Drug and Pharmacies Regulation Act
Loi sur la réglementation des médicaments etAdeset des pharmacies

ONTARIO REGULATION 58/11
GENERAL

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~~*This Regulation is made in English only.*~~

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PART I
INTERPRETATION

Interpretation

1. ~~**1.** (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;

~~"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;

"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;

"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;~~

~~"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;

"~~Manual~~National Drug Schedules" means the ~~manual~~National Drug Schedules that are part of the National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities ~~entitled "Canada's National Drug Scheduling System" and dated September 25, 1998~~, as ~~that manual is~~those Schedules are amended from time to time;

"medications" means drugs and other substances usually maintained in ~~the dispensary~~a pharmacy, including substances used in the compounding of drugs;

"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.

"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;

"Prescription Drug List" means the list established under section 29.1 of the *Food and Drugs Act* (Canada), as amended from time to time;

"sell" includes offer for sale, expose for sale, have in possession for sale, and distribute, whether or not the distribution is for consideration;

~~"signature" includes an electronic signature, and "signed" includes signed by an electronic signature;~~

"targeted substance" means~~,~~

~~(a) a~~ targeted substance ~~that is included in Schedule I of~~as defined in the Benzodiazepines and Other Targeted Substances ~~*Regulation*~~Regulations 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).~~

(2) In this Regulation, unless the context provides otherwise, reference to a "pharmacy" includes a hospital pharmacy.

"Remote dispensing location"

~~2.~~ For purposes of the Act and this Regulation,

2. "remote dispensing location" means ~~a premises~~:

(a) in a pharmacy that is accredited as a community pharmacy, a place where drugs are dispensed or sold by retail to the public ~~and that is operated by, but is not at~~under the ~~same location~~

~~as, a pharmacy whose certificate~~supervision of ~~accreditation permits its operation. O. Reg. 58/11, s. 2.~~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.

PART II
~~DRUG SCHEDULES~~DRUGS

~~Schedules and special cases~~

~~3. (1)~~ **Drug schedules**

~~2.~~3. ~~(1)~~ Schedules I, II, III and U are established for the purposes of the Act. ~~O. Reg. 58/11, s. 3 (1).~~

~~(1) (2)~~ ~~(2)~~ The following substances are prescribed as being included in Schedule I for the purposes of the Act:

1. ~~1.~~ The substances listed in Schedule I of the ~~Manual~~National Drug Schedules.
2. ~~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).~~the Prescription Drug List.
3. ~~3.~~ The substances listed in the Schedules ~~I, II, III, IV, V, VI, VII and VIII of~~ to the *Controlled Drugs and Substances Act* (Canada). ~~O. Reg. 58/11, s. 3 (2).~~

~~(3)~~ The substances listed in Schedule II of the ~~Manual~~National Drug Schedules 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~~National Drug Schedules are prescribed as being included in Schedule III for the purposes of the Act. ~~O. Reg. 58/11, s. 3 (4).~~

~~(5)~~ The substances listed in the Unscheduled Category of the ~~Manual~~National Drug Schedules 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).~~

Location of Schedule I, ~~conditions on sale~~II and III drugs

4. ~~4. The following conditions apply to the sale in~~In a pharmacy ~~of~~ accredited as a ~~drug referred to in~~ community pharmacy,

(a) Schedule I~~:~~ drugs shall only be available for sale from,

~~1. Subject to paragraph 2, a pharmacist must be physically present in the pharmacy.~~

(i) ~~2. Where the drug is~~ the dispensary, or

~~(i)~~(ii) where 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.~~the dispensary or an automated pharmacy system,

~~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~~(b) Schedule II drugs shall only be available for sale from ~~the dispensary.~~,

(i) ~~6. Where the drug is~~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 ~~drug~~dispensary or an automated pharmacy system,

(c) Schedule III drugs shall only be available for sale from ~~the dispensary or from an automated pharmacy system. O. Reg. 58/11, s. 4; O. Reg. 301/12, s. 1.~~,

~~**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~~dispensary or an area in the pharmacy~~.~~

(i) ~~2. Where the drug~~ that allows for self-selection of drugs by patients and where a member is available for consultation, or

where 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.~~

~~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.~~

(ii) ~~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.~~

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.

PART III
CERTIFICATES OF ACCREDITATION: ISSUANCE AND RENEWAL

Definition

~~**3.**~~**6.** ~~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 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.~~

Classes of accreditation

7. (1) The following classes of accreditation are hereby established:

(a) community pharmacy; and

(b) hospital pharmacy.

(2) 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.

Qualifications for the issuance of a certificate of accreditation of any class

~~4.~~**8.** ~~8. (1) Subject to section 9, a person~~ (1) An applicant is qualified for the issuance of a certificate of accreditation to establish and operate a pharmacy ~~if all of the following requirements are met~~of any class if:

1. ~~A~~The applicant files a completed application in the form required by the College ~~has been filed with the College, along with~~and pays the required ~~application fee.~~

~~2. The~~ 1. fees ~~required to be paid for the issuance of a certificate of accreditation have been submitted to the College~~.

