

Appendix 1:

Table Of Revisions To The Proposed DPRA Regulation

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PART I INTERPRETATION	PART I INTERPRETATION
<p>Interpretation “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</p>	<p>Interpretation “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 patientsthe public</p>
<p>“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</p>	<p>“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</p>
<p>“holder of the certificate” means the person to whom a certificate of accreditation has been issued;</p>	<p>Removed</p>
	<p>Added to s.1(1) “verbal prescription narcotic” means a verbal prescription narcotic as defined in the Narcotic Control Regulations under the <i>Controlled Drugs and Substances Act</i> (Canada).</p>
<p>“Remote dispensing location” 2. For purposes of the Act and this Regulation, “remote dispensing location” means:</p> <p>(a) in a pharmacy that is accredited as a community pharmacy, a place where drugs are dispensed or sold by retail to the public under the supervision of a pharmacist who is not physically present; and (b) in a pharmacy that is accredited as a hospital pharmacy, a place where drugs are dispensed or supplied to patients of the hospital under the supervision of a pharmacist who is not physically present.</p>	<p>“Remote dispensing location” 2. For purposes of the Act and this Regulation, “remote dispensing location” means: (a) in a pharmacy that is accredited as a community pharmacy, a place where drugs are dispensed or sold by retail to the public under the supervision of a pharmacist who is not physically present; and (b) in a pharmacy that is accredited as a hospital pharmacy, a place where drugs are dispensed or supplied to patients of the hospital under the supervision of a pharmacist who is not physically present.</p>
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<p align="center">CERTIFICATES OF ACCREDITATION: ISSUANCE AND RENEWAL</p>	<p align="center">CERTIFICATES OF ACCREDITATION: ISSUANCE AND RENEWAL</p>
<p>Classes of accreditation 7. (1) The following classes of accreditation are hereby established:</p> <p>(a) community pharmacy; and (b) hospital pharmacy.</p> <p>(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.</p>	<p>Classes of <u>certificates of</u> accreditation 7. (1) The following classes of <u>certificates of</u> accreditation are hereby established:</p> <p>(a) community pharmacy; and (b) hospital pharmacy.</p> <p>(2) A pharmacy that holds a certificate of accreditation to operate a pharmacy <u>is accredited by the College</u> as of the date this Regulation comes into force is deemed to be accredited as a community pharmacy.</p> <p><u>3) If an applicant intends to sell drugs by retail, the applicant shall apply for a certificate of accreditation of the community pharmacy class.</u></p> <p><u>(4) Only a certificate of accreditation of the community pharmacy class may permit the operation of a remote dispensing location.</u></p>
<p>Qualifications for the issuance of a certificate of accreditation of any class 8. (1) An applicant is qualified for the issuance of a certificate of accreditation to establish and operate a pharmacy of any class if:</p> <p>1. The applicant files a completed application in the form required by the College and pays the required fees.</p> <p>2. The applicant provides further information to the College if requested by the Registrar or the Accreditation Committee.</p> <p>3. All information provided by the applicant to the College is full, accurate and complete.</p> <p>4. The past and present conduct of each person who is an applicant, and in the case of a corporation, of each director, and of each shareholder who directly or indirectly owns five percent or more of the voting shares of that corporation, affords reasonable grounds for the belief that the pharmacy will be operated with decency, honesty and integrity and in</p>	<p>Qualifications for the issuance of a certificate of accreditation of any class 8. (1) An applicant is qualified for the issuance of a certificate of accreditation <u>of any class</u> to establish and operate a pharmacy of any class if:</p> <p>1. The applicant files a completed application in the form required by the College and pays the required fees.</p> <p>2. The applicant provides further information to the College if requested by the Registrar or the Accreditation Committee.</p> <p>3. All information provided by the applicant to the College is full, accurate and complete.</p> <p>4. The past and present conduct of each person who is an applicant, and in the case of a corporation, <u>I. of each director, and</u> II. <u>other than in the case of a corporation referred to in section 142(4) of the Act,</u> of each shareholder who directly or indirectly owns five percent or</p>

