation **8.** (1) Subject to section 9, a person is qualified for the issuance of a certificate of accreditation to establish and operate a pharmacy if all of the following requirements are met: 1. A completed application in the form required by the College has been filed with the College, along with the required application fee. 2. The fees required to be paid for the issuance of a certificate of accreditation have been submitted to the College. 3. Where requested by the Registrar or the Accreditation	**Qualifications for the issuance of a certificate of accreditation of any class** **8.** (1) An applicant is qualified for the issuance of a certificate of accreditation to establish and operate a pharmacy of any class if: 1. The applicant files a completed application in the form required by the College and pays the required fees. 2. The applicant provides further information to the College if requested by the Registrar or the Accreditation Committee. 3. All information provided by the applicant to the	Authority DPRA **s. 139. (1)**. The intention in redrafting these qualifications is to reduce duplication, combine provisions, simplify and ensure flexibility while retaining the ability to enforce. A declaration of good character is required to be completed on application. The College's website provides a significant amount of information on opening and operating a pharmacy, along with information on purchasing, relocating, renovating and closing a pharmacy.

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Committee, an applicant has provided full and complete information to the College relating to, i. any currently outstanding charge in relation to an offence under any Act regulating the practice of pharmacy or relating to the sale of drugs, ii. any currently outstanding charge relating to any criminal offence, iii. any finding of guilt in relation to an offence under any Act relating to the practice of pharmacy or relating to the sale of drugs, iv. any finding of guilt in relation to any criminal offence, v. any outstanding proceeding, whether in Ontario or another jurisdiction, in which the applicant is alleged to have committed an act of professional misconduct or to be incompetent, or in which similar allegations have been made, vi. any completed proceeding, whether in Ontario or another jurisdiction, in which the applicant was alleged to have committed an act of professional misconduct or to be incompetent, or in which similar allegations were made, and a finding of misconduct or incompetence or a similar finding has been made, vii. any proceeding, whether in Ontario or another jurisdiction, in which the applicant was alleged to have committed an act of professional misconduct or to be incompetent, or in which similar allegations were made, and the allegation was withdrawn, except where the withdrawal was unconditional, viii. any outstanding proceeding where any allegation of improper business practice was made against the applicant in any jurisdiction, whether in relation to the operation of a pharmacy or any other regulated profession or business, and ix. any completed proceeding where any allegation of improper business practice was made against the applicant whether in relation to the operation of a pharmacy or any other regulated profession or business, other than a proceeding	College is full, accurate and complete. 4. The past and present conduct of each person who is an applicant, and in the case of a corporation, of each director, and of each shareholder who directly or indirectly owns five percent or more of the voting shares of that corporation, affords reasonable grounds for the belief that the pharmacy will be operated with decency, honesty and integrity and in accordance with the law. (2) It is a condition for the issuance of a certificate of accreditation that the Registrar or the Accreditation Committee be satisfied that the pharmacy meets the applicable standards for accreditation.	Policy development will be undertaken to provide additional information, if any, outlining the circumstances in which an inspection is required prior to issuance and to address the requirement for continuous quality improvement activities. Standards are outlined in **Part IV**.

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completed on its merits in which the applicant was found not to have engaged in any improper business practice. 4. Where requested by the Registrar or the Accreditation Committee, an applicant has provided additional information sufficient to determine whether a certificate of accreditation should be issued. 5. The past and present conduct of each person who is an applicant affords reasonable grounds for the belief that the pharmacy will be operated with decency, honesty and integrity and in accordance with the law. O. Reg. 58/11, s. 8 (1). (2) Subject to subsection (3), it is a condition for the issuance of a certificate of accreditation that the Registrar or the Accreditation Committee be satisfied that the pharmacy meets the standards for accreditation as referred to in subsection 20 (1). O. Reg. 58/11, s. 8 (2). (3) The Registrar may issue a certificate of accreditation in respect of a pharmacy which does not meet the requirements of clause 21 (3) (k) if the Registrar has received reasonable assurances that the required equipment will be obtained by the pharmacy within a reasonable period of time after issuance of the certificate of accreditation. O. Reg. 58/11, s. 8 (3). (4) Where the Registrar uses the authority of subsection (3), the Registrar shall ensure that an inspection is made of the pharmacy within a reasonable period of time to verify the presence of the equipment which was not in place at the time the certificate of accreditation was issued. O. Reg. 58/11, s. 8 (4).		

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Additional requirements, remote dispensing location **9.** (1) A person is qualified for the issuance of a certificate of accreditation to establish and operate a pharmacy that permits the operation of remote dispensing locations if all of the following requirements, in addition to those set out in section 8, are met: 1. The additional fees required to be paid for the issuance of a certificate of accreditation that permits the operation of remote dispensing locations have been submitted to the College. 2. Where requested by the Registrar or the Accreditation Committee, an applicant has provided additional information sufficient to determine whether permission to operate remote dispensing locations should be granted. 3. There are reasonable grounds for the belief that the pharmacy will be able to supervise all aspects of the operation of the proposed remote dispensing locations, properly and effectively. O. Reg. 58/11, s. 9 (1). (2) It is an additional condition for the issuance of a certificate of accreditation that permits the operation of remote dispensing locations that the Registrar or the Accreditation Committee be satisfied that each remote dispensing location meets the additional standards for accreditation as referred to in subsection 20 (3). O. Reg. 58/11, s. 9 (2).	**Additional requirements, remote dispensing location** **9.** An applicant is qualified for the issuance of a certificate of accreditation to establish and operate a pharmacy of any class that permits the operation of remote dispensing locations if, in addition to the requirements set out in section 8, there are reasonable grounds for the belief that the applicant will be able to supervise all aspects of the operation of the proposed remote dispensing locations properly and effectively.	This ensures that remote dispensing locations continue to be linked to an accredited pharmacy to ensure clear lines of accountability. The proposed regulations clarify that all standards of accreditation that apply to a pharmacy, apply to a remote dispensing location unless otherwise specified. By adopting this approach, a significant amount of duplication was removed from the proposed regulations. The specific provisions that apply to remote dispensing ,which are not addressed elsewhere, are retained.
Deemed reasonable grounds for belief **10.** For the purposes of paragraph 5 of subsection 8 (1), and without limiting its generality, there shall be deemed to be reasonable grounds for the belief that the pharmacy will not be operated with decency, honesty and integrity and in accordance with the law where any one or more of the	**Deemed reasonable grounds for belief** **10.** For the purposes of paragraph 4 of subsection 8 (1), and without limiting its generality, there shall be deemed to be reasonable grounds for the belief that the pharmacy will not be operated with decency, honesty and integrity and in accordance with the law where any one or more of the	

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following has occurred: 1. An applicant made a false or misleading statement or representation in the application or in any information provided to the College in respect of the application. 2. An applicant failed or refused to provide information requested under paragraph 3 or 4 of subsection 8 (1). O. Reg. 58/11, s. 10.	following has occurred: 1. A false or misleading statement or representation was made in the application or in any information provided to the College in respect of the application. 2. There was a failure or refusal to provide information requested under paragraph 2 of subsection 8 (1).	Removed reference to 'the applicant' which is addressed above in **s. 8 (1) 4** and not required to be duplicated here.
Issuance, name and address **11.** A certificate of accreditation shall be issued in the specific name of the owner of the pharmacy and for the specific municipal address at which the pharmacy is to be operated. O. Reg. 58/11, s. 11.	**Issuance, name and address** 11. (1) A certificate of accreditation shall be issued in the specific name of the person who owns the pharmacy and for the specific municipal address or addresses at which the pharmacy is to be operated. b. A certificate of accreditation that permits the operation of remote dispensing locations shall specify the locations of the permitted remote dispensing locations.	The By-law requires notification of change of address or ownership
Amendment for remote dispensing locations **12.** (1) A pharmacy whose certificate of accreditation does not permit the operation of remote dispensing locations may apply for an amended certificate of accreditation that permits the operation of remote dispensing locations. O. Reg. 58/11, s. 12 (1). (2) A pharmacy whose certificate of accreditation permits the operation of remote dispensing locations may apply for an amended certificate of accreditation that permits the operation of additional remote dispensing locations. O. Reg. 58/11, s. 12 (2). (3) A pharmacy that applies under this section is qualified for the issuance of an amended certificate of accreditation if the requirements set out in subsections 8 (1) and 9 (1) are met, and	**Amendment** 12. If an owner wishes to: (a) operate a remote dispensing location where the certificate of accreditation does not already permit the operation of remote dispensing locations, or (b) operate a remote dispensing location at a location other than the location specified on the certificate of accreditation, the owner shall apply for an amended certificate of accreditation.	**s. 139(1)** of the Act requires a person to have a certificate of accreditation to operate a pharmacy, including a remote dispensing location. The section is simplified by combining provisions and removing duplication.

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the conditions set out in subsections 8 (2) and 9 (2) apply to the issuance of an amended certificate of accreditation under this section. O. Reg. 58/11, s. 12 (3).		
Remote dispensing certificate **13.** (1) A certificate of accreditation that permits the operation of remote dispensing locations shall specify the locations of the permitted remote dispensing locations. O. Reg. 58/11, s. 13 (1). (2) A pharmacy whose certificate of accreditation permits the operation of remote dispensing locations may only operate remote dispensing locations at the specific locations referred to in the certificate of accreditation. O. Reg. 58/11, s. 13 (2). (3) Only the specific pharmacy whose certificate of accreditation permits the operation of a remote dispensing location at a specific location may operate that remote dispensing location. O. Reg. 58/11, s. 13 (3). (4) The permission granted in a certificate of accreditation for a pharmacy to operate a remote dispensing location shall be deemed to have been revoked if there is a permanent discontinuance of service at, or closure of, the pharmacy or the remote dispensing location. O. Reg. 58/11, s. 13 (4).		These provisions are no longer required as they are addressed elsewhere or are a repetition of what is already stated in **s. 139** of the Act. The proposed regulations clarify that all standards of accreditation that apply to a pharmacy, apply to a remote dispensing location unless otherwise specified. By adopting this approach, a significant amount of duplication was removed from the proposed regulations and the specific provisions that apply to remote dispensing are highlighted where required.
Expiry of certificates of accreditation **14.** Subject to section 15, every certificate of accreditation automatically expires on the 10th day of May in each year unless renewed on or before that date. O. Reg. 58/11, s. 14.	**Expiry of certificates of accreditation** 13 (1) Subject to subsections (2) to (5), every certificate of accreditation automatically expires on the 10th day of May in each year unless renewed on or before that date. (2) A certificate of accreditation shall be deemed to have expired if there is a permanent discontinuance of service at, or closure of, the pharmacy.	The College provides information on the web on Closing a Pharmacy

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	(3) The permission granted in a certificate of accreditation to operate a remote dispensing location shall be deemed to have expired if there is a permanent discontinuance of service at, or closure of, the pharmacy whose certificate of accreditation permits its operation. (4) Where the Registrar refers an application for the renewal of a certificate of accreditation to the Accreditation Committee, the certificate of accreditation does not expire until the decision of the Accreditation Committee becomes final. (5) Where the Accreditation Committee directs the Registrar not to renew the certificate of accreditation of a pharmacy, the certificate of accreditation shall be deemed to have expired as of the date the decision of the Accreditation Committee becomes final.	**Section 12.4** of the By-law addresses what information is required to be provided on the closure of a pharmacy, this will be amended to refer to the closure of a RDL.
Renewal of certificates of accreditation **15.** (1) The Registrar may renew the certificate of accreditation where the Registrar is satisfied that the requirements for renewal have been met or substantially met. O. Reg. 58/11, s. 15 (1). (2) Where the Registrar is not satisfied that the requirements for renewal have been met or substantially met, or where the Registrar proposes that terms, conditions or limitations be attached to the certificate, the Registrar shall refer the application for renewal to the Accreditation Committee. O. Reg. 58/11, s. 15 (2). (3) Where the Registrar refers an application for renewal to the Accreditation Committee, the Registrar shall provide to the		The intention in redrafting these qualifications is to combine provisions, simplify, and ensure flexibility while retaining the ability to enforce. The qualifications for both issuance and renewal have been combined to reduce duplication.