~~3. Where~~ 2. The applicant provides further information to the College if requested by the Registrar or the Accreditation Committee~~, an~~.

~~2.~~3. All information provided by the applicant ~~has provided~~ to the College is full, accurate 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 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.~~

~~3.~~4. ~~5.~~ The past and present conduct of each person who is an applicant, and in the case of a corporation, of each director who is a member, and of each shareholder who is a member 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. ~~O. Reg. 58/11, s. 8 (1).~~

~~(1) (2)~~ ~~(2) Subject to subsection (3), it~~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 ~~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).~~

Additional requirements, remote dispensing location

~~5.~~9. ~~**9.** (1) A person~~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 ~~all of the following requirements~~, in addition to ~~those~~the requirements set out in section 8, there are ~~met:~~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.

~~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).~~

Deemed reasonable grounds for belief

~~6.~~10. ~~**10.** For the purposes of paragraph ~~5~~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 following has occurred:

1. ~~1. An applicant made a~~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. ~~2. An applicant failed~~There was a failure or ~~refused~~refusal to provide information requested under paragraph ~~3 or 4~~2 of subsection 8 (1). ~~O. Reg. 58/11, s. 10.~~

Issuance, name and address

~~7.~~11. ~~**11.** (1)~~ A certificate of accreditation shall be issued in the specific name of the ~~owner of~~person who owns the pharmacy and for the specific municipal address or addresses at which the pharmacy is to be operated. ~~O. Reg. 58/11, s. 11.~~

~~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 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**~~

~~(1)~~ (2) ~~**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).~~

Amendment ~~(2) A pharmacy whose~~

12. If an owner wishes to:

(a) operate a remote dispensing location where the certificate of accreditation ~~permits~~does not already permit the operation of remote dispensing locations ~~may only~~, or

(b) operate a remote dispensing ~~locations~~location at a location other than the ~~specific locations referred to in~~location specified on the certificate of accreditation~~. O. Reg. 58/11, s. 13 (2).~~,

~~(3) Only~~ the ~~specific pharmacy whose~~owner shall apply for an amended 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).~~

Expiry of certificates of accreditation

~~8.~~13. ~~**14.** (1)~~ Subject to ~~section 15,~~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. ~~O. Reg. 58/11, s. 14.~~

~~**Renewal of certificates of accreditation**~~

~~**15.** (1) The Registrar may renew the~~ A 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).~~

~~(1)~~ (2) ~~(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).~~be deemed to have expired if there is a permanent discontinuance of service at, or closure of, the pharmacy.

~~(3) Where the Registrar refers an application for renewal to the Accreditation Committee, the Registrar shall provide to the 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).

(3) (5) 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.

(2) (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. 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).

(3) (5) (7) 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 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 of any class

16. (1) In this section,

"owner" includes any person or persons who own the pharmacy and if the (6) An 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).

9.14. (2) Subject to subsections (3) and (4), the following are the requirements that must be metqualified for the renewal of a certificate of accreditation in respect of a pharmacy:if:

(a) 1. AThe owner files a completed application in the form required by the College must have been filed with and pays the required fees.

(b) The owner provides further information to the College. if requested by the Registrar or the Accreditation Committee,

(c) 2. The fees required to be paid forAll information provided by the renewal of a certificate of accreditation must have been submittedowner to the College is full, accurate and complete.

(d) 3. There must beis 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) 4. The holdercriteria for the issuance of the certificate must of accreditation continue to own and operate be satisfied.

The operation of 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.~~

~~(e)~~(f) ~~9. The pharmacy must be~~ is 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 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).~~

(1) ~~(4) Subject to subsection (5), a~~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~~a failure to conform to the requirements of the Act and its ~~Regulations~~regulations that poses a risk of harm to the public, unless the Registrar is satisfied that ~~each of the deficiencies~~such failure 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 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).~~

Removal of terms, conditions and limitations

~~10.~~15. ~~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.

Revocation

11.16. **18.** (1) (1) The Registrar may propose to the Accreditation 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. O. Reg. 58/11, s. 18 (1). or owner.

(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).

(1) (2) (4) If the requirements of subsections (2) and (3) have been met, theThe 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. O. Reg. 58/11, s. 18 (4).

PART IV
STANDARDS FOR ACCREDITATION AND OPERATION

Remote dispensing locations

12.17. **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.

Standards for accreditation of any class

13.18. **20.** (1) (1) The standards for accreditation are those set out in sections 21 19 to 26. O. Reg. 58/11, s. 20 (1).23.

(1) (2) (2) Every pharmacy owner and designated manager shall maintainensure that the standards for accreditation. O. Reg. 58/11, s. 20 (2). of a pharmacy are maintained.

(2) (3) (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).24 to 27.

(4) STANDARDS FOR ACCREDITATION OF ANY CLASS

Requirements of a pharmacy

19. Every pharmacy must,

(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,

(i) safe to use and fit for their purpose, including, as applicable, for the preparation, dispensing, distribution, storage, and compounding of drugs and other medications;

(ii) safeguarded from unauthorised access; and

(iii)in a state of good repair;

(g) have information management systems that,

(i) support the delivery of patient care,

(ii) permit information to be recorded, displayed, stored and exchanged; and

(iii)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.