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<p>accordance with the law.</p>	<p>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.</p>
<p>Additional requirements, remote dispensing location 9. An applicant is qualified for the issuance of a certificate of accreditation to establish and operate a pharmacy of any class that permits the operation of remote dispensing locations if, in addition to the requirements set out in section 8, there are reasonable grounds for the belief that the applicant will be able to supervise all aspects of the operation of the proposed remote dispensing locations properly and effectively.</p>	<p>Additional requirements, remote dispensing location 9. An applicant is qualified for the issuance of a certificate of accreditation to establish and operate a pharmacy of any class that permits the operation of remote dispensing locations if, in addition to the requirements set out in section 8, there are reasonable grounds for the belief that the applicant will be able to supervise all aspects of the operation of the proposed remote dispensing locations properly and effectively.</p>
<p>Qualifications for renewal of any class 14. (1) An owner is qualified for the renewal of a certificate of accreditation if: (a) The owner files a completed application in the form required by the College and pays the required fees. (b) The owner provides further information to the College if requested by the Registrar or the Accreditation Committee, (c) All information provided by the owner to the College is full, accurate and complete. (d) There is no default in the payment of any fees required to be paid to the College or any money owed to the College concerning the pharmacy. (e) The criteria for the issuance of the certificate of accreditation continue to be satisfied. (f) The operation of the pharmacy is in compliance with the Act, the regulations under the Act and the by-laws of the College governing the establishment and operation of a pharmacy. (2) A certificate of accreditation shall not be</p>	<p>Qualifications for renewal of any class <u>certificate of accreditation</u> 14. (1) An owner is qualified for the renewal of a certificate of accreditation if: 1.(a) The owner files a completed application in the form required by the College and pays the required fees. 2.(b) The owner provides further information to the College if requested by the Registrar or the Accreditation Committee, 3.(c) All information provided by the owner to the College is full, accurate and complete. 4.(d) There is no default in the payment of any fees required to be paid to the College or any money owed to the College concerning the pharmacy. 5.(e) <u>The past and present conduct of each person who is an owner, and in the case of a corporation,</u> <u>(I) of each director, and,</u> <u>(II) other than in the case of a corporation referred to in section 142(4) of the Act, of each shareholder who directly or indirectly owns five percent or more of the voting shares of that</u></p>

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<p>renewed where an inspection of the pharmacy or of any of its remote dispensing locations has taken place under the Act and where the inspector identified a failure to conform to the requirements of the Act and its regulations that poses a risk of harm to the public, unless the Registrar is satisfied that such failure has been addressed either to the Registrar's satisfaction or, failing that, to the satisfaction of the Accreditation Committee.</p>	<p><u>corporation.</u></p> <p><u>affords reasonable grounds for the belief that the pharmacy will be operated with decency, honesty and integrity and in accordance with the law.</u> The criteria for the issuance of the certificate of accreditation continue to be satisfied.</p> <p>6.(f). The operation of the pharmacy is in compliance with the Act, the regulations under the Act and the by-laws of the College governing the establishment and operation of a pharmacy.</p>
<p>Standards for accreditation of any class 18. (1) The standards for accreditation are those set out in sections 19 to 23. (2) Every owner and designated manager shall ensure that the standards for accreditation of a pharmacy are maintained. (3) The additional standards for accreditation relative to a remote dispensing location are those set out in sections 24 to 27.</p> <p>STANDARDS FOR ACCREDITATION OF ANY CLASS</p> <p>Requirements of a pharmacy 19. Every pharmacy must,</p>	<p>Standards for accreditation of any class 18. (1) The standards for accreditation are those set out in sections 19 to 23. (2) Every owner and designated manager shall ensure that the standards for accreditation of a pharmacy are maintained. (3) The additional standards for accreditation relative to a remote dispensing location are those set out in sections 24 to 27.</p> <p>STANDARDS FOR ACCREDITATION OF ANY CLASS</p> <p>Requirements of a pharmacy 19. Every pharmacy must,</p>
<p>PART IV STANDARDS FOR ACCREDITATION AND OPERATION</p>	<p>PART IV STANDARDS FOR ACCREDITATION AND OPERATION</p>
<p>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 <i>Pharmacy Act, 1991</i> 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.</p> <p>(2) The records and documents referred to in subsection (1) shall be maintained in the pharmacy</p>	<p>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 <i>Pharmacy Act, 1991</i> 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.</p> <p>(2) The records and documents referred to in subsection (1) shall be maintained in the pharmacy</p>