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person responsible for the filing of the application notice in writing of that fact and notice that the holder of the certificate has the right to make a submission in writing to the Accreditation Committee within 30 days of the receipt of the notice by the person responsible for filing. O. Reg. 58/11, s. 15 (3). (4) Where notice is given by the Registrar under subsection (3), the Registrar shall also provide along with the notice, the reasons why the Registrar, (a) has proposed to refuse to renew the certificate of accreditation; or (b) has proposed that terms, conditions or limitations should be attached to the certificate of accreditation. O. Reg. 58/11, s. 15 (4). (5) Where the Registrar refers an application for the renewal of a certificate of accreditation to the Accreditation Committee, the certificate of accreditation does not expire until the decision of the Accreditation Committee becomes final. O. Reg. 58/11, s. 15 (5). (6) After considering the application for renewal and any submission made on behalf of the pharmacy, the Accreditation Committee shall either, (a) direct the Registrar to renew the certificate of accreditation, which renewal may be subject to such terms, conditions and limitations as the Committee considers appropriate; or (b) direct the Registrar not to renew the certificate of accreditation. O. Reg. 58/11, s. 15 (6). (7) Where the Accreditation Committee directs the Registrar not to renew the certificate of accreditation of a pharmacy, the		

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certificate of accreditation shall be deemed to have expired and be revoked as of the date the decision of the Accreditation Committee becomes final. O. Reg. 58/11, s. 15 (7). (8) Nothing in this Regulation affects in any way the right to revoke or suspend a certificate of accreditation for non-payment of fees as provided for under subsection 140 (4) of the Act. O. Reg. 58/11, s. 15 (8).		
Qualifications for renewal **16.** (1) In this section, "owner" includes any person or persons who own the pharmacy and if the owner is or includes, (a) a corporation, other than a non-profit corporation referred to in subsection 142 (5) of the Act, includes each officer and director of the corporation and each shareholder of the corporation who is a member, if that member owns, directly or indirectly, five per cent or more of the voting shares of that corporation, and (b) a non-profit corporation as referred to in subsection 142 (5) of the Act, includes each officer and director of that corporation. O. Reg. 58/11, s. 16 (1). (2) Subject to subsections (3) and (4), the following are the requirements that must be met for the renewal of a certificate of accreditation in respect of a pharmacy: 1. A completed application in the form required by the College must have been filed with the College. 2. The fees required to be paid for the renewal of a certificate of accreditation must have been submitted to the College.	**Qualifications for renewal of any class** 14. (1) An owner is qualified for the renewal of a certificate of accreditation if: (a) The owner files a completed application in the form required by the College and pays the required fees. (b) The owner provides further information to the College if requested by the Registrar or the Accreditation Committee, (c) All information provided by the owner to the College is full, accurate and complete. (d) There is no default in the payment of any fees required to be paid to the College or any money owed to the College concerning the pharmacy. (e) The criteria for the issuance of the certificate of accreditation continue to be satisfied. (f) The operation of the pharmacy is in compliance with the Act, the regulations under the Act and the by-laws of the College governing the establishment	"owner" is defined above (**s.1.(1)**). The College will determine what information is to be provided on the renewal form and will address details through policy/process documents. Fees are established in the By-law. The bylaw will be revised to reflect any differences in fees related to a class

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3. There must be no default in the payment of any fees required to be paid to the College or any money owed to the College concerning the pharmacy. 4. The holder of the certificate must continue to own and operate the pharmacy. 5. There must have been no change in the municipal address of the pharmacy since the certificate of accreditation was issued other than a change in the municipal address which occurred before this provision came into force and which was approved by the College. 6. There must have been no material change to the size or physical layout of the pharmacy since the certificate of accreditation was issued other than a change which was approved by the College. 7. Where requested in writing by the Registrar or the Accreditation Committee, the owner must have provided additional information in order to determine whether the certificate of accreditation should be renewed. 8. The owner's past and present conduct must afford reasonable grounds for the belief that the pharmacy will be operated with decency, honesty and integrity and in accordance with the law. 9. The pharmacy must be in compliance with the Act, the regulations under the Act and the by-laws of the College governing the establishment and operation of a pharmacy. O. Reg. 58/11, s. 16 (2). (3) The following additional requirements must be met for the renewal of a certificate of accreditation that permits the operation of remote dispensing locations: 1. The pharmacy must continue to operate the remote dispensing locations. 2. There must have been no change in the locations of the	and operation of a pharmacy. (2) A certificate of accreditation shall not be renewed where an inspection of the pharmacy or of any of its remote dispensing locations has taken place under the Act and where the inspector identified a failure to conform to the requirements of the Act and its regulations that poses a risk of harm to the public, unless the Registrar is satisfied that such failure has been addressed either to the Registrar's satisfaction or, failing that, to the satisfaction of the Accreditation Committee.	The threshold at which a certificate will not be renewed is failure that places the public at risk. The regulator may decide to renew a certificate on evidence that deficiencies have been addressed. Preserves the authority of the Registrar to renew a certificate of accreditation, even after referral of the matter to the Accreditation Committee (as per current **s. 16(5)(a)**)

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remote dispensing locations since the certificate of accreditation was issued, other than a change that was approved by the College. 3. There must have been no material change to the size or physical layout of the remote dispensing locations since the certificate of accreditation was issued, other than a change that was approved by the College. 4. The pharmacy that operates the remote dispensing locations must be in compliance with the Act and the regulations under the Act governing the establishment and operation of remote dispensing locations. 5. The pharmacy that operates the remote dispensing locations must have demonstrated to the satisfaction of the Registrar or the Accreditation Committee that it is able to supervise all aspects of the operation of its permitted remote dispensing locations, properly and effectively. O. Reg. 58/11, s. 16 (3). (4) Subject to subsection (5), a certificate of accreditation shall not be renewed where an inspection of the pharmacy or of any of its remote dispensing locations has taken place under the Act and where the inspector identified one or more failures to conform to the requirements of the Act and its Regulations unless the Registrar is satisfied that each of the deficiencies has been addressed either to the Registrar's satisfaction or, failing that, to the satisfaction of the Accreditation Committee. O. Reg. 58/11, s. 16 (4). (5) The Registrar may renew a certificate of accreditation, (a) where the application for renewal has yet to be considered by the Accreditation Committee and the Registrar is now satisfied that the pharmacy meets the qualifications for renewal; (b) for a period not to exceed 30 days to permit the pharmacy an opportunity to satisfy the Registrar that the pharmacy is		The information outlined in s. (5) (a) (b) and (c) and s. 6 will be addressed through a procedural policy. **Section 139(4)** of the DPRA provides the authority to the Registrar to impose terms, conditions or limitations on a certificate of accreditation.

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qualified for the renewal of its certificate of accreditation including an opportunity to satisfy the Registrar that any deficiencies as referred to in subsection (4) have been corrected; or (c) subject to terms, conditions and limitations agreed upon by the Registrar and the holder of the certificate, subject to the approval of those terms, conditions and limitations by the Accreditation Committee. O. Reg. 58/11, s. 16 (5). (6) Where the current certificate of accreditation has terms, conditions and limitations attached to it, the Registrar shall not renew the certificate of accreditation, and shall refer an application for renewal to the Accreditation Committee, unless the Registrar is satisfied that the terms, conditions and limitations have been complied with. O. Reg. 58/11, s. 16 (6). (7) Subsection (6) applies to a certificate of accreditation renewed by the Registrar pursuant to clause (5) (c). O. Reg. 58/11, s. 16 (7).		If the Registrar proposes to refuse an application for renewal for failure to comply with terms, conditions and limitation, the Registrar must refer the matter to the Accreditation Committee pursuant to **s. 139(2)** of the DPRA.
Removal of terms, conditions and limitations **17.** Where terms, conditions and limitations are imposed on the certificate of accreditation, the Registrar may remove any or all of them, (a) where the Registrar is satisfied that the terms, conditions or limitations have been complied with; or (b) with the approval of the Accreditation Committee. O. Reg. 58/11, s. 17.	**Removal of terms, conditions and limitations** 15. Where terms, conditions and limitations are imposed on the certificate of accreditation, the Registrar may remove any or all of them, (a) where the Registrar is satisfied that the terms, conditions or limitations have been complied with; or (b) with the approval of the Accreditation Committee.	
Revocation **18.** (1) The Registrar may propose to the Accreditation Committee the revocation of a certificate of accreditation	**Revocation** 16. a.The Registrar may propose to the Accreditation	**s. 140. (1)** provides the Accreditation Committee with the

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where the Registrar is satisfied that the certificate was issued or renewed based on the false or misleading information of an applicant. O. Reg. 58/11, s. 18 (1). (2) Where the Registrar makes a proposal to the Accreditation Committee under subsection (1), the Registrar shall give written notice to the holder of the certificate including, the reasons why the Registrar proposes that the certificate of accreditation be revoked. O. Reg. 58/11, s. 18 (2). (3) The holder of a certificate that receives a notice referred to in subsection (2) may make a written submission to the Accreditation Committee within 15 days of receiving the notice or such greater period of time as shall be agreed to by either the Registrar or the Accreditation Committee. O. Reg. 58/11, s. 18 (3). (4) If the requirements of subsections (2) and (3) have been met, the Accreditation Committee may direct the Registrar to revoke a certificate of accreditation where it is satisfied that it was issued or renewed based on the false or misleading information of an applicant and where it is satisfied that it is appropriate to do so. O. Reg. 58/11, s. 18 (4).	Committee the revocation of a certificate of accreditation where the Registrar is satisfied that the certificate was issued or renewed based on the false or misleading information of an applicant or owner. b. The Accreditation Committee may direct the Registrar to revoke a certificate of accreditation where it is satisfied that it was issued or renewed based on the false or misleading information of an applicant or owner and where it is satisfied that it is appropriate to do so.	authority to revoke a certificate. There is no requirement to provide written notice to the holder of the certificate of the proposal to revoke a certificate of accreditation. This will be addressed in policy. Noted that in the case of an accredited hospital pharmacy, the College has an obligation to give notice to the Minister should it propose to take action against the certificate of accreditation (**s. 166.1**)
PART IV STANDARDS FOR ACCREDITATION AND OPERATION	**PART IV STANDARDS FOR ACCREDITATION AND OPERATION**	The College considered the necessity to find a balance between performance based and prescriptive language. On the one hand it was determined that the regulations needed to avoid overly broad standards and on the other, it should not be difficult for an Accreditation Committee to interpret what is meant by, for example “a safe, clean environment”. This model will provide flexibility in regulatory control and in turn encourage practice innovation without unduly diluting or complicating enforcement capabilities. The new regulations

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		will rationalize the oversight of practice across various practice settings and codify the College's role in inspection/site visits as a mechanism for raising the practice standards over time as well as fulfilling the need to ensure minimum standards are being upheld.
Remote dispensing locations **19.** For greater clarity, every standard for accreditation that applies to a pharmacy applies to a remote dispensing location, unless the standard provides otherwise. O. Reg. 58/11, s. 19.	**Remote dispensing locations** 17. For greater clarity, every standard for accreditation that applies to a pharmacy applies to a remote dispensing location, unless the standard provides otherwise.	
Standards for accreditation **20.** (1) The standards for accreditation are those set out in sections 21 to 26. O. Reg. 58/11, s. 20 (1). (2) Every pharmacy shall maintain the standards for accreditation. O. Reg. 58/11, s. 20 (2). (3) The additional standards for accreditation relative to a remote dispensing location are those set out in sections 27 to 37. O. Reg. 58/11, s. 20 (3). (4) Every pharmacy whose certificate of accreditation permits the operation of remote dispensing locations shall maintain the additional standards for accreditation. O. Reg. 58/11, s. 20 (4).	**Standards for accreditation of any class** 18. a.The standards for accreditation are those set out in sections 19 to 23. b. Every owner and designated manager shall ensure that the standards for accreditation of a pharmacy are maintained. c. The additional standards for accreditation relative to a remote dispensing location are those set out in sections 24 to 27.	The proposed regulations are high-level and outcomes-based, and set the standards and objectives that must be met by pharmacy operators. It is intended that this oversight will be supported by policies, standards and guidelines which will define specific expectations where necessary.
Dispensary **21.** (1) Subject to subsection (6), each pharmacy shall have a dispensary which shall be designed, constructed and maintained so that it is not accessible to the public. O. Reg. 58/11, s. 21 (1).	STANDARDS FOR ACCREDITATION OF ANY CLASS	Wherever possible the College will rely on National Standards to outline the detailed steps required to meet the standards of practice. The College's oversight will be supported by policies, standards and guidelines which will define specific expectations where necessary.