Recordkeeping

20. (1) In every pharmacy, the following records and documents shall be maintained:

(a) those required under the Act and its regulations;

(b) 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;

(c) those required to be made by members practising in the pharmacy in order to meet the standards of practice of the profession; and

(d) those relating to the acquisition and movement of drugs.

(2) 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.

(3) 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 ~~the~~its operation ~~of remote dispensing locations shall maintain the additional standards for accreditation. O. Reg. 58/11, s. 20 (4).~~.

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.

Dispensary, pharmacies accredited as community pharmacies

~~14.~~**22.** ~~21. (1)~~ (1) Subject to subsection (~~6), each~~2), every pharmacy that is accredited as a community 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).~~

~~(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).~~

~~(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 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 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).

(1) (2) (6) A remote dispensing location in which all drugs are dispensed or distributed from an automated pharmacy system is not required to have a dispensary. O. Reg. 58/11, s. 21 (6).

Lock and leave**Other requirements**

22. (1) Subject**, pharmacies accredited as community pharmacies**

Where, pursuant to subsectionssubsection 146 (2) to (5), everyof the Act, a pharmacy must,

(a) have that is accredited as a floor area of sufficient size for the safe and orderly operation of the community 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 is operated without the supervision of a pharmacist who is physically present, the public shall be completely restricted, by physical impediments, from the dispensary for the purposes of facilitating compliance with the condition in paragraph 4 of section 6;

15.23. (d) have a separate and distinct patient consultation area access to any drugs referred to in Schedule I, II or III that are 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

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:

is physically present 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).~~

(a) ~~(2) The requirements of clause (1) (a) do not apply to a pharmacy until May 11, 2012, if a~~whose certificate of accreditation ~~was issued in respect of the pharmacy before that clause came into force. O. Reg. 58/11, s. 22 (2).~~permits its operation; and

~~(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).~~

~~(4) The requirements of clause (1) (a) do not apply to a remote dispensing location in which all drugs are dispensed~~is communicating with pharmacy technicians, members of the public, 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~~ hospital patients, as applicable, at the remote dispensing location~~. O. Reg. 58/11, s. 22 (5).~~

~~**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.~~

~~**Standards for operation**~~

~~**24.** (1) The pharmacy including all rooms and passage ways must be,~~

~~(a) kept in a clean and orderly fashion;~~

~~(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, 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.

(b) 2. A drug interaction publication approved by the Council means of a live, two-way audio-visual link.

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 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.

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.

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 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).

Safety and security, remote dispensing locations

29. **Technology**

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

16.25. (d) employ technology for the creation and transmission of a digitally scanned image of a paper-based prescription, which technology must havehas been approved by the Council as,for this purpose.

(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 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 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~~

~~17.~~**26.** ~~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.~~

~~**Signage**~~

~~34. The following shall be prominently~~

Information and ~~appropriately~~ **notices to be displayed** ~~in~~

27. (1) At every remote dispensing location, ~~so as to be easily visible to the public either before entering~~ contact information for the pharmacy under whose certificate of accreditation the remote dispensing location operates shall be clearly and prominently displayed.

~~(1)~~ (2) The containers in which drugs are dispensed, supplied or ~~immediately after entering:~~sold from a remote dispensing location shall be clearly marked with,

~~1. The College's Point of Care symbol, as required by section 26.~~

~~2. The name, address, accreditation number and telephone number~~contact information for the pharmacy under whose certificate of ~~the pharmacy that operates the remote dispensing location, as well as the name of the pharmacy's designated manager.~~

(a) ~~3. Notification that the patient records for every patient who purchases drugs at~~accreditation the remote dispensing location ~~are located at the pharmacy mentioned in paragraph 2.~~operates, and

(b) ~~4. The~~information identifying from which remote dispensing location the drug was dispensed, supplied or sold, as applicable.

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 Dispensing Fee Act~~. O. Reg. 58/11, s. 34.~~

~~**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~~ shall be displayed, including at a remote dispensing location that ~~is operated by the pharmacy;~~

~~(c) the municipal address of the remote dispensing location; and~~

~~(2)~~ (3) ~~(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.~~without a dispensary.

~~**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,~~

~~(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

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 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

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, 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 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,

(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. 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 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**~~

~~**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.~~

~~**PART VIII**~~
ADVERTISING

Definitions

~~18.~~28. ~~**46.**~~ In this Part and for the purposes of section ~~50~~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~~;~~.