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<p>in an electronic format and in a manner that is secure, auditable, traceable and allows for their easy retrieval.</p> <p>(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 its operation.</p>	<p>in an electronic format and in a manner that is secure, auditable, traceable and allows for their easy retrieval.</p> <p>(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 its operation.</p>
<p>Access and supervision</p> <p>24. A remote dispensing location shall only be accessible to the public or to hospital patients, as applicable, when a pharmacist:</p> <p>(a) is physically present in the pharmacy whose certificate of accreditation permits its operation; and</p> <p>(b) is communicating with pharmacy technicians, members of the public, or hospital patients, as applicable, at the remote dispensing location by means of a live, two-way audio-visual link.</p>	<p>Access and supervision, <u>remote dispensing locations</u></p> <p>24. A remote dispensing location shall only be accessible to the public or to hospital patients, as applicable, when a pharmacist:</p> <p>(a) is physically present in the pharmacy whose certificate of accreditation permits its operation; and</p> <p>(b) is communicating with pharmacy technicians <u>or</u> members of the public, or hospital patients, as at the remote dispensing location by means of a live, two-way audio-visual link.</p>
<p>Technology</p> <p>25. Every automated pharmacy system that is contained in a remote dispensing location must employ technology for the creation and transmission of a digitally scanned image of a paper-based prescription which has been approved by the Council for this purpose.</p>	<p>Technology, <u>remote dispensing locations</u></p> <p>25. Every automated pharmacy system that is contained in a remote dispensing location must employ technology for the creation and transmission of a digitally scanned image of a paper-based prescription which has been approved by the Council for this purpose as:</p> <p><u>(i) enabling verification of the prescription's authenticity; and</u></p> <p><u>(ii) ensuring the confidentiality and integrity of all personal information transmitted using the technology.</u></p>
<p>Controlled drugs, narcotic drugs and targeted substances</p> <p>26. No controlled drugs, narcotic drugs, verbal prescription narcotics or targeted substances shall be located at or available from a remote dispensing location.</p>	<p>Controlled drugs, narcotic drugs and targeted substances, <u>remote dispensing locations</u></p> <p>26. No controlled drugs, narcotic drugs, verbal prescription narcotics or targeted substances shall be located at or available from a remote dispensing location, <u>unless the remote dispensing location has safeguards in place that have been approved by the Council as preventing the unauthorized access to, or diversion of, such drugs and substances.</u></p>
<p>Information and notices to be displayed</p> <p>27. (1) At every remote dispensing location, contact information for the pharmacy under whose</p>	<p>Information and notices to be displayed, <u>remote dispensing locations</u></p> <p>27. (1) At every remote dispensing location, contact</p>