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(2) The dispensary must be of sufficient size for the safe and orderly compounding and dispensing of drugs and other medications, but in any event must have a floor area of not less than 9.3 square metres. O. Reg. 58/11, s. 21 (2).	**Requirements of a pharmacy** 19. Every pharmacy must,	Every pharmacy must be appropriate for the services provided, for example, compounding or methadone services. As pharmacy practice evolves it is unreasonable to expect a regulation to address all the requirements necessary to ensure the pharmacy is suitable. This provides flexibility to the pharmacy operator to meet the standards.
(3) The dispensary shall have, (a) a sink with a supply of hot and cold running water adequate for the safe and appropriate operation of the pharmacy; (b) facilities and equipment necessary for the appropriate cleaning of utensils and equipment used in the preparation, dispensing, distribution and storage of drugs, as well as a separate hand washing facility; (c) an adequate supply of anti-microbial scrub or soap; (d) a work surface for the preparation for dispensing and for the compounding of drugs adequate for the safe and appropriate operation of the pharmacy but having not less than 1.12 square metres of surface area; (e) a refrigerator that is of sufficient size to store drugs and other medications requiring refrigeration and which, (i) is not used for the refrigeration and storage of anything other than drugs and other medications, (ii) is maintained at a temperature between 2 degrees Celsius and 8 degrees Celsius, and (iii) has the facility to accurately display the temperature inside the refrigerator or alternatively has maintained in it a device which accurately displays the temperature inside of the refrigerator; (f) a computer system which, (i) meets the requirements of subsection (4), and (ii) allows members practising at the pharmacy to access Internet sites and other electronic resources required by them to meet the standards of practice of the profession and to	(a) be safe, clean, orderly, and properly maintained; (b) be suitable for the pharmacy services provided therein; (c) be designed, constructed and maintained so as to ensure the integrity, and the safe and appropriate storage, of all drugs, other medications, natural health products, and substances and preparations referred to in Schedule U; (d) have procedures in place to protect the privacy of persons who receive pharmacy services and the confidentiality of their information; (e) be secure and safeguarded from unauthorised access; (f) contain equipment, technology, and facilities that are, 1. safe to use and fit for their purpose, including, as applicable, for the preparation, dispensing, distribution, storage, and compounding of drugs and other medications; 2. safeguarded from unauthorised access; and 3. in a state of good repair; (g) have information management systems that, (iv) support the delivery of patient care, 5. permit information to be recorded, displayed, stored and exchanged; and	As pharmacy services evolve, it will be necessary to provide an appropriate location for administering injections and other services, in addition to the acoustical privacy required for counselling. Concerns for privacy also extend to the care and treatment of patients in a hospital setting. National minimum requirements for the information systems used by pharmacists and pharmacy technicians have been developed in compliance with Canadian regulations and standards. The College's Professional Practice Committee

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display and print information from those sites as well as resource materials required by subsection 25 (1); (g) equipment to allow the pharmacy to receive, send and make accurate copies of both electronic and non-electronic documents; (h) equipment to allow the pharmacy to scan documents including written prescriptions and to store those scanned documents electronically; (i) equipment to allow the pharmacy to receive and make telephone calls; (j) equipment and systems needed for the input, storage and retrieval of all records and documents to allow the pharmacy to meet the requirements of the Act and its regulations as well as to allow the members practising in the pharmacy to comply with the *Pharmacy Act, 1991* and its regulations and to meet the standards of practice of the profession including but not limited to those requirements respecting recordkeeping and labelling; (k) equipment necessary for the safe and appropriate operation of the dispensary of the pharmacy including an appropriate supply of metric graduates, mortars and pestles, spatulas, funnels, stirring rods and ointment pads; (l) a balance to be used to weigh drugs and other substances, either torsion or electronic; and (m) an appropriate supply of consumable materials sufficient for the safe and appropriate operation of the pharmacy including an appropriate supply of, (i) bottles and caps, (ii) plastic vials with caps, some of the vials being light resistant, (iii) ointment jars with caps, (iv) child resistant packages, and (v) distilled or deionized water, or water purified using reverse	6. facilitate information exchange with external systems, while preserving the confidentiality, security and integrity of all personal information; (h) have an environment, including the provision of equipment, systems and staffing, that are necessary for the members practising in the pharmacy to meet the standards of practice of the profession; (i) have available the references and resources that are required by members practising in the pharmacy to meet the standards of practice of the profession and to support the pharmacy services they provide; (j) have the Symbol clearly displayed so as to be easily visible to patients or the public either before or immediately after entering the pharmacy; and (k) have systems in place to maintain an audit trail of the acquisition and movement of drugs.	reviewed a draft of this document in 2012 and provided feedback and comments that were shared with Council in September 2012. The Committee stressed the criticality of system compatibility and the need for clearly stated national requirements. The thirty-five technical, functional and administrative requirements for pharmacy management systems set out in the NAPRA document Pharmacy Practice Management Systems are designed to ensure the safety and efficacy of e-prescriptions and related electronic pharmacy records. The effective date for these requirements to come into effect is January 1, 2016. The resources, number and type of staff, and reference material required by members to support practice is related to the services provided and the characteristics of the patients receiving care. It is expected that pharmacy operators will provide what is reasonably required by the members in practice. It is fundamental that a pharmacy will maintain detailed drug records that indicate their provenance and disposition. The ability to trace drugs (i.e. lot number) will ensure that patient safety is protected in the event of a drug recall.

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osmosis technology or any other equivalent method of purification approved by the Council. O. Reg. 58/11, s. 21 (3). (4) The computer system must, (a) be capable of storing and reporting the information required in a patient record; (b) be capable of storing and reporting the information required in a transaction describing the dispensing of a drug; (c) incorporate sufficient security to ensure that only persons who are authorized by the pharmacy have access to the system; (d) have the ability to uniquely identify each staff member who has been granted access to the system; (e) have the ability to control which functions may be accessed by each person employed in the pharmacy; (f) create an accurate audit trail of persons using the system; (g) be capable of collating and generating reports related to drugs dispensed pursuant to prescriptions chronologically and by drug name and strength, patient name and prescriber name; (h) have sufficient speed and capacity to enable efficient and effective practice by the members practising at the pharmacy; and (i) require deliberate and auditable procedures to be carried out by the pharmacy or by a person authorized by the pharmacy before any information can be purged from the system. O. Reg. 58/11, s. 21 (4). (5) The requirements of clause (3) (h) do not apply to a pharmacy until May 11, 2012, if a certificate of accreditation was issued in respect of the pharmacy before that clause came into force. O. Reg. 58/11, s. 21 (5). (6) A remote dispensing location in which all drugs are dispensed or distributed from an automated pharmacy system		

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is not required to have a dispensary. O. Reg. 58/11, s. 21 (6).		
Other requirements **22.** (1) Subject to subsections (2) to (5), every pharmacy must, (a) have a floor area of sufficient size for the safe and orderly operation of the pharmacy, but in any event a floor area of not less than 18.6 square metres; (b) have been constructed and finished in a manner which permits the effective cleaning of all surfaces including the walls, floors and ceilings; (c) have a clearly defined designated area not extending beyond 10 metres from the dispensary for the purposes of facilitating compliance with the condition in paragraph 4 of section 6; (d) have a separate and distinct patient consultation area in the pharmacy offering acoustical privacy in which pharmacists may engage their patients in dialogue about their medications and related matters; and (e) have sufficient shelving, drawers or other suitable fixtures or facilities to allow for the appropriate storage in the pharmacy of all drugs, natural health products and substances and preparations referred to in Schedule U. O. Reg. 58/11, s. 22 (1). (2) The requirements of clause (1) (a) do not apply to a pharmacy until May 11, 2012, if a certificate of accreditation was issued in respect of the pharmacy before that clause came into force. O. Reg. 58/11, s. 22 (2). (3) The Accreditation Committee may exempt a pharmacy from meeting the requirements of clause (1) (a) for a specified period of time if the pharmacy satisfies the Accreditation Committee that despite all reasonable efforts the pharmacy is unable to meet those requirements. O. Reg. 58/11, s. 22 (3).		Detailed requirements such as these will be addressed in supporting materials.

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(4) The requirements of clause (1) (a) do not apply to a remote dispensing location in which all drugs are dispensed or distributed from an automated pharmacy system. O. Reg. 58/11, s. 22 (4). (5) The requirements of clause (1) (c) do not apply to a remote dispensing location. O. Reg. 58/11, s. 22 (5).		
	Recordkeeping 20. a. In every pharmacy, the following records and documents shall be maintained: (g) those required under the Act and its regulations; (h) those required to be made by members under the *Pharmacy Act, 1991* and its regulations and any federal or provincial legislation governing the purchase or sale of drugs; (i) those required to be made by members practising in the pharmacy in order to meet the standards of practice of the profession; and (j) those relating to the acquisition and movement of drugs. b. The records and documents referred to in subsection (1) shall be maintained in the pharmacy in an electronic format and in a manner that is secure, auditable, traceable and allows for their easy retrieval. c. The records and documents referred to in subsection (1) in respect of a remote dispensing location shall be maintained in the pharmacy whose certificate of accreditation permits its operation.	The general requirement to keep records and documents, and the length of retention is moved forward from the current stand-alone **Part X** and stands as a Standard of Accreditation. This replaces and clarifies the current provisions of **s.58 (1)** with respect to RDLs.