~~"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.~~

~~**Advertisement of drug services**~~

~~47. **(1) Every pharmacy**~~

Advertising requirements

29.No person 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).~~

~~19.~~30. ~~(2) A pharmacy shall not, through any medium, publish, display, distribute or use,~~advertise or permit, directly or indirectly, ~~the publication, display, distribution or use through any medium of, an advertisement relating to drug services~~another person to advertise a pharmacy or its services in a manner that,

(a) ~~(a)~~ is false, misleading or deceptive, ~~whether~~including 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;~~

(b) ~~(c)~~ is not dignified and in good taste;

(c) ~~(d)~~ contains anything that cannot be verified;

(d) ~~(e)~~ contains testimonials, comparative statements or endorsements~~;~~ relating to the quality of drugs or services provided in the pharmacy or in any other pharmacy;

~~(f) contains~~inappropriately uses a ~~reference~~term, title or designation to ~~a member's area of practice or to a procedure~~indicate or ~~treatment available from~~ imply that 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;~~

(e) ~~(g) contains references to a particular brand of equipment used to assist~~a specialization in ~~providing drug services;~~the profession; or

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

(f) ~~(i)~~ contains any representations as to the safety or effectiveness or an indication for use of ~~any drug referred to in~~a Schedule I~~. O. Reg. 58/11, s. 47 (2).~~ drug.

~~(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.~~

~~16. Skin and mucous membrane preparations.~~

~~17. Spasmolytics.~~

~~18. Unclassified therapeutic agents.~~

~~19. Vitamins. O. Reg. 58/11, s. 47 (3).~~

(1) ~~(4)~~ Where an advertisement includes price information relating to ~~drugs referred to in~~ a Schedule I~~,~~ drug the advertisement shall ~~include at a minimum the following information with respect to each drug:~~,

(a) ~~1. The~~include the following information with respect to the drug:

(i) the quantity, strength, brand name, and dosage form of the drug being advertised at the advertised price~~.~~;

(ii) ~~2. The~~the total cost for the drug to the purchaser including any dispensing fee~~.~~; and

(iii) ~~3. The~~the time period during which the advertised price will be available~~.~~ ~~O. Reg. 58/11, s. 47 (4).~~; and

~~(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).~~

~~(g)~~(b) ~~(6) Where an advertisement includes price information relating to drugs referred to in Schedule I, equal prominence shall be given to each drug~~give equal prominence to each drug advertised 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).~~paragraph (a).

ODBA information

~~20.~~31. ~~48.~~ Nothing in this Part prohibits ~~a pharmacy from publishing, displaying, distributing or using, or permitting, directly or indirectly,~~ the ~~publication, display, distribution or use~~advertising of~~, an advertisement that relates solely to~~ the co-payment or dispensing fee charged ~~by the~~in a 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.~~

PART ~~IX~~VI
PROPRIETARY MISCONDUCT~~/CONFLICT OF INTEREST~~

Definition

~~21.~~32. ~~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.~~ in a pharmacy.

Acts of proprietary misconduct

~~22.~~33. ~~50.~~ The following are acts of proprietary misconduct for the purpose of section 140 of the Act:

~~1.~~ CERTIFICATES AND STANDARDS OF ACCREDITATION

1. Contravening a term, condition or limitation imposed ~~upon~~on a certificate of accreditation.
2. ~~2.~~ Failing to ~~provide the equipment, systems and staffing necessary for the members practising in the pharmacy to~~ maintain any of the standards of ~~practice of the profession~~accreditation.

~~3.~~ 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 ~~conducting~~.

5. Failing to comply with an ~~inspection pursuant to~~order of a Committee or a panel of a Committee of the College.

~~3.~~6. Failing to carry out or abide by an undertaking given to the College or breaching an agreement with the ~~Act~~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.

~~4.~~9. Signing or issuing a document that contains a false or misleading statement.

10. ~~4.~~ 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.

~~5.~~11. Disclosing prescription information ~~without ensuring compliance with section 51 of this Regulation.~~to another person unless:

(i) ~~5.~~ 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.

~~6.~~12. Failing to respond, or to respond accurately, to an inquiry about whether or not ~~a pharmacy discloses~~ 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 ~~the pharmacy discloses~~is disclosed to third parties, or to whom ~~the pharmacy discloses~~ such information is disclosed.

~~6. Carrying on business as a~~ BUSINESS PRACTICES

~~7.~~13. Operating a pharmacy while in a conflict of interest as defined by sections ~~52 and 53~~34 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.~~

~~8.~~14. ~~14. Signing or issuing a document that contains a false or misleading statement.~~

~~9.~~15. ~~15.~~ Submitting an account or charge ~~which~~that is false or misleading.

~~10.~~16. ~~16.~~ Charging a fee or an amount that is excessive in relation to the service or product provided.

~~11.~~17. ~~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~~Charging a

person, including the executive officer under the *Ontario Drug Benefit Act*, more for ~~the~~a Schedule I drug than what was advertised, pursuant to ~~paragraph 2 of subsection 47 (4~~subparagraph 29(2)(a)(ii)), as the total cost for the drug including any dispensing fee.