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<p>certificate of accreditation the remote dispensing location operates shall be clearly and prominently displayed.</p> <p>(2) The containers in which drugs are dispensed, supplied or sold from a remote dispensing location shall be clearly marked with,</p> <ul style="list-style-type: none"> (a) contact information for the pharmacy under whose certificate of accreditation the remote dispensing location operates, and (b) information identifying from which remote dispensing location the drug was dispensed, supplied or sold, as applicable. <p>(3) At every remote dispensing location operating under the certificate of accreditation of a pharmacy that is accredited as a community pharmacy, the notices required by the regulations under the <i>Drug Interchangeability and Dispensing Fee Act</i> shall be displayed, including at a remote dispensing location that operates without a dispensary.</p>	<p>information for the pharmacy under whose certificate of accreditation the remote dispensing location operates <u>and where the patient records are kept</u> shall be clearly and prominently displayed.</p> <p>(2) The containers in which drugs are dispensed, supplied or sold from a remote dispensing location shall be clearly marked with,</p> <ul style="list-style-type: none"> (a) contact information for the pharmacy under whose certificate of accreditation the remote dispensing location operates, and (b) information identifying from which remote dispensing location the drug was dispensed, supplied or sold, as applicable. <p>(3) At every remote dispensing location, <u>operating under the certificate of accreditation of a pharmacy that is accredited as a community pharmacy</u>, the notices required by the regulations under the <i>Drug Interchangeability and Dispensing Fee Act</i> shall be displayed, including at a remote dispensing location that operates without a dispensary.</p>
<p>PART V ADVERTISING</p>	<p>PART V ADVERTISING</p>
<p>Advertising requirements</p> <p>29. (1) No person shall advertise or permit, directly or indirectly, another person to advertise a pharmacy or its services in a manner that, (a) is false, misleading or deceptive, including as a result of the inclusion or omission of information;</p> <ul style="list-style-type: none"> (b) is not dignified and in good taste; (c) contains anything that cannot be verified; (d) contains testimonials, comparative statements or endorsements relating to the quality of drugs or services provided in the pharmacy or in any other pharmacy; (e) inappropriately uses a term, title or designation to indicate or imply that a member practising in the pharmacy has a specialization in the profession; or (f) contains any representations as to the safety or effectiveness or an indication for use of a Schedule I drug. <p>(2) Where an advertisement includes price</p>	<p>Advertising requirements</p> <p>29. (1) No person shall advertise or permit, directly or indirectly, another person to advertise a pharmacy or its services in a manner that, (a) is false, misleading or deceptive, including as a result of the inclusion or omission of information;</p> <ul style="list-style-type: none"> (b) is not dignified and in good taste; (c) contains anything that cannot be verified; (d) contains testimonials, comparative statements or endorsements relating to the quality of drugs or services provided in the pharmacy or in any other pharmacy; (e) inappropriately uses a term, title or designation to indicate or imply that a member practising in the pharmacy has a specialization in the profession; or (f) contains any representations as to the safety or effectiveness or an indication for use of a Schedule I drug.

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<p>information relating to a Schedule I drug the advertisement shall,</p> <p>(a) include the following information with respect to the drug:</p> <p>(i) the quantity, strength, brand name, and dosage form of the drug being advertised at the advertised price;</p> <p>(ii) the total cost for the drug to the purchaser including any dispensing fee; and</p> <p>(iii) the time period during which the advertised price will be available; and</p> <p>(b) give equal prominence to each drug advertised and, for each of those drugs, equal prominence shall be given to all the information required under paragraph (a).</p>	<p>(1)(2) Where an advertisement includes price information relating to a Schedule I drug, the advertisement shall <u>contain sufficient information to enable a reasonable member of the public to understand the price of the drug having regard to its quantity, strength, dosage and the fee for dispensing it, and the length of time the advertised price will be available.</u></p> <p>(a) include the following information with respect to the drug:</p> <p>(i) the quantity, strength, brand name, and dosage form of the drug being advertised at the advertised price;</p> <p>(ii) the total cost for the drug to the purchaser including any dispensing fee; and</p> <p>(iii) the time period during which the advertised price will be available; and</p> <p>(b) give equal prominence to each drug advertised and, for each of those drugs, equal prominence shall be given to all the information required under paragraph (a).</p> <p><u>(3) No person shall advertise the price of a Schedule I drug unless the advertisement also contains prices of a sufficient number of other drugs such that members of the public are not encouraged to obtain pharmacy services from a pharmacy, or to transfer their prescriptions between pharmacies, solely or principally on the basis of the price of a Schedule I drug.</u></p>
<p>PART VI PROPRIETARY MISCONDUCT</p>	<p>PART VI PROPRIETARY MISCONDUCT</p>
<p>Acts of proprietary misconduct</p> <p>32. The following are acts of proprietary misconduct for the purpose of section 140 of the Act:</p> <p>4. Failing to co-operate with an inspector of the College.</p> <p>7. Failing to keep records as required respecting the operation of the pharmacy and the patients and practice of members practising in the pharmacy.</p>	<p>Acts of proprietary misconduct</p> <p>32. The following are acts of proprietary misconduct for the purpose of section 140 of the Act:</p> <p>4. Failing to co-operate with an inspector <u>or investigator</u> of the College.</p> <p>7. Failing to keep records as required respecting the operation of the pharmacy <u>and/or</u> the patients <u>and/or</u> practice of members practising in the pharmacy.</p>