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	Length of retention 21. Subject to the Act, records and other documents relating to the care of a patient shall be maintained for a period of at least 10 years from the last recorded pharmacy service provided to the patient, or until 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer.	The general requirement to keep records and documents, and the length of retention is moved forward from the current stand-alone **Part X** and stands as a Standard of Accreditation.
Sterile compounding **23.** Every pharmacy in which sterile products are compounded must have, (a) a well lit and appropriately ventilated preparation area, (i) which is not accessible to the public, (ii) which is specifically designed for sterile compounding, and (iii) which contains a counter constructed of a non-porous surface capable of being appropriately cleaned; (b) a sink with a supply of hot and cold running water located in close proximity to the sterile compounding area; (c) adequate and secure storage space to keep drugs, medications and equipment used in sterile compounding segregated from the balance of the drugs, medications and equipment used in the dispensary; and (d) such other facilities and equipment as are reasonably necessary in the circumstances to allow the members engaged in the practice of the profession in the pharmacy to compound sterile products. O. Reg. 58/11, s. 23.		This section was removed. The proposed **s.19 (b)** above requires the pharmacy to be suitable for all the pharmacy services required, including sterile compounding. It is the intention of OCP that, wherever possible, national standards will be adopted. The Thiessen Report recommends the development of national compounding standards. NAPRA will release Model Standards of Practice with respect to both Hazardous and Non-Hazardous Sterile Compounding in 2015 and shortly thereafter, Model Standards of Practice with respect to Non-Sterile Compounding. These standards were adapted from the approved Quebec standards and subject to national review and approval. The College's Professional Practice Committee has reviewed the draft standards and provided feedback. When finalized at the national level, these standards will be brought forward for consideration for adoption by OCP Council.
Standards for operation **24.** (1) The pharmacy including all rooms and passage ways must be, (a) kept in a clean and orderly fashion;	**Dispensary, pharmacies accredited as community pharmacies** 22. (1) Subject to subsection (2), every pharmacy that is accredited as a community pharmacy shall have a dispensary	

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(b) maintained in a good state of repair; and (c) kept well lit and ventilated. O. Reg. 58/11, s. 24 (1). (2) All equipment including the appliances in the pharmacy must be, (a) kept in a clean and orderly fashion; and (b) maintained in a good state of repair. O. Reg. 58/11, s. 24 (2). (3) All furniture and fixtures including storage facilities in the pharmacy must be, (a) kept clean; and (b) maintained in a good state of repair. O. Reg. 58/11, s. 24 (3). (4) The dispensary and every room where drugs and other medications are compounded, dispensed or stored must be kept in an orderly fashion and free from materials and equipment not regularly used in the compounding, dispensing or storage of drugs and other medications. O. Reg. 58/11, s. 24 (4). (5) The pharmacy must be designed, constructed and maintained so as to ensure the integrity, and the safe and appropriate storage, of all drugs and other medications. O. Reg. 58/11, s. 24 (5). (6) The pharmacy must have and maintain a program to ensure, (a) the regular cleaning of the pharmacy including all premises, furniture, equipment and appliances, including automated pharmacy systems; (b) the regular maintenance of all equipment and appliances,	which shall be designed, constructed and maintained so that it is not accessible to the public. (2) A remote dispensing location in which all drugs are dispensed or distributed from an automated pharmacy system is not required to have a dispensary.	

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including automated pharmacy systems; (c) the safe and appropriate disposal of waste and expired consumables, including drugs and other medications; and (d) the appropriate hygienic behaviour of all persons performing dispensing or compounding activities including, (i) the wearing of suitable attire and protective coverings, and (ii) procedures for appropriate hand washing. O. Reg. 58/11, s. 24 (6). (7) The program referred to in subsection (6) must be set out in writing and must comply in all respects with this Regulation as well as with any applicable federal, provincial or municipal laws. O. Reg. 58/11, s. 24 (7).		
Availability of publications **25.** (1) The pharmacy must provide members working in the pharmacy with access to a current edition of the following publications: 1. A Compendium of Pharmaceutical Specialties or other comparable compendium approved by the Council. 2. A drug interaction publication approved by the Council. 3. A pharmacotherapeutics publication approved by the Council. 4. Publications approved by the Council from a subscription maintained by the pharmacy in respect to drug information services. 5. A patient counselling publication approved by the Council. 6. The Act and its regulations. 7. The *Regulated Health Professions Act, 1991* and its regulations. 8. The *Pharmacy Act, 1991* and its regulations. 9. The *Ontario Drug Benefit Act* and its regulations. 10. The *Drug Interchangeability and Dispensing Fee Act* and		Rather than having Council approve publications, it is proposed that the pharmacy will provide the appropriate references and resources required by members (**s. 19 (i)** above). This is stated as an outcome as the resources required in each pharmacy will be relevant to each location, as pharmacy services evolve.

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its regulations. 11. The *Controlled Drugs and Substances Act* (Canada) and its regulations. 12. The *Food and Drugs Act* (Canada) and its regulations. 13. Any other publication reasonably required by members to meet the standards of practice of the profession. O. Reg. 58/11, s. 25 (1). (2) If any of the publications in subsection (1) are not readily available through a computer system, a current edition must be made physically available in the pharmacy. O. Reg. 58/11, s. 25 (2). (3) This section does not apply to a remote dispensing location in which all drugs are dispensed or distributed from an automated pharmacy system. O. Reg. 58/11, s. 25 (3).		
Point of Care **26.** Each pharmacy must have the College's Point of Care symbol in its unaltered trademarked form prominently and appropriately displayed so as to be easily visible to the public either before entering the pharmacy or immediately after entering. O. Reg. 58/11, s. 26.		The provisions in the current **s. 26** with respect to **Point of care** are now addressed in the **Interpretation** section and, where required, references to the College's 'Symbol' are made where appropriate.
	Lock and leave, pharmacies accredited as community pharmacies 23. Where, pursuant to subsection 146 (2) of the Act, a pharmacy that is accredited as a community pharmacy is operated without the supervision of a pharmacist who is physically present, the public shall be completely restricted, by physical impediments, from access to any drugs referred to in Schedule I, II or III that are in the pharmacy.	The provisions related to **Lock and leave** are moved from the current stand-alone **Part V** to be addressed as a standard of accreditation. Provisions are now presented in terms of the appropriate outcome, that the public is restricted from access to the specified schedules of drugs when a pharmacist is not present. The terms for seeking approval to operate a pharmacy without the supervision of a pharmacist are stated in the By-Law and don't require to be repeated here. The College will develop any required additional information in related documents: standards of operations, guidelines or policies.

Existing Clause	Proposed New Clause February 20, 2015	Rationale
Location and access, remote dispensing locations **27.** Every remote dispensing location must be, (a) located indoors, in a well-lit and well-ventilated area that is appropriate for the provision of health care services; and (b) accessible to the public only during the hours that a pharmacist is physically present either in the remote dispensing location or in the pharmacy that operates the remote dispensing location. O. Reg. 58/11, s. 27.		The proposed regulations clarify that all standards of accreditation that apply to a pharmacy, apply to a remote dispensing location unless otherwise specified. By adopting this approach, a significant amount of duplication was removed from the proposed regulations and the specific provisions that apply to remote dispensing are highlighted where required.
Safety and security, remote dispensing locations **28.** (1) Every automated pharmacy system that is located in a remote dispensing location must be designed, constructed and maintained so as to ensure that, (a) all drugs and other medications requiring refrigeration are refrigerated at a temperature between 2 degrees Celsius and 8 degrees Celsius; and (b) any refrigerator has the facility to accurately display the temperature inside the refrigerator or alternatively have maintained in it a device which accurately displays the temperature inside of the refrigerator. O. Reg. 58/11, s. 28 (1). (2) Every remote dispensing location must be designed, constructed and maintained so as to prevent unauthorized access. O. Reg. 58/11, s. 28 (2). (3) Every remote dispensing location must be protected by an alarm system that will provide immediate notification to the designated manager or his or her delegate of, (a) any theft or attempted theft of the drugs or other medications; (b) any tampering or attempted tampering with, or alteration or		Safety and security provisions are equally applicable to all areas of the pharmacy, as necessary.

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attempted alteration of, the remote dispensing location or any of its equipment; or (c) any reduction below 2 degrees Celsius, or any increase above 8 degrees Celsius, of the temperature inside any of its refrigerators. O. Reg. 58/11, s. 28 (3). (4) Upon the receipt of notification referred to in subsection (3), all dispensing at the remote dispensing location shall cease immediately and shall not resume until the designated manager is satisfied that the remote dispensing location, including any automated pharmacy system, has been fully secured and is fully operational. O. Reg. 58/11, s. 28 (4).		
	ADDITIONAL STANDARDS FOR ACCREDITATION THAT APPLY TO REMOTE DISPENSING LOCATIONS **Access and supervision** 24. A remote dispensing location shall only be accessible to the public or to hospital patients, as applicable, when a pharmacist:	Accountability for a remote dispensing location (RDL) is the same in a hospital as it is in a community pharmacy. The College has provided information and a check list for opening and operating a new pharmacy, including opening a Remote Dispensing Location . The proposed regulations clarify that all standards of accreditation that apply to a pharmacy, apply to a remote dispensing location unless otherwise specified. By adopting this approach, a significant amount of duplication was removed from the proposed regulations. The specific provisions that apply to remote dispensing, that are not addressed elsewhere, are retained.

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	(a) is physically present in the pharmacy whose certificate of accreditation permits its operation; and (b) is communicating with pharmacy technicians, members of the public, or hospital patients, as applicable, at the remote dispensing location by means of a live, two-way audio-visual link.	The use of the phrase 'is communicating' is intentional and ensures that the pharmacist is present
Safety and security, remote dispensing locations **29.** Every automated pharmacy system that is contained in a remote dispensing location must, (a) at all times be locked by key, combination or other mechanical or electronic means so as to prevent unauthorized access; (b) be sufficiently affixed within the remote dispensing location so that it cannot be moved by unauthorized persons; (c) use bar-coding, micro chips or other technologies that ensure that drugs are accurately loaded into the automated pharmacy system, and that verify that the correct drugs are selected robotically during the dispensing process and that correct labels are affixed to the containers for the drugs; and (d) employ technology for the creation and transmission of a digitally scanned image of a paper-based prescription, which technology must have been approved by the Council as, (i) enabling a member who is practising at the pharmacy that receives the transmission to authenticate the prescription, including the prescriber's signature, and to verify that the prescription has not been altered; (ii) employing reasonable technical and administrative safeguards, including strong encryption of data during transmission or storage on mobile media, to ensure the confidentiality and integrity of all personal information contained in the prescription or its accompanying data streams	**Technology** 25. Every automated pharmacy system that is contained in a remote dispensing location must employ technology for the creation and transmission of a digitally scanned image of a paper-based prescription which has been approved by the Council for this purpose.	This proposed Standard is both high-level and outcome based, as per the principles agreed upon by Council. College staff members don't necessarily have the expertise to ensure the security provisions employed to create and transmit digital images are adequate. The College will be developing a method to ensure that the standards approved by Council are being met. It was determined that (a) – (c) are operational issues and will be addressed in a guidance document. The wording in the current (d) forms the basis of the new proposed Standard and the subheadings will be developed in the form of a policy.

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of audio-visual communications; and (iii) employing reasonable technical and administrative safeguards, including strong encryption and authentication, to ensure that only the pharmacy that operates the remote dispensing location can exercise remote control of the automated pharmacy system. O. Reg. 58/11, s. 29.		
Accountability, remote dispensing locations **30.** (1) Only the designated manager of a pharmacy that operates a remote dispensing location, or his or her delegate, shall load drugs into an automated pharmacy system. O. Reg. 58/11, s. 30 (1). (2) The designated manager is responsible to ensure the accurate loading, integrity, and safe and appropriate storage, of all drugs that are loaded into an automated pharmacy system. O. Reg. 58/11, s. 30 (2).		
Drug distribution, remote dispensing locations **31.** Every pharmacy that operates one or more remote dispensing locations must, (a) have systems in place to track and maintain an audit trail of the acquisition and all movement of inventory of drugs and other medications between and among the pharmacy and its remote dispensing locations; and (b) maintain records and other documents of all such acquisition and movement of inventory. O. Reg. 58/11, s. 31.		
Audio-Visual link, remote dispensing locations **32.** (1) Every remote dispensing location at which a pharmacist is not physically present must be equipped with a live, two-way audio-visual link that permits dialogue and communication between the patient and a pharmacist who is physically present in the pharmacy that operates the remote		The reference to the audio-visual link has been moved forward to the proposed **s.24** and addressed in the context of access and supervision.