~~18. Failing to provide the College with prompt notice in writing of the purchase or sale of a pharmacy.~~

18. ~~19. Contravening~~Soliciting or permitting the solicitation of an individual unless, the person who is the ~~Act or~~subject of the ~~regulations made under~~ solicitation is advised, at the ~~Act.~~

~~20. Operating a remote dispensing location without being permitted to do so in~~earliest possible time during the ~~certificate of accreditation.~~

~~21. Operating a pharmacy at a municipal address other than~~communication, that the ~~municipal address for which~~ purpose of the ~~certificate~~communication is to solicit use of ~~accreditation was issued.~~

(i) ~~22. Operating a remote dispensing location at a location other than one referred to in~~ the ~~certificate of accreditation.~~pharmacy's services, and

~~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.~~

(ii) ~~25.~~ the communication ends immediately if the person who is the subject of the solicitation so elects.

Entering into any agreement that restricts a person's choice of a pharmacy or pharmacist without the ~~written~~ consent ~~of that person.~~

~~12.~~19. ~~26. Returning to stock a drug dispensed pursuant to a prescription where the purchaser had taken possession~~ of that ~~drug~~person.

~~27. Selling~~PHARMACY SERVICES AND PROFESSIONALISM MATTERS

20. 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 ~~pursuant to a prescription where~~, 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 ~~purchaser had taken possession~~return of ~~that drug~~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.

21. ~~28. Engaging in~~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.

22. 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.

23. Permitting, counselling or assisting, whether expressly or by implication, any member to contravene, or to practise in a manner that is inconsistent with, a term, condition or limitation on that member's certificate of registration.

24. 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.

25. Inappropriately using a term, title or designation in respect of the practice of a member practising in the pharmacy.

26. 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

27. 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.

28. 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.

~~13.~~29. Using, or knowingly permitting~~, unlawful conduct in~~ the premises in which ~~the~~a pharmacy is located, ~~including an offence pursuant to the *Criminal Code* (Canada) or pursuant to the *Controlled Drugs and Substances Act* (Canada).~~or the area adjacent to such a premise to be used, for unlawful purposes.

~~14.~~30. ~~29.~~ Permitting, consenting to, approving, counselling or assisting, whether expressly or by implication, the commission of an offence ~~under~~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 ~~business~~operation of a pharmacy that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful ~~or~~, dishonourable~~. O. Reg. 58/11, s. 50.~~

~~**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.~~

~~15.~~31. ~~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~~ or unprofessional.

Conflict of interest, definitions

~~23.~~34. ~~52.~~ In this section, and ~~section 53~~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*;

"~~owner~~non-arm's length relationship" means ~~the owner of the pharmacy and where the owner of the pharmacy 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 corporation who is a member if~~ relationship between two parties such that ~~member owns~~one party has the ability to exercise, directly or indirectly, ~~five per cent~~control or ~~more of the voting shares of that corporation,~~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

~~(b)~~ a ~~non-profit corporation as referred to in subsection 142 (5) of the Act, includes each officer and director of that~~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 ~~owner of a pharmacy~~ responsible person or a related person of the ~~owner of a pharmacy~~responsible person;

"related person" means ~~the owner of the pharmacy and~~ any person who has one of the following relationships to the ~~owner~~responsible person or to the spouse of the ~~owner of the pharmacy~~responsible person, whether based on blood, marriage, common-law or adoption:

~~(h)~~(c) ~~1.~~ A child or the spouse of a child.

~~(i)~~(d) ~~2.~~ A grandchild or the spouse of a grandchild.

~~(j)~~(e) ~~3.~~ A parent or the spouse of a parent.

~~(k)~~(f) ~~4.~~ A grandparent or the spouse of a grandparent.

~~(l)~~(g) ~~5. A~~ sibling or spouse of a sibling;

"responsible person" means the designated manager and the owner of the pharmacy;

"spouse" means,

~~(a)~~1. a spouse as defined in section 1 of the *Family Law Act*, or

~~(b)~~2. either of two persons who live together in a conjugal relationship outside marriage. ~~O. Reg. 58/11, s. 52.~~

Conflict of interest

~~**53.** (1) Subject to subsections (2) to (5), a pharmacy~~ It is ~~in~~ a conflict of interest~~,~~

~~(a) where a reasonable~~ for a responsible person ~~knowing the relevant facts would conclude~~to do, or ~~perceive that the action of the pharmacy in relation to the dispensing, selling~~to cause 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~~permit another 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;~~

35. ~~(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~~to do, directly or indirectly ~~influencing or encouraging a prescriber to promote the use of the pharmacy by~~, any of the following:

refer a patient~~; or~~

~~(d) where the pharmacy or a related person or a related corporation,~~

(a) ~~(i)~~ 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 ~~of a patient to any other person,~~;

(b) ~~(ii) offers, makes~~offer, make or ~~confers~~confer a benefit to a person by reason of the referral of a patient to ~~the pharmacy, or~~a pharmacy with which the responsible person is associated;

(c) ~~(iii) offers, makes~~offer, make or ~~confers~~confer 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,

(i) ~~(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

(ii) ~~(B)~~ 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~~. O. Reg. 58/11, s. 53 (1).~~;

(d) ~~(2)~~ 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 with the standards of practice of the profession.