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<p>11. Disclosing prescription information to another person unless: (i) the disclosure is made in accordance with a written agreement between the owner and the person to whom the disclosure is made, and that agreement requires that any prescription information that is disclosed will not include anything that would be reasonably expected to identify a patient; and (ii) the designated manager or contact person of the pharmacy, as applicable, is aware of the existence of the written agreement referred to in paragraph 1.</p>	<p>11. Disclosing prescription information to another person unless: (i) the disclosure is made in accordance with a written agreement between the owner and the person to whom the disclosure is made, and that agreement requires that any prescription information that is disclosed will not include anything that would be reasonably expected to identify a patient; and (ii) the designated manager or contact person of the pharmacy, as applicable, is aware of the existence of the written agreement referred to in subparagraph 1(i).</p>
<p>PART VII INFORMATION, EXAMINATION AND AUDIT</p>	<p>PART VII INFORMATION, EXAMINATION AND AUDIT</p>
<p>Information return 36. The owner of a pharmacy shall, within 30 days of a written request from the Registrar, complete and file with the College a return in Form 1 (Return by Owner of a Pharmacy) as set out on the website of the College.</p>	<p>Removed</p>
<p>Examination and audit 37. (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 owner, the designated manager, or anyone acting on their behalf, including the information contained in the Form 1 return, is correct.</p>	<p>Examination and audit 37. (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 owner, the designated manager, or anyone acting on their behalf, including the information contained in the Form 1 return, is correct.</p>
<p>Schedule B PART I</p>	<p>Schedule B PART I</p>

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

ONTARIO REGULATION 58/11

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PART I INTERPRETATION

Interpretation

1. (1) In this Regulation,

“automated pharmacy system” means a mechanical system that performs operations or activities with respect to the storage and packaging of drugs or medications, and with respect to their dispensing or distribution directly to the public;

“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;

“medications” means drugs and other substances usually maintained in a pharmacy, including substances used in the compounding of drugs;

“National Drug Schedules” means the National Drug Schedules that are part of the National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as those Schedules are amended from time to time;

“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.

“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;

“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;

“targeted substance” means a targeted substance as defined in the Benzodiazepines and Other Targeted Substances Regulations under the *Controlled Drugs and Substances Act* (Canada); and

“verbal prescription narcotic” means a verbal prescription narcotic as defined in the Narcotic Control Regulations under the *Controlled Drugs and Substances Act* (Canada).

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

“Remote dispensing location”

2. For purposes of the Act and this Regulation, “remote dispensing location” means a place where drugs are dispensed or sold by retail to the public under the supervision of a pharmacist who is not physically present.

PART II DRUGS

Drug schedules

3. (1) Schedules I, II, III and U are established for the purposes of the Act.

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

1. The substances listed in Schedule I of the National Drug Schedules.
2. The substances listed in the Prescription Drug List.
3. The substances listed in the Schedules to the *Controlled Drugs and Substances Act* (Canada).

(3) The substances listed in Schedule II of the National Drug Schedules are prescribed as being included in Schedule II for the purposes of the Act.

(4) The substances listed in Schedule III of the National Drug Schedules are prescribed as being included in Schedule III for the purposes of the Act.

(5) The substances listed in the Unscheduled Category of the National Drug Schedules are prescribed as being included in Schedule U for the purposes of the Act.

(6) The substances listed in Schedules A and B to this Regulation are not drugs for the purposes of the Act.

(7) Despite clause (f) of the definition of “drug” in subsection 1 (1) of the Act, any substance that is a natural health product containing pseudoephedrine or its salts, or ephedrine or its salts, or any combination of any of them, is a drug for the purposes of the Act.

Location of Schedule I, II and III drugs

4. In a pharmacy that is accredited as a community pharmacy,

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

- (i) the dispensary, or
- (ii) where sold in a remote dispensing location, the dispensary or an automated pharmacy system,

(b) Schedule II drugs shall only be available for sale from,

- (i) the dispensary or other area in the pharmacy to which the public does not have access and which does not permit self-selection of drugs by patients, or
- (ii) where sold in a remote dispensing location, the dispensary or an automated pharmacy system,

(c) Schedule III drugs shall only be available for sale from,

- (i) the dispensary or an area in the pharmacy that allows for self-selection of drugs by patients and where a member is available for consultation, or
- (ii) where sold in a remote dispensing location, an area in the remote dispensing location to which the public does not have access.

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

6. In this Part,

“applicant” means each proposed owner of the pharmacy.