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dispensing location. O. Reg. 58/11, s. 32 (1). (2) In the event of any disruption of the audio-visual link between a remote dispensing location and the pharmacy that operates it, all remote dispensing at the remote dispensing location shall cease immediately and shall not resume until the audio-visual link has been fully restored. O. Reg. 58/11, s. 32 (2).		
Controlled drugs, narcotic drugs and targeted substances, remote dispensing locations **33.** No controlled drugs, narcotic drugs, verbal prescription narcotics or targeted substances shall be located at or available from a remote dispensing location. O. Reg. 58/11, s. 33.	**Controlled drugs, narcotic drugs and targeted substances** 26. No controlled drugs, narcotic drugs, verbal prescription narcotics or targeted substances shall be located at or available from a remote dispensing location.	No change proposed in order to continue to prevent diversion of controlled substances.
Signage **34.** The following shall be prominently and appropriately displayed in every remote dispensing location, so as to be easily visible to the public either before entering the remote dispensing location or immediately after entering: 1. The College's Point of Care symbol, as required by section 26. 2. The name, address, accreditation number and telephone number of the pharmacy that operates the remote dispensing location, as well as the name of the pharmacy's designated manager. 3. Notification that the patient records for every patient who purchases drugs at the remote dispensing location are located at the pharmacy mentioned in paragraph 2. 4. The notices required by the regulations under the *Drug Interchangeability and Dispensing Fee Act*. O. Reg. 58/11, s. 34.	**Information and notices to be displayed** 27. (1) At every remote dispensing location, contact information for the pharmacy under whose certificate of accreditation the remote dispensing location operates shall be clearly and prominently displayed. (2) The containers in which drugs are dispensed, supplied or sold from a remote dispensing location shall be clearly marked with, (a) contact information for the pharmacy under whose certificate of accreditation the remote dispensing location operates, and (b) information identifying from which remote dispensing location the drug was dispensed, supplied or sold, as applicable. (3) At every remote dispensing location operating under the certificate of accreditation of a pharmacy that is accredited as a community pharmacy, the notices required by the regulations under the *Drug Interchangeability and*	This provision combines the requirement to both display information, and mark containers with the appropriate contact information together in one provision, therefore reducing duplication.

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	Dispensing Fee Act shall be displayed, including at a remote dispensing location that operates without a dispensary.	
Marking of containers, remote dispensing locations **35.** In addition to what is required under applicable legislation and regulations, the container in which a drug is dispensed from a remote dispensing location pursuant to a prescription must be marked with, (a) the name, address and telephone number of the pharmacy that operates the remote dispensing location; (b) a unique identifier, attached to the prescription number, that identifies the drug as having been dispensed from a remote dispensing location that is operated by the pharmacy; (c) the municipal address of the remote dispensing location; and (d) a toll-free telephone number at which the patient may contact the pharmacy that operates the remote dispensing location regarding the drug, during business hours. O. Reg. 58/11, s. 35.		
On-site inspection by pharmacy of remote dispensing locations **36.** (1) Every pharmacy that operates a remote dispensing location shall conduct an on-site inspection of the remote dispensing location at least once in every 30-day period. O. Reg. 58/11, s. 36 (1). (2) The on-site inspection shall be carried out by the designated manager of the pharmacy or his or her delegate, who shall be a pharmacist or a pharmacy technician who does not regularly work at the remote dispensing location. O. Reg. 58/11, s. 36 (2). (3) The inspection shall include,		Detailed provisions such as these will be published as procedure documents.

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(a) testing of all automated pharmacy systems and other equipment, including audio-visual links, to ensure that the integrity of the system is being maintained; (b) inspection of the inventory of drugs and other medications at the remote dispensing location and prompt removal of any damaged or outdated products from the inventory; and (c) verification that policies and procedures are being followed and that the remote dispensing location is being operated in accordance with the Act and this Regulation. O. Reg. 58/11, s. 36 (3). (4) The findings from each on-site inspection shall be recorded and shall be maintained at the pharmacy in accordance with the record-keeping requirements under Part X. O. Reg. 58/11, s. 36 (4).		
Policies and procedures, remote dispensing locations **37.** Every pharmacy that operates a remote dispensing location shall establish and maintain written policies and procedures for the remote dispensing location that address, at minimum, (a) operation and maintenance of all equipment and processes including any automated pharmacy systems; (b) accuracy of loading of drugs into the automated pharmacy system; (c) safety; and (d) maintenance of patient confidentiality and privacy of health information and access. O. Reg. 58/11, s. 37.		
PART V **LOCK AND LEAVE**		The provisions related to **Lock and leave** are moved from stand-alone **Part V** to be addressed as a standard of accreditation. Provisions are now presented in terms of the appropriate outcome, that the public is restricted from access to the specified schedules of drugs when a pharmacist is not present.

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Lock and leave **38.** (1) Subject to subsection (8), a pharmacy that wishes to operate without the supervision of a pharmacist who is physically present, pursuant to subsection 146 (2) of the Act, shall apply to the Registrar for approval to do so by completing an application in the form provided by the Registrar and submitting it together with the requested supporting documentation and the fees set out in the by-laws. O. Reg. 58/11, s. 38 (1). (2) It is a requirement of the granting of approval under subsection (1) that the pharmacy has the means to completely restrict the public, by physical impediments, from access to any drugs referred to in Schedule I, II or III that are in the pharmacy. O. Reg. 58/11, s. 38 (2). (3) Upon receipt of an application under subsection (1), the Registrar shall arrange for an inspection of the pharmacy by an inspector of the College, and at that inspection the pharmacy shall demonstrate how it would be able to meet the requirements of subsection (2). O. Reg. 58/11, s. 38 (3). (4) The inspector shall file an inspection report with the Registrar within a reasonable period of time following the inspection. O. Reg. 58/11, s. 38 (4). (5) If, after receiving the inspection report, the Registrar is satisfied that the pharmacy has met the requirements of subsection (2), the Registrar shall give the approval required by subsection (1). O. Reg. 58/11, s. 38 (5). (6) If the Registrar proposes to refuse to give the approval, the Registrar shall refer the application to the Accreditation		The terms for seeking approval to operate a pharmacy without the supervision of a pharmacist are stated in the By-Law and don't require to be repeated here. The College will develop any required additional information in related documents: standards of operations, guidelines or policies.

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Committee who, after considering the matter, shall direct the Registrar whether to give or refuse the approval. O. Reg. 58/11, s. 38 (6). (7) A pharmacy that obtains approval under this section shall only operate without the supervision of a pharmacist who is physically present, in accordance with the provisions of subsection 146 (2) of the Act, if the pharmacy completely restricts the public, by physical impediments, from access to any drugs referred to in Schedule I, II or III that are in the pharmacy. O. Reg. 58/11, s. 38 (7). (8) A pharmacy that, as of the day this Regulation comes into force, has been operating from time to time without the supervision of a pharmacist who is physically present in accordance with the provisions of subsection 146 (2) of the Act, may continue to so operate without applying to the Registrar for approval under subsection (1), so long as, when it so operates, the pharmacy completely restricts the public, by physical impediments, from access to any drugs referred to in Schedule I, II or III that are in the pharmacy. O. Reg. 58/11, s. 38 (8).		
PART VI **PRESCRIPTIONS, REFILLS AND TRANSFERS**		The sections addressing prescription transfers have been moved forward to **Part II** which now addresses all provisions dealing with drugs, including drug schedules, the location of scheduled drugs in the pharmacy, and transferring prescriptions.
Federal law prevails **39.** Where the provisions of this Part are inconsistent with a law of Canada governing the dispensing, refilling or transfer of prescriptions, including those related to a targeted substance,		In the proposed regulations a reference to federal legislation is included where required.

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the law of Canada shall prevail and the provisions of this Part to the extent they are inconsistent with that law shall not apply. O. Reg. 58/11, s. 39.		
Rules re dispensing **40.** (1) A drug shall not be dispensed in a pharmacy pursuant to a prescription unless the prescription has been authorized by a prescriber. O. Reg. 58/11, s. 40 (1); O. Reg. 301/12, s. 2 (1). (2) Subject to subsections (3) and (4), the authorization required by subsection (1) may be given verbally or by signature. O. Reg. 58/11, s. 40 (2). (3) A drug shall not be dispensed in a pharmacy pursuant to a prescription given verbally unless all of the following conditions have been met: 1. The drug is not a narcotic drug. (This does not prevent the dispensing of a verbal prescription narcotic.) 2. The verbal direction was received by a member who was practising at the pharmacy. 3. The member receiving the verbal direction recorded, i. the date the verbal direction was received, ii. the number of refills authorized by the verbal direction, and iii. the name of the member who received the verbal direction. 4. The prescription was recorded and signed by the member receiving the verbal direction. O. Reg. 58/11, s. 40 (3). (4) A drug shall not be dispensed in a pharmacy pursuant to a prescription given by signature that has been transmitted by means of fax, electronic mail or other form of electronic transmission, except where a member who is practising at the pharmacy either, (a) has received the prescription directly from the prescriber by		No references to authorization verbally or by signature are used in the proposed regulations. The College has provided guidance to members through the position statement on the 'Authenticity of Prescriptions Using Unique Identifiers for Prescribers' The position statement provides a list of references and principles and provides guidance to members.

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means of a transmission process that ensures the security, confidentiality and integrity of all personal information contained in the prescription and, before dispensing drugs pursuant to the prescription, has verified that the prescription, including the prescriber's signature, is authentic and has not been altered; or (b) has received the prescription through an automated pharmacy system that is contained in a remote dispensing location and that employs technology for the creation and transmission of a digitally scanned image of a paper-based prescription that has been approved in accordance with clause 29 (d). O. Reg. 58/11, s. 40 (4). (5) A drug shall not be dispensed in a pharmacy pursuant to a transferred prescription unless the provisions of section 43 have been complied with. O. Reg. 58/11, s. 40 (5). (6) For greater certainty, this section also applies where a prescriber authorizes a refill in an original prescription or authorizes a repeat of a prescription previously given. O. Reg. 301/12, s. 2 (2).		
41. Revoked: O. Reg. 301/12, s. 3		
42. Revoked: O. Reg. 301/12, s. 3.		
Transferred prescriptions **43.** (1) Subject to subsections (2) to (7), a prescription shall be transferred from a pharmacy upon the request of the patient or a person acting on behalf of the patient. O. Reg. 58/11, s. 43 (1). (2) A prescription shall not be transferred from a pharmacy where,		The sections addressing prescription transfers have been moved forward to **Part II** which now addresses all provisions dealing with drugs, including drug schedules, the location of scheduled drugs in the pharmacy, and transferring prescriptions. The *Public Hospitals Act* addresses transfers and

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(a) all of the drugs authorized to be dispensed by the prescription have already been dispensed; (b) the prescription is one for a narcotic drug, a verbal prescription narcotic or a controlled drug; or (c) subject to subsection (3), the prescription has been previously transferred by that pharmacy. O. Reg. 58/11, s. 43 (2). (3) A prescription that has been transferred from a pharmacy and subsequently transferred back to that pharmacy shall not be considered to have been previously transferred for the purposes of clause (2) (c). O. Reg. 58/11, s. 43 (3). (4) Where a prescription is transferred from a pharmacy, the pharmacy shall provide the following information to the pharmacy to which the prescription is transferred: 1. The name and address of the patient for whom the drug was prescribed. 2. The name and, if applicable, strength of the drug prescribed. 3. The directions for use, as prescribed. 4. The name and address of the prescriber. 5. The identity of the manufacturer of the drug product most recently dispensed. 6. The identification number of the prescription. 7. The total quantity of the drug remaining to be dispensed under the prescription. 8. The date the drug was first dispensed under the prescription and the date of the last refill. 9. The quantity most recently dispensed, if different from the quantity prescribed. 10. The name of the member who is responsible for the transfer of the prescription by the pharmacy. O. Reg. 58/11, s.		prescriptions/orders. The College has developed a Fact Sheet on Prescription Transfers that provides greater detail and clarity regarding prescription transfers. The Fact Sheet brings together references from Federal and Provincial legislation to present an up-to-date summary of the framework governing transfers, including the record-keeping required by both the transferring and receiving pharmacy. The Fact Sheet also addresses the conditions under which a prescription transfer is not permitted. Combined with this information is additional advice concerning misconceptions and best practices.