Examples of not being in conflict

~~24.~~36. (1) No conflict of interest arises under subclause ~~(1) (d) (i~~34 (a) or (~~ii),~~b),

(a) ~~(a)~~ solely as a result of a referral ~~by the pharmacy~~ to a ~~related~~ person ~~or~~who is in a ~~related corporation~~non-arm's length relationship with the responsible person where,

(i) ~~(i)~~ no direct benefit is received by the ~~pharmacy~~responsible person, and

(ii) ~~(ii)~~ before making the referral, the nature of the relationship between the ~~pharmacy~~ responsible person and the ~~related~~ person ~~or related corporation~~in the non-arm's length relationship is ~~fully~~ disclosed to the patient ~~at the time of the referral~~; or

(b) ~~(b)~~ solely as a result of a referral ~~to a pharmacy~~ from a ~~related person or a related corporation~~person who is in a non-arm's length relationship with the responsible person where,

(i) ~~(i)~~ no direct benefit is ~~conferred~~received by the responsible person, and before any pharmacy~~, and~~

~~(iii)~~(ii) ~~(ii)~~ services are provided, the nature of the relationship between the ~~pharmacy~~responsible person and the ~~related~~ person ~~or related corporation~~in the non-arm's length relationship is ~~fully~~ disclosed to the patient ~~prior to the pharmacy providing pharmacy services. O. Reg. 58/11, s. 53 (2).~~.

(2) ~~(3)~~ No conflict of interest arises ~~as a result of~~under section 34 in connection with the paying of rent ~~payable in~~with respect ~~of the lease of~~to premises ~~in which~~leased for the purposes of operating a pharmacy ~~is situated~~ if the rent ~~charged is~~reflects the normal ~~and customary~~rent payable for the same type of premises ~~and~~in the same geographical area ~~in which the premises are located. O. Reg. 58/11, s. 53 (3).~~.

(3) ~~(4)~~ No conflict of interest arises under ~~clause (1) (a) by virtue of the pharmacy~~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 ~~included in Schedule I, II or III established under the Act,~~or substance if,

(a) ~~(a)~~ ~~the~~ before any pharmacy services are provided in relation to the drug or substance, 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 or substance is a corporation, the shares of which are publicly traded through a stock exchange, and ~~fewer than 25 per cent~~none of the ~~shares of the~~

corporation are owned or controlled by the pharmacyresponsible person, 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)thereof, wholly or (b) by virtue of a pharmacy or a related personsubstantially owns the corporation, or has the ability to exercise, directly or a related corporation acceptingindirectly, control 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).

PART X
RECORDKEEPING

Recordkeeping

54. (1) A pharmacy shall,

(a) maintain the records and documents required under the Act andsignificant influence over 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 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).

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,

(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).

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;~~

~~(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;~~

(b) ~~(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~~or financial decisions.

~~(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~~VII
INFORMATION, EXAMINATION AND AUDIT

Information return

~~**25.**~~**37.** ~~**59.** A~~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. ~~O. Reg. 58/11, s. 59.~~

Examination and audit

~~**26.**~~**38.** ~~**60.** (1)~~ (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~~owner, the designated manager, or anyone acting on ~~its~~their behalf, including the information contained in the Form 1 return, is correct. ~~O. Reg. 58/11, s. 60 (1).~~

~~(1)~~ (2) ~~(2)~~ Where the Registrar appoints a person under subsection (1), the ~~pharmacy~~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 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).~~

~~**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

1.	Acid (calcium d-pantothenate)
2.	Acid (dexpanthenol)
3.	Alginic acid
4.	Allantoin
5.	Aloe
6.	Aloin
7.	Alum
8.	Aralia racemosa
9.	Arrowroot
10.	Attapulgite (activated)
11.	Balmony
12.	Balsam tolu
13.	Balsam mecca
14.	Benzoic acid
15.	Benzoin
16.	Benzyl alcohol
17.	Bile extract
18.	Bile salts
19.	Caffeine
20.	Caffeine citrate
21.	Calcium carbonate
22.	Calcium gluconate, except in injectable form for parenteral nutrition
23.	Calcium glycerophosphate
24.	Calcium hydroxide
25.	Calcium lactate
26.	Calcium phosphate (dibasic)
27.	Calcium undecylenate
28.	Canada balsam
29.	Capsicum oleoresin
30.	Castor oil
31.	Cocoa butter
32.	Cod liver oil
33.	Copper sulfate, except in injectable form for parenteral nutrition
34.	Creosote
35.	Cynara scolymus
36.	Eucalyptol
37.	Eucalyptus
38.	Eucalyptus oil
39.	Eugenol
40.	Fennel
41.	Fir
42.	Gelatin
43.	Gentiana lutea
44.	Ginger
45.	Glycerine
46.	Guaiacol
47.	Guaifenesin
48.	Hamamelis virginiana
49.	Hemlock spruce
50.	Honey
51.	Juniper tar
52.	Lanolin
53.	Linseed
54.	Liquid paraffin (mineral oil)
55.	Magnesium sulfate (epsom salts)
56.	Motherwort common
57.	Myrrh
58.	Oats
59.	Octocrylene
60.	Oil of anise