Classes of certificates of accreditation

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

- (a) community pharmacy; and
- (b) hospital pharmacy.

(2) A pharmacy that is accredited by the College as of the date this Regulation comes into force is deemed to be accredited as a community pharmacy.

(3) If an applicant intends to sell drugs by retail, the applicant shall apply for a certificate of accreditation of the community pharmacy class.

(4) Only a certificate of accreditation of the community pharmacy class may permit the operation of a remote dispensing location.

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

8. (1) An applicant is qualified for the issuance of a certificate of accreditation of any class to establish and operate a pharmacy if:

- 1. The applicant files a completed application in the form required by the College and pays the required fees.
- 2. The applicant provides further information to the College if requested by the Registrar or the Accreditation Committee.
- 3. All information provided by the applicant to the College is full, accurate and complete.
- 4. The past and present conduct of each person who is an applicant, and in the case of a corporation,
 - (I) of each director, and,
 - (II) other than in the case of a corporation referred to in section 142(4) of the Act, of each shareholder who directly or indirectly owns five percent or more of the voting shares of that corporation,

affords reasonable grounds for the belief that the pharmacy will be operated with decency, honesty and integrity and in accordance with the law.

(2) It is a condition for the issuance of a certificate of accreditation that the Registrar or the Accreditation Committee be satisfied that the pharmacy meets the applicable standards for accreditation.

Additional requirements, remote dispensing location

9. An applicant is qualified for the issuance of a certificate of accreditation to establish and operate a pharmacy that permits the operation of remote dispensing locations if, in addition to the requirements set out in section 8, there are reasonable grounds for the belief that the applicant will be able to supervise all aspects of the operation of the proposed remote dispensing locations properly and effectively.

Deemed reasonable grounds for belief

10. For the purposes of paragraph 4 of subsection 8 (1), and without limiting its generality, there shall be deemed to be reasonable grounds for the belief that the pharmacy will not be operated with decency, honesty and integrity and in accordance with the law where any one or more of the following has occurred:

1. A false or misleading statement or representation was made in the application or in any information provided to the College in respect of the application.
2. There was a failure or refusal to provide information requested under paragraph 2 of subsection 8 (1).

Issuance, name and address

11. (1) A certificate of accreditation shall be issued in the specific name of the person who owns the pharmacy and for the specific municipal address or addresses at which the pharmacy is to be operated.

(2) A certificate of accreditation that permits the operation of remote dispensing locations shall specify the locations of the permitted remote dispensing locations.

Amendment

12. If an owner wishes to:

- (a) operate a remote dispensing location where the certificate of accreditation does not already permit the operation of remote dispensing locations, or
- (b) operate a remote dispensing location at a location other than the location specified on the certificate of accreditation,

the owner shall apply for an amended certificate of accreditation.

Expiry of certificates of accreditation

13. (1) Subject to subsections (2) to (5), every certificate of accreditation automatically expires on the 10th day of May in each year unless renewed on or before that date.

(2) A certificate of accreditation shall be deemed to have expired if there is a permanent discontinuance of service at, or closure of, the pharmacy.

(3) The permission granted in a certificate of accreditation to operate a remote dispensing location shall be deemed to have expired if there is a permanent discontinuance of service at, or closure of, the pharmacy whose certificate of accreditation permits its operation.

(4) Where the Registrar refers an application for the renewal of a certificate of accreditation to the Accreditation Committee, the certificate of accreditation does not expire until the decision of the Accreditation Committee becomes final.

(5) Where the Accreditation Committee directs the Registrar not to renew the certificate of accreditation of a pharmacy, the certificate of accreditation shall be deemed to have expired as of the date the decision of the Accreditation Committee becomes final.

Qualifications for renewal of a certificate of accreditation

14. (1) An owner is qualified for the renewal of a certificate of accreditation if:

1. The owner files a completed application in the form required by the College and pays the required fees.

2. The owner provides further information to the College if requested by the Registrar or the Accreditation Committee.
3. All information provided by the owner to the College is full, accurate and complete.
4. There is no default in the payment of any fees required to be paid to the College or any money owed to the College concerning the pharmacy.
5. The past and present conduct of each person who is an owner, and in the case of a corporation,
 - (I) of each director, and,
 - (II) other than in the case of a corporation referred to in section 142(4) of the Act, of each shareholder who directly or indirectly owns five percent or more of the voting shares of that corporation,affords reasonable grounds for the belief that the pharmacy will be operated with decency, honesty and integrity and in accordance with the law.
6. The operation of the pharmacy is in compliance with the Act, the regulations under the Act and the by-laws of the College governing the establishment and operation of a pharmacy.