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43 (4). (5) The information required by subsection (4) shall be provided, (a) under the signature of a member who is practising at the pharmacy transferring the prescription; or (b) verbally by a member who practises at the pharmacy making the transfer to, (i) in the case of a pharmacy in Ontario, a member who is practising at the pharmacy to which the prescription is to be transferred, and (ii) in the case of a pharmacy outside Ontario, a person authorized to practise pharmacy at the pharmacy to which the prescription is to be transferred. O. Reg. 58/11, s. 43 (5). (6) A prescription shall not be transferred from a pharmacy unless a record is made in that pharmacy containing, (a) the date of the transfer of the prescription; (b) the identity of the pharmacy to which the prescription was transferred; (c) the name of the member who was responsible for the transfer of the prescription by the pharmacy; and (d) where the prescription was transferred verbally, the name of the person to whom the transfer was made. O. Reg. 58/11, s. 43 (6). (7) A drug shall not be dispensed in a pharmacy pursuant to a transferred prescription unless all of the following conditions have been met: 1. The prescription was transferred to that pharmacy from a pharmacy duly licensed or accredited in a province or territory of Canada. 2. A record has been made in that pharmacy which includes all		

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of the information required by subsection (4). 3. Where the prescription was transferred verbally, i. the information required by subsection (4) was received by and recorded by a member who was practising at the pharmacy, and ii. a prescription was recorded and signed by the member receiving the verbal prescription. O. Reg. 58/11, s. 43 (7).		
PART VII **CHILD RESISTANT PACKAGING**		This is a federal requirement and not required to be duplicated here.
Definition **44.** In this Part, "child resistant package" means a container or a package that meets the standards for child resistant packages prescribed by the *Food and Drug Regulations* under the *Food and Drugs Act* (Canada). O. Reg. 58/11, s. 44.		
Child resistant package **45.** Every person who fills a prescription shall dispense the drug in a child resistant package unless, (a) the prescriber or the person who presents the prescription directs otherwise; (b) in the professional judgment of the member who is responsible for the dispensing of the drug, it is advisable not to use a child resistant package given the particular circumstances; or (c) a child resistant package is not suitable because of the physical form of the drug. O. Reg. 58/11, s. 45.		

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PART VIII **ADVERTISING**	**PART V** **ADVERTISING**	
Definitions **46.** In this Part and for the purposes of section 50, "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. O. Reg. 58/11, s. 46.	**Definitions** 28. In this Part and for the purposes of section 32, "advertise" includes advertising through any medium and includes the publication, display, distribution or use of an advertisement; "advertisement" includes an announcement, directory listing or other form of communication similar to an advertisement.	The College created a fact sheet on Advertising which brings together the professional and legislative references to be considered in determining the appropriateness of an advertisement. FDA Regulations: **C.01.044**. If a person advertises a prescription drug to the general public, the person shall not make any representation other than with respect to the brand name, the proper name, the common name and the price and quantity of the drug.
Advertisement of drug services **47.** (1) Every pharmacy shall ensure that any advertisement of drug services available through the pharmacy is in compliance with this Part. O. Reg. 58/11, s. 47 (1). (2) A pharmacy 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;	**Advertising requirements** 29. a. No person shall advertise or permit, directly or indirectly, another person to advertise a pharmacy or its services in a manner that, (c) is false, misleading or deceptive, including as a result of the inclusion or omission of information; (d) is not dignified and in good taste; (e) contains anything that cannot be verified; (f) contains testimonials, comparative statements or endorsements relating to the quality of drugs or services provided in the pharmacy or in any other pharmacy; (g) inappropriately uses a term, title or designation to indicate or imply that a member practising in the	The focus of the College is on public protection and safety. The proprietary misconduct provisions also address the inappropriate use of a title, etc. At present, in Ontario there is

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(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 pharmacy; or (i) contains any representations as to the safety or effectiveness or an indication for use of any drug referred to in Schedule I. O. Reg. 58/11, s. 47 (2). (3) An advertisement that includes price information relating to drugs referred to in Schedule I 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.	pharmacy has a specialization in the profession; or (h) contains any representations as to the safety or effectiveness or an indication for use of a Schedule I drug. b. Where an advertisement includes price information relating to a Schedule I drug the advertisement shall, (i) include the following information with respect to the drug: 1. the quantity, strength, brand name, and dosage form of the drug being advertised at the advertised price; 2. the total cost for the drug to the purchaser including any dispensing fee; and 3. the time period during which the advertised price will be available; and (j) give equal prominence to each drug advertised and, for each of those drugs, equal prominence shall be given to all the information required under paragraph (a).	no specialist registration; although, a pharmacy may specialize in the delivery of services to patients with diabetes, for example. The proposed provisions share commonalities with pharmacy regulations in other Canadian jurisdictions and the requirements of the *Food and Drugs Act*. The section requiring 15 drugs to be listed in price information has been removed. The requirement is specific to Ontario and one other jurisdiction in Canada. There is no evidence of public harm in the jurisdictions that do not require this provision. While not directly related to this specific regulation, the Competition Bureau has indicated support for a competitive approach to the manufacture, distribution and retailing of pharmaceutical drugs.

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16. Skin and mucous membrane preparations. 17. Spasmolytics. 18. Unclassified therapeutic agents. 19. Vitamins. O. Reg. 58/11, s. 47 (3). (4) Where an advertisement includes price information relating to drugs referred to in Schedule I, 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. O. Reg. 58/11, s. 47 (4). (5) An advertisement that includes price information relating to drugs referred to in Schedule I 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. O. Reg. 58/11, s. 47 (5). (6) Where an advertisement includes price information relating to drugs referred to in Schedule I, 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). O. Reg. 58/11, s. 47 (6).		
ODBA information **48.** Nothing in this Part prohibits a pharmacy from publishing, displaying, distributing or using, or permitting, directly or	**ODBA information** 30. Nothing in this Part prohibits the advertising of the co-payment or dispensing fee charged in a pharmacy for	

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indirectly, the publication, display, distribution or use of, an advertisement that relates solely to the co-payment or dispensing fee charged by the pharmacy for supplying a drug that is a listed drug product under the *Ontario Drug Benefit Act* to an eligible person under that Act. O. Reg. 58/11, s. 48.	supplying a drug that is a listed drug product under the *Ontario Drug Benefit Act* to an eligible person under that Act.	
PART IX **PROPRIETARY MISCONDUCT/CONFLICT OF INTEREST**	**PART VI** **PROPRIETARY MISCONDUCT**	With the appropriate adjustment for context, the proprietary misconduct regulations align to the language recently agreed to with the Ministry with respect to professional misconduct.
Definition **49.** In this Part, "prescription information" means information recorded in a pharmacy that relates to the prescribing and dispensing of drugs pursuant to prescriptions, but does not include the name of patients or any information that would be reasonably expected to identify any patient. O. Reg. 58/11, s. 49.	**Definition** 31. In this Part, "prescription information" means information that relates to the prescribing and dispensing of drugs pursuant to prescriptions in a pharmacy.	
Acts of proprietary misconduct **50.** The following are acts of proprietary misconduct for the purpose of section 140 of the Act: 1. Contravening a term, condition or limitation imposed upon a certificate of accreditation. 2. Failing to provide the equipment, systems and staffing necessary for the members practising in the pharmacy to maintain the standards of practice of the profession. 3. Failing to co-operate with an inspector of the College conducting an inspection pursuant to the Act. 4. Disclosing prescription information without ensuring compliance with section 51 of this Regulation. 5. Failing to respond, or to respond accurately, to an inquiry about whether or not a pharmacy discloses prescription information to third parties, or, where there is a response, failing to provide to the person making the inquiry either the nature of the information that the pharmacy discloses to third parties, or to whom the pharmacy discloses such information.	**Acts of proprietary misconduct** 32. The following are acts of proprietary misconduct for the purpose of section 140 of the Act: CERTIFICATES AND STANDARDS OF ACCREDITATION 1. Contravening a term, condition or limitation imposed on a certificate of accreditation. 2. Failing to maintain any of the standards of accreditation. RELATIONSHIP WITH THE COLLEGE 3. Failing to reply within a reasonable time to a written or electronic inquiry or request from the College. 4. Failing to co-operate with an inspector of the College.	

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6. Carrying on business as a pharmacy while in a conflict of interest as defined by sections 52 and 53 of this Regulation. 7. Failing to provide a system to monitor the expiry date of drugs and natural health products. 8. Failing to remove a drug or natural health product from pharmacy stock beyond its expiry date. 9. Failing to respond to a College enquiry within 30 days from receipt of a written enquiry from the College. 10. Employing, permitting, counselling or assisting a member to practise in a manner which is inconsistent with any terms, conditions or limitations on the certificate of registration of the member. 11. Failing to keep confidential personal health information or other personal information concerning a patient without the patient's consent unless permitted or required to do so by law. 12. Failing to keep records required to be kept by the pharmacy respecting the patients and the practice of the pharmacy. 13. Falsifying a record of the pharmacy. 14. Signing or issuing a document that contains a false or misleading statement. 15. Submitting an account or charge which is false or misleading. 16. Charging a fee or an amount that is excessive in relation to the service or product provided. 17. Where an advertisement in respect of drug services available through the pharmacy includes price information relating to a drug referred to in Schedule I, charging a purchaser, including the executive officer under the *Ontario Drug Benefit Act*, more for the drug than what was advertised, pursuant to paragraph 2 of subsection 47 (4), as the total cost for the drug including any dispensing fee.	5. Failing to comply with an order of a Committee or a panel of a Committee of the College. 6. Failing to carry out or abide by an undertaking given to the College or breaching an agreement with the College, a Committee or a panel of a Committee of the College or the Registrar. RECORDS AND INFORMATION PRACTICES 7. Failing to keep records as required respecting the operation of the pharmacy and the patients and practice of members practising in the pharmacy. 8. Falsifying a record relating to the pharmacy or a patient's health record. 9. Signing or issuing a document that contains a false or misleading statement. 10. Failing to keep confidential personal health information or other personal information concerning a patient, except with the consent of the patient or the patient's authorized representative or as otherwise permitted or required by law. 11. Disclosing prescription information to another person unless: i. the disclosure is made in accordance with a written agreement between the owner and the person to whom the disclosure is made, and that agreement requires that any prescription information that is disclosed will not include anything that would be reasonably expected to identify a patient; and ii. the designated manager or contact person of the pharmacy, as applicable, is aware of the existence of the written agreement referred to in paragraph 1. 12. Failing to respond, or to respond accurately, to an	