61.	Oil of cajeput
62.	Oil of camphor
63.	Oil of cinnamon
64.	Oil of clove
65.	Oil of dill
66.	Oil of fennel
67.	Oil of fir
68.	Oil of hemlock canadian
69.	Oil of mustard expressed
70.	Oil of peppermint
71.	Oil of pine needles
72.	Oil of sassafras
73.	Oil of sweet almond
74.	Oil of thyme
75.	Oil of turpentine
76.	Olive oil
77.	Ox bile extract
78.	Pancreatin, except in products for the treatment of established pancreatic insufficiency
79.	Papain
80.	Pectin
81.	Pepsin
82.	Peptone
83.	Petrolatum
84.	Petrolatum liquid
85.	Pine tar
86.	Plantago seed
87.	Poplar bud
88.	Prune
89.	Saccharine and sodium saccharine
90.	Sassafras
91.	Shark liver oil
92.	Simethicone
93.	Sodium alginate
94.	Sodium benzoate
95.	Sodium bicarbonate
96.	Sodium carbonate
97.	Sodium carboxymethyl cellulose
98.	Sodium chloride, except in injectable form for parenteral nutrition or single ingredient solutions for parenteral or ophthalmic use in concentrations of more than 0.9% (note: does not apply to contact lens solutions intended to be rinsed off prior to insertion into eye)
99.	Sodium citrate, except for parenteral use
100.	Sodium dioctyl sulfosuccinate
101.	Sodium lauryl sulfate
102.	Sodium monofluorophosphate
103.	Sodium oleate
104.	Sodium phosphate dibasic
105.	Sodium tartrate
106.	Spruce gum
107.	Strawberry
108.	Sulfur
109.	Tartaric acid
110.	Thymol
111.	Turpentine
112.	White petroleum
113.	White pine
114.	Wild cherry
115.	Yeast

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SCHEDULE B
PART I

1.	2-phenylbenzimidazole-5-sulfonic acid
2.	4-methylbenzylidene camphor
3.	Acetaminophen — when sold in standard unit doses of 325mg 25 or less
4.	Acetylsalicylic acid — when sold in standard unit doses of 325 mg 51 or less
5.	Alpha-galactosidase
6.	Aluminium chlorohydrate
7.	Aluminum chloride — when in an antiperspirant preparation, not more than 5 per cent
8.	Aluminum chlorohydrate
9.	Aluminum hydroxide
10.	Aluminum hydroxide — magnesium carbonate codried gel
11.	Aluminum potassium sulfate
12.	Aluminum sesquichlorohydrate
13.	Aluminum zirconium tetrachlorohydrex glycine
14.	Aluminum zirconium trichlorohydrex glycine
15.	Ammonium bicarbonate
16.	Ammonium carbonate
17.	Ammonium chloride
18.	Ammonium hydrozide (anethole)
19.	Bacitracin and its salts and derivatives — for topical use
20.	Beef, iron and wine
21.	Benzalkonium chloride — in liquid preparations in concentrations not more than 2 per cent
22.	Benzethonium chloride — in liquid preparations in concentrations not more than 1 per cent
23.	Biguanide polyaminopropyl
24.	Bioflavanoids
25.	Biotin
26.	Bismuth subcarbonate (oxycarbonate)
27.	Bismuth subgallate
28.	Bismuth subsalicylate
29.	Boldo
30.	Buchu
31.	Butyl methoxydibenzoylmethane
32.	Carbetapentane citrate
33.	Cascara sagrada and its extracts and derivatives
34.	Cetrimide
35.	Cetylpyridinium gluconate
36.	Chamomile
37.	Charcoal (activated) — except for use in poisoning treatment
38.	Chloral hydrate — for topical use
39.	Chlorhexidine gluconate
40.	Chlorhydrol — when in an antiperspirant preparation
41.	Chlorobutanol
42.	Chloroxylenol
43.	Chlorpheniramine maleate and its salts and preparations — except for parenteral use
44.	Choline
45.	Cinnamedrine
46.	Citric acid
47.	Clove
48.	Coal tar — in concentrations of up to and including 10 per cent
49.	Cochineal
50.	Cocillana
51.	Croton oil

52.	Culver's root
53.	Dea methoxycinnamate
54.	Dimethicone
55.	Disodium edetate
56.	Disodium lauroamphodiacetate conc.
57.	Domiphen bromide
58.	Docusate and its salts
59.	Dyclonine hydrochloride for use in lozenges only
60.	Edetic acid
61.	Essence of peppermint
62.	Frangula
63.	Glycyrrhiza glabra
64.	Glycyrrhizin
65.	Gramicidin and its salts — for topical use
66.	Hexylresorcinol
67.	Homosalate
68.	Hydrogen peroxide — not more than 3 per cent
69.	Hydroquinone — when in skin bleaching preparations, not more than 2 per cent
70.	Hydroxyquinoline
71.	Inositol
72.	Irgasan DP 300 — when in an antiperspirant preparation, not more than 0.4 per cent
73.	Iron and its salts and derivatives — in preparations containing 30 mg or less elemental iron per dosage unit or 5 ml oral liquid
74.	Juglans
75.	Ketoconazole and its salts — as a shampoo
76.	Lactic acid (CDSS) (in preparations in concentrations greater than 10 per cent — Schedule 3)
77.	Lidocaine (hydrochloride) and its salts — for topical use on the skin, including lozenge
78.	Linum usitatissimum
79.	Magaldrate
80.	Magnesium carbonate
81.	Magnesium chloride
82.	Magnesium citrate except for cathartics
83.	Magnesium hydroxide
84.	Magnesium oxide
85.	Magnesium trisilicate
86.	Menthol
87.	Menthyl anthranilate
88.	Merbromin (mercurochrome) solution — not more than 2 per cent
89.	Methyl salicylate (in liquid dosage forms in concentrations up to and including 30%)
90.	Methylbenzethonium chloride — when in an antiperspirant preparation not more than 0.25 per cent
91.	Methylene blue except for parenteral use
92.	Miconazole and its salts — for topical use
93.	Naphazoline (hydrochloride) and its salts — in oral preparations for adult use and in ophthalmic products
94.	Octyl methoxycinnamate
95.	Octyl salicylate
96.	Oil of eucalyptus
97.	Oxybenzone
98.	Oxymetazoline — in nasal preparations for adult use and in ophthalmic products, except for pediatric use
99.	Padimate O
100.	Pamabrom
101.	Pheniramine maleate and its salts
102.	Phenoxyethanol
103.	Phenyl salicylate
104.	Phenylephrine (hydrochloride) and salts and

	preparations for oral use, in nasal preparations for adults and in ophthalmic preparations in concentrations of 2.5 per cent or less
105.	Phosphorus (calcium hypophosphite)
106.	Phosphorus (calcium phosphate (dibasic))
107.	Phosphorus (potassium hypophosphite)
108.	Phosphorus (sodium hypophosphite)
109.	Phytolacca decandra
110.	Polyaminopropyl biguanide
111.	Polyethylene glycol (400) — for topical administration
112.	Polyhexanide
113.	Polymyxin B (polymyxin B sulfate) and its salts and derivatives — for topical use, or in oral cavity or nasal passages
114.	Polyoxypropylene-polyoxyethylene BL copolymer
115.	Polyquaternium-1
116.	Potassium acid tartrate (cream of tartar)
117.	Potassium bicarbonate — in preparations with not more than 5 mmol/single dose
118.	Potassium chlorate — in preparations with not more than 5 mmol/single dose
119.	Potassium chloride — as a salt substitute
120.	Potassium iodide — not more than 0.01 per cent when in salt substitutes
121.	Potassium nitrate (saltpetre)
122.	Pramoxine hydrochloride
123.	Propylene glycol — topical application
124.	Pyrilamine maleate
125.	Ranitidine and its salts — when sold in a dosage form containing not more than the equivalent of 75 mg of ranitidine
126.	Resorcinol
127.	Rhubarb root
128.	Salicylic acid and its salts — in topical preparations in concentrations up to/including 40 per cent
129.	Sanguinaria canadensis
130.	Seidlitz powders
131.	Selenium and its salts — in a preparation for internal use when sold as a nutritional supplement
132.	Selenium sulfide — when in an anti-dandruff preparation not more than 1 per cent
133.	Senecio aureus
134.	Senega
135.	Senna and its extracts and derivatives
136.	Silver acetate
137.	Sodium acid pyrophosphate
138.	Sodium fluoride — when in dentifrices not more than 0.25 per cent
139.	Sodium glycerophosphate
140.	Sodium phosphate except for cathartics
141.	Sodium potassium tartrate (rochelle salts)
142.	Sodium salicylate
143.	Sodium sulfate
144.	Spirit of aromatic ammonia
145.	Spirit of nitrous ether
146.	Squill
147.	Stannous fluoride — when in dentifrices not more than 0.4 per cent
148.	Storax
149.	Strontium chloride — when in dentifrices not more than 10 per cent
150.	Sulisobenzone
151.	Tannic acid

152.	Taraxacum officinale weber
153.	Tea tree oil
154.	Terpin hydrate
155.	Tetrahydrozoline hydrochloride — except in nasal preparations for pediatric use
156.	Tetrapotassium pyrophosphate
157.	Tetrasodium pyrophosphate
158.	Teucrium scorodonia
159.	Titanium dioxide
160.	Titanium dioxide coated mica
161.	Triclocarban
162.	Triclosan
163.	Trolamine salicylate
164.	Undecylenic acid
165.	Urea hydrogen peroxide
166.	Viburnum opulus
167.	Xanthoxylum
168.	Xylitol
169.	Xylometazoline hydrochloride — except for nasal preparations for pediatric use
170.	Yellow dock
171.	Zinc oxide
172.	Zinc phenolsulphonate
173.	Zinc pyridinethione — when in anti-dandruff preparations, not more than 2 per cent
174.	Zinc sulphate — in preparations containing 25 mg or less of elemental zinc
175.	Zirconium hydrochloride — when in an antiperspirant preparation, not more than 5 per cent

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