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18. Failing to provide the College with prompt notice in writing of the purchase or sale of a pharmacy. 19. Contravening the Act or the regulations made under the Act. 20. Operating a remote dispensing location without being permitted to do so in the certificate of accreditation. 21. Operating a pharmacy at a municipal address other than the municipal address for which the certificate of accreditation was issued. 22. Operating a remote dispensing location at a location other than one referred to in the certificate of accreditation. 23. Making a material change to the size or physical layout of a pharmacy after a certificate of accreditation was issued, without the prior approval of the College. 24. Contravening any law of Canada or Ontario or any municipal by-law with respect to the distribution, purchase, sale or dispensing of any drugs or product in a pharmacy. 25. Entering into any agreement that restricts a person's choice of a pharmacy without the written consent of that person. 26. Returning to stock a drug dispensed pursuant to a prescription where the purchaser had taken possession of that drug. 27. Selling or dispensing a drug previously dispensed pursuant to a prescription where the purchaser had taken possession of that drug. 28. Engaging in, or knowingly permitting, unlawful conduct in the premises in which the pharmacy is located, including an offence pursuant to the *Criminal Code* (Canada) or pursuant to the *Controlled Drugs and Substances Act* (Canada). 29. Permitting, consenting to, approving, counselling or assisting, whether expressly or by implication, the commission	inquiry about whether or not prescription information in the pharmacy is disclosed to third parties, or, where there is a response, failing to provide to the person making the inquiry either the nature of the information that is disclosed to third parties, or to whom such information is disclosed. BUSINESS PRACTICES 13. Operating a pharmacy while in a conflict of interest as defined by sections 34 of this Regulation. 14. Submitting an account or charge that is false or misleading. 15. Charging a fee or an amount that is excessive in relation to the service or product provided. 16. Charging a person, including the executive officer under the *Ontario Drug Benefit Act*, more for a Schedule I drug than what was advertised, pursuant to subparagraph 29(2)(a)(ii), as the total cost for the drug including any dispensing fee. 17. Soliciting or permitting the solicitation of an individual unless, i. the person who is the subject of the solicitation is advised, at the earliest possible time during the communication, that the purpose of the communication is to solicit use of the pharmacy's services, and ii. the communication ends immediately if the person who is the subject of the solicitation so elects. 18. Entering into any agreement that restricts a person's choice of a pharmacy or pharmacist without the consent of that person. PHARMACY SERVICES AND PROFESSIONALISM MATTERS	

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of an offence under any Act relating to the practice of pharmacy or the sale of drugs. 30. Engaging in conduct or performing an act relevant to the business of a pharmacy that would reasonably be regarded by members as disgraceful or dishonourable. O. Reg. 58/11, s. 50.	19. In a pharmacy that is accredited as a community pharmacy, returning to stock or selling or dispensing again a drug that was previously sold or dispensed, except that it will not be proprietary misconduct to i. return to stock or re-sell or re-dispense a drug that does not require refrigeration, that is listed on Schedule II or Schedule III and that is in its original, unopened packaging, or ii. accept the return of a drug from a patient for purposes of re-packaging and re-dispensing the drug to the same patient, as long as that the drug is suitable for re-packaging.	These provisions outline the limited circumstances in which returning a drug to stock is permitted in a community pharmacy, once it has been sold or dispensed.
	20. In a pharmacy that is accredited as a hospital pharmacy, returning to stock or selling or dispensing again a drug, that was previously sold or dispensed, except that it will not be proprietary misconduct to return to stock or re-sell or re-dispense a drug i. that is returned to the pharmacy in a sealed dosage unit or container as originally dispensed, ii. that is returned with the labelling intact and includes a legible drug lot number and expiry date, and iii. the integrity of which can be verified.	Returning a drug to stock or selling/dispensing it again in hospital pharmacy is considered differently in hospital pharmacy as it is under the care and control of regulated health professionals until administration to a patient.
	21. Dispensing, selling or compounding a drug, or administering a substance, that is not of good quality or does not meet the standards required by law, or, in the case of a drug, does not contain a substance that the drug is meant to contain.	The term ‘not of good quality’ is meant to broadly include drugs that are past expiry, counterfeit drugs and drugs that have been exposed to conditions which alter the effectiveness of the drug; for example, if a pharmacy discovers a cold chain breach but sells or administers the drugs anyway.
	22. Permitting, counselling or assisting, whether expressly or by implication, any member to	

Existing Clause	Proposed New Clause February 20, 2015	Rationale
	contravene, or to practise in a manner that is inconsistent with, a term, condition or limitation on that member's certificate of registration. 23. Permitting, counselling or assisting a person who is not a member to represent himself or herself as a member or to perform a controlled act that the person is not authorized to perform. 24. Inappropriately using a term, title or designation in respect of the practice of a member practising in the pharmacy. 25. Inappropriately using a term, title or designation indicating or implying that a member practising in the pharmacy has a specialization in the profession. MISCELLANEOUS MATTERS 26. Contravening the Act, the *Pharmacy Act, 1991*, the *Regulated Health Professions Act, 1991*, the *Narcotics Safety and Awareness Act, 2010*, the *Drug Interchangeability and Dispensing Fee Act*, the *Ontario Drug Benefit Act* or the regulations under those Acts. 27. Contravening any federal, provincial or territorial law or any municipal by-law, i. with respect to the distribution, purchase, sale, or dispensing or prescribing of any drug product, the administering of any substance, or the piercing of the dermis, ii. the purpose of which is to protect or promote public health, or iii. that is otherwise relevant to the operation of the pharmacy or the provision of pharmacy services. 28. Using, or knowingly permitting the premises in which a pharmacy is located, or the area adjacent to	

Existing Clause	Proposed New Clause February 20, 2015	Rationale
	such a premise to be used, for unlawful purposes. 29. Permitting, consenting to, approving, counselling or assisting, whether expressly or by implication, the commission of an offence against any Act relating to the practice of pharmacy or the sale of drugs. 30. Engaging in conduct or performing an act relevant to the operation of a pharmacy that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional.	
Disclosure of prescription information **51.** A pharmacy may disclose prescription information if all of the following conditions have been met: 1. The disclosure is made in accordance with a written agreement between the holder of the certificate in respect of the pharmacy and the person to whom the disclosure is made, and that agreement requires that any prescription information that is disclosed will not include anything that would be reasonably expected to identify a patient. 2. The designated manager of the pharmacy is aware of the existence of the written agreement referred to in paragraph 1. O. Reg. 58/11, s. 51.		
Conflict of interest, definitions **52.** In this section and section 53, "benefit" means any incentive or inducement of more than nominal value, whether direct or indirect, and includes a rebate, credit or gift; "child" means a child within the meaning of the *Family Law Act*; "owner" means the owner of the pharmacy and where the owner of the pharmacy is,	**Conflict of interest, definitions** 33. In this section, and in sections 34 and 35, "benefit" means any incentive or inducement of more than nominal value, whether direct or indirect, and includes a rebate, credit or gift; "child" means a child within the meaning of the *Family Law Act*; "non-arm's length relationship" means a relationship between	In these provisions, references are made to the 'responsible

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(a) a corporation other than a non-profit corporation referred to in subsection 142 (5) of the Act, includes each officer and director of the corporation and each shareholder of the corporation who is a member if that member owns, directly or indirectly, five per cent or more of the voting shares of that corporation, or (b) a non-profit corporation as referred to in subsection 142 (5) of the Act, includes each officer and director of that corporation; "parent" means a parent within the meaning of the *Family Law Act*; "related corporation" means a corporation wholly or substantially owned or controlled, whether directly or indirectly, by the owner of a pharmacy or a related person of the owner of a pharmacy; "related person" means the owner of the pharmacy and any person who has one of the following relationships to the owner or to the spouse of the owner of the pharmacy, whether based on blood, marriage, common-law or adoption: 1. A child or the spouse of a child. 2. A grandchild or the spouse of a grandchild. 3. A parent or the spouse of a parent. 4. A grandparent or the spouse of a grandparent. 5. A sibling or spouse of a sibling; "spouse" means, (a) a spouse as defined in section 1 of the *Family Law Act*, or (b) either of two persons who live together in a conjugal relationship outside marriage. O. Reg. 58/11, s. 52.	two parties such that one party has the ability to exercise, directly or indirectly, control or significant influence over the operating and financial decisions of the other party and includes a relationship between a responsible person and a related person or a related corporation; "parent" means a parent within the meaning of the *Family Law Act*; "related corporation" means a corporation wholly or substantially owned or controlled, whether directly or indirectly, by the responsible person or a related person of the responsible person; "related person" means any person who has one of the following relationships to the responsible person or to the spouse of the responsible person, whether based on blood, marriage, common-law or adoption: a) A child or the spouse of a child. b) A grandchild or the spouse of a grandchild. c) A parent or the spouse of a parent. d) A grandparent or the spouse of a grandparent. e) sibling or spouse of a sibling; "responsible person" means the designated manager and the owner of the pharmacy; "spouse" means, 1. a spouse as defined in section 1 of the *Family Law Act*, or 2. either of two persons who live together in a conjugal relationship outside marriage.	person' as defined below – the designated manager and the owner of the pharmacy. Small change made to align with the Professional Misconduct regulations. Conflicts of interest are a matter a proprietary misconduct. The only persons who are held accountable for proprietary misconduct are owners, directors and designated managers. The new proposed definition of 'owner' will include directors.
Conflict of interest **53.** (1) Subject to subsections (2) to (5), a pharmacy is in a	**Conflict of interest** 34. It is a conflict of interest for a responsible person to do,	The concern is where a responsible person makes or influences

Existing Clause	Proposed New Clause February 20, 2015	Rationale
conflict of interest, (a) where a reasonable person knowing the relevant facts would conclude or perceive that the action of the pharmacy in relation to the dispensing, selling or compounding of a drug was adversely influenced or would likely have been adversely influenced by the financial interests of the pharmacy or of a related person or a related corporation; (b) where the pharmacy or a related person or a related corporation enters into an arrangement or agreement which a reasonable person knowing the relevant facts would conclude or perceive would likely have the effect of adversely influencing the exercise of a member's professional judgment or influencing or impeding a member's ability to engage in the practice of pharmacy in an ethical manner or in accordance with the standards of practice of the profession; (c) where the pharmacy or a related person or a related corporation enters into an arrangement or agreement which a reasonable person knowing the relevant facts would perceive as directly or indirectly influencing or encouraging a prescriber to promote the use of the pharmacy by a patient; or (d) where the pharmacy or a related person or a related corporation, (i) accepts or receives a benefit by reason of the referral of a patient to any other person, (ii) offers, makes or confers a benefit to a person by reason of the referral of a patient to the pharmacy, or (iii) offers, makes or confers a benefit to a patient in relation to the sale of a drug referred to in Schedule I or the provision of professional pharmacy services other than, (A) an adjustment in the fee or amount that would otherwise be charged by the pharmacy with regard to that patient for that drug or that professional pharmacy service, or (B) the provision to a patient, at no charge, of an item of a nominal value, to be used in maintaining or promoting well-	or to cause or permit another person to do, directly or indirectly, any of the following: (a) refer a patient to another person if the responsible person, or a person in a non-arm's length relationship with the responsible person, requests, accepts or receives a benefit by reason of the referral; (b) offer, make or confer a benefit to a person by reason of the referral of a patient to a pharmacy with which the responsible person is associated; (c) offer, make or confer a benefit to a patient in relation to the sale of a drug or the provision of pharmacy services other than, 1. an adjustment in the fee or amount that would otherwise be charged with regard to that patient for that drug or that professional pharmacy service, or 2. the provision to a patient, at no charge, of an item of a nominal value, to be used in maintaining or promoting well-being or health; (d) enters into any agreement or arrangement that influences or encourages, or appears to influence or encourage, a prescriber to promote the services of the pharmacy with which the responsible person is associated; (e) enters into any agreement or arrangement that adversely influences or appears to adversely influence the exercise of professional expertise or judgment or the ability of a member working in the pharmacy to engage in the practice of the profession in an ethical manner or in accordance	a corporate decision relating to any of the actions below.

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being or health. O. Reg. 58/11, s. 53 (1). (2) No conflict of interest arises under subclause (1) (d) (i) or (ii), (a) solely as a result of a referral by the pharmacy to a related person or a related corporation where, (i) no direct benefit is received by the pharmacy, and (ii) the nature of the relationship between the pharmacy and the related person or related corporation is fully disclosed to the patient at the time of the referral; or (b) solely as a result of a referral to a pharmacy from a related person or a related corporation where, (i) no direct benefit is conferred by the pharmacy, and (ii) the nature of the relationship between the pharmacy and the related person or related corporation is fully disclosed to the patient prior to the pharmacy providing pharmacy services. O. Reg. 58/11, s. 53 (2). (3) No conflict of interest arises as a result of the rent payable in respect of the lease of premises in which the pharmacy is situated if the rent charged is normal and customary for the type of premises and the geographical area in which the premises are located. O. Reg. 58/11, s. 53 (3). (4) No conflict of interest arises under clause (1) (a) by virtue of the pharmacy or a related person or a related corporation having a financial interest in the manufacturer, vendor or supplier of a drug included in Schedule I, II or III established under the Act, if, (a) the fact of the financial interest is appropriately disclosed to the patient prior to the pharmacy providing pharmacy services in relation to the drug; or (b) the manufacturer, vendor or supplier of the drug is a	with the standards of practice of the profession.	

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corporation, the shares of which are publicly traded through a stock exchange, and fewer than 25 per cent of the shares of the corporation are owned or controlled by the pharmacy, a related person or a related corporation, or any combination of them. O. Reg. 58/11, s. 53 (4); O. Reg. 301/12, s. 4. (5) No conflict of interest arises under clause (1) (a) or (b) by virtue of a pharmacy or a related person or a related corporation accepting or receiving from a manufacturer, vendor or supplier of drugs, (a) a reasonable discount based on volume or prompt payment offered in the ordinary course of business; or (b) a benefit that is specifically permitted by an Ontario statute or regulation. O. Reg. 58/11, s. 53 (5).		
	Examples of not being in conflict 35. (1) No conflict of interest arises under subclause 34 (a) or (b), i. solely as a result of a referral to a person who is in a non-arm's length relationship with the responsible person where, 1. no direct benefit is received by the responsible person, and 2. before making the referral, the nature of the relationship between the responsible person and the person in the non-arm's length relationship is disclosed to the patient; or ii. solely as a result of a referral from a person who is in a non-arm's length relationship with the responsible person where,	The changes provided here are intended to simplify this section and avoid repetition. The language is also intended to align with the proposed Professional Misconduct Regulation. The obligation is on the responsible person to disclose. Disclosure could be made in the context of a contract.

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	1. no direct benefit is received by the responsible person, and 2. before any pharmacy services are provided, the nature of the relationship between the responsible person and the person in the non-arm's length relationship is disclosed to the patient. b. No conflict of interest arises under section 34 in connection with the paying of rent with respect to premises leased for the purposes of operating a pharmacy if the rent reflects the normal rent payable for the same type of premises in the same geographical area. c. No conflict of interest arises under section 34 in connection with a responsible person or a related person or a related corporation having a financial interest in the manufacturer, vendor or supplier of a drug or substance if, i. before any pharmacy services are provided in relation to the drug or substance, the fact of the financial interest is disclosed to the patient; or ii. the manufacturer, vendor or supplier of the drug or substance is a corporation, the shares of which are publicly traded through a stock exchange, and none of the responsible person, a related person, a related corporation, or any combination thereof, wholly or substantially owns the corporation, or has the ability to exercise, directly or indirectly, control or significant influence over its operating or financial decisions.	
PART X		The general requirement to keep records and documents, and the length of retention is moved forward from the current

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RECORDKEEPING		stand-alone **Part X** and stands as a Standard of Accreditation.
Recordkeeping **54.** (1) A pharmacy shall, (a) maintain the records and documents required under the Act and its regulations, in the required manner; (b) maintain the records and documents required to be made by members under the *Pharmacy Act, 1991* and its regulations and to meet the standards of practice of the profession, in the required manner; (c) maintain the records and documents required to be made by the pharmacy or members practising at the pharmacy under any federal legislation governing the purchase or sale of drugs in the required manner; (d) make and maintain a scanned electronic copy of every original written prescription pursuant to which a drug is dispensed as well as a copy of the information required by subsection 156 (1) of the Act and retain those copies as part of the patient record; (e) make the original prescriptions and other records referred to in clause (a), (b), (c) or (d) available for inspection by an inspector of the College; and (f) assist the inspector to make or obtain copies of any records or documents referred to in clause (a), (b), (c) or (d), if requested by the inspector. O. Reg. 58/11, s. 54 (1). (2) The requirements of clause (1) (d) do not apply to a pharmacy until May 11, 2012, if a certificate of accreditation was issued in respect of the pharmacy before that clause came into force. O. Reg. 58/11, s. 54 (2). (3) A pharmacy shall maintain the records and documents referred to in subsection (1) in a computer system where possible and, where that is not possible, shall maintain them in		

Existing Clause	Proposed New Clause February 20, 2015	Rationale
a systematic manner that allows for their easy retrieval. O. Reg. 58/11, s. 54 (3).		
Length of retention **55.** (1) Subject to subsection (3), records and other documents relating to the care of a patient, other than original written prescriptions, shall be maintained for a period of at least 10 years from the last recorded professional pharmacy service provided to the patient or until 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer. O. Reg. 58/11, s. 55 (1). (2) All prescription records required to be maintained by the Act shall be maintained for the period specified in the Act or if no period is specified in the Act, for the period set out in subsection (1). O. Reg. 58/11, s. 55 (2). (3) While an audit or inspection is being performed by or on behalf of the College in respect of the pharmacy or in respect of a member who is practising at the pharmacy, no record or document shall be destroyed until the audit or inspection is completed, except with the written approval of the Registrar. O. Reg. 58/11, s. 55 (3).		Now stands as **s. 21** within the context of the standards of accreditation
Safeguards **56.** (1) A pharmacy shall ensure that appropriate safeguards are installed and maintained to ensure that the records and documents required to be kept by a pharmacy which contain personal health information are collected, recorded, used, stored, handled and destroyed in a manner that protects confidentiality and privacy. O. Reg. 58/11, s. 56 (1). (2) The pharmacy shall ensure that all records and documents that are not stored in a computer system,		National minimum requirements for the information systems used by pharmacists and pharmacy technicians have been developed in compliance with Canadian regulations and standards. The thirty-five technical, functional and administrative requirements for pharmacy management systems set out in the NAPRA document Pharmacy Practice Management Systems are designed to ensure the safety and efficacy of e-prescriptions and related electronic pharmacy records. The effective date for these requirements to come into

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(a) are legible; (b) are made using non-erasable ink; (c) are readily retrievable; and (d) are stored securely and in an appropriate manner to provide reasonable protection from damage. O. Reg. 58/11, s. 56 (2).		effect is January 1, 2016.
Backup **57.** A pharmacy shall ensure that, (a) it has adequate backup and recovery systems to back up and recover information stored in its computer system; (b) records and documents stored in a computer system are backed up at least once a day, unless the computer system was not used during that day; (c) a copy of the backup is stored off site or in a fireproof and theft-resistant safe; (d) all copies of the backup are kept secure to avoid unauthorized acts, use or disclosure; and (e) one copy of the backup is stored in a manner that allows for its ready retrieval in the event it is required to continue the orderly operation of the pharmacy. O. Reg. 58/11, s. 57.		
Remote dispensing locations **58.** (1) The obligations to which a pharmacy is subject under this Part apply with respect to the records, documents and information of every remote dispensing location that the pharmacy operates. O. Reg. 58/11, s. 58 (1). (2) In addition, a pharmacy that operates a remote dispensing location shall maintain the following records and documents with respect to the remote dispensing location, (a) a record of all testing done on any automated pharmacy system prior to first use and of all on-site inspections conducted pursuant to section 36;		All general requirements for a pharmacy are required in relation to RDLs and do not require duplication.

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(b) a record of all maintenance done on any automated pharmacy system; (c) a record of all technical malfunctions that occur in any automated pharmacy system that includes the cause of the malfunction, and the amount of time and the steps taken to repair it; (d) all documentation received from the manufacturer or vendor of an automated pharmacy system, including the name of the manufacturer, the model number, a description of how the machine operates and an operating manual; and (e) all written policies and procedures with respect to the operation of automated pharmacy systems at the remote dispensing location. O. Reg. 58/11, s. 58 (2).		
PART XI **INFORMATION, EXAMINATION AND AUDIT**	**PART VII** **INFORMATION, EXAMINATION AND AUDIT**	
Information return **59.** A pharmacy shall, within 30 days of a written request from the Registrar, complete and file with the College a return in Form 1 (Return by Owner of a Pharmacy) as set out on the website of the College. O. Reg. 58/11, s. 59.	~~**Information return**~~ 36. ~~The owner of a pharmacy shall, within 30 days of a written request from the Registrar, complete and file with the College a return in Form 1 (Return by Owner of a Pharmacy) as set out on the website of the College.~~	To be deleted
Examination and audit **60.** (1) The Registrar may at any time require an examination and audit to be made by such persons appointed by the Registrar, including without limitation a public accountant, for the purposes of ascertaining whether information provided to the College by the pharmacy or anyone acting on its behalf, including the information contained in the Form 1 return, is correct. O. Reg. 58/11, s. 60 (1). (2) Where the Registrar appoints a person under subsection (1), the pharmacy shall co-operate fully and shall provide to the person appointed all evidence, vouchers, records, books,	**Examination and audit** 37. a.The Registrar may at any time require an examination and audit to be made by such persons appointed by the Registrar, including without limitation a public accountant, for the purposes of ascertaining whether information provided to the College by the owner, the designated manager, or anyone acting on their behalf, ~~including the information contained in the Form 1 return,~~ is correct. b. Where the Registrar appoints a person under subsection (1), the owner and the designated manager shall co-operate fully and shall provide to the person appointed all evidence, vouchers, records, books, documents and papers that may be	Change made to conform to changes elsewhere in the regulation: since the term “pharmacy” is now used only to refer to the physical premises, instead of referring to information provided “by the pharmacy or anyone acting on its behalf” now refer to the owner, designated manager or anyone acting on their behalf The “contact person” was not mentioned as a hospital is incorporated as an owner.

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documents and papers that may be requested for the purpose of the examination and audit and the person so appointed shall report the results of the examination and audit to the Registrar forthwith after completing the examination and audit. O. Reg. 58/11, s. 60 (2).	requested for the purpose of the examination and audit and the person so appointed shall report the results of the examination and audit to the Registrar forthwith after completing the examination and audit.	
PART XII (OMITTED)		
61. Omitted (revokes other Regulations). O. Reg. 58/11, s. 61.		
62. Omitted (provides for coming into force of provisions of this Regulation). O. Reg. 58/11, s. 62.		
SCHEDULE A	SCHEDULE A	No change
SCHEDULE B PART I	SCHEDULE B PART I	No change