(2) A certificate of accreditation shall not be renewed where an inspection of the pharmacy or of any of its remote dispensing locations has taken place under the Act and where the inspector identified a failure to conform to the requirements of the Act and its regulations that poses a risk of harm to the public, unless the Registrar is satisfied that such failure has been addressed either to the Registrar's satisfaction or, failing that, to the satisfaction of the Accreditation Committee.

Removal of terms, conditions and limitations

15. Where terms, conditions and limitations are imposed on the certificate of accreditation, the Registrar may remove any or all of them,

- (a) where the Registrar is satisfied that the terms, conditions or limitations have been complied with;
or
- (b) with the approval of the Accreditation Committee.

Revocation

16. (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 or owner.

(2) The Accreditation Committee may direct the Registrar to revoke a certificate of accreditation where it is satisfied that it was issued or renewed based on the false or misleading information of an applicant or owner and where it is satisfied that it is appropriate to do so.

PART IV STANDARDS FOR ACCREDITATION

Remote dispensing locations

17. For greater clarity, every standard for accreditation that applies to a pharmacy applies to a remote dispensing location, unless the standard provides otherwise.

Standards for accreditation

18. (1) The standards for accreditation are those set out in sections 19 to 23.

(2) Every owner and designated manager shall ensure that the standards for accreditation of a pharmacy are maintained.

(3) The additional standards for accreditation relative to a remote dispensing location are those set out in sections 24 to 27.

STANDARDS FOR ACCREDITATION

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 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 its operation.

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

22. (1) Subject to subsection (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.

(2) A remote dispensing location in which all drugs are dispensed or distributed from an automated pharmacy system is not required to have a dispensary.

Lock and leave, pharmacies accredited as community pharmacies

23. Where, pursuant to subsection 146 (2) of the Act, a pharmacy that is accredited as a community pharmacy is operated without the supervision of a pharmacist who is physically present, the public shall be completely restricted, by physical impediments, from access to any drugs referred to in Schedule I, II or III that are in the pharmacy.

ADDITIONAL STANDARDS FOR ACCREDITATION THAT APPLY TO REMOTE DISPENSING LOCATIONS

Access and supervision, remote dispensing locations

24. A remote dispensing location shall only be accessible to the public when a pharmacist:

- (a) is physically present in the pharmacy whose certificate of accreditation permits its operation; and
- (b) is communicating with pharmacy technicians or members of the public, as applicable, at the remote dispensing location by means of a live, two-way audio-visual link.

Technology, remote dispensing locations

25. Every automated pharmacy system that is contained in a remote dispensing location must employ technology for the creation and transmission of a digitally scanned image of a paper-based prescription which has been approved by the Council for this purpose as:

- (a) enabling verification of the prescription's authenticity; and
- (b) ensuring the confidentiality and integrity of all personal information transmitted using the technology.

Controlled drugs, narcotic drugs and targeted substances, remote dispensing locations

26. No controlled drugs, narcotic drugs, verbal prescription narcotics or targeted substances shall be located at or available from a remote dispensing location, unless the remote dispensing location has safeguards in place that have been approved by the Council as preventing the unauthorized access to, or diversion of, such drugs and substances.

Information and notices to be displayed, remote dispensing locations

27. (1) At every remote dispensing location, contact information for the pharmacy under whose certificate of accreditation the remote dispensing location operates and where the patient records are kept shall be clearly and prominently displayed.

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

- (a) contact information for the pharmacy under whose certificate of accreditation the remote dispensing location operates, and
- (b) information identifying from which remote dispensing location the drug was dispensed, supplied or sold, as applicable.

(3) At every remote dispensing location, the notices required by the regulations under the *Drug Interchangeability and Dispensing Fee Act* shall be displayed, including at a remote dispensing location that operates without a dispensary.

PART V ADVERTISING

Definitions

28. In this Part and for the purposes of section 32,

“advertise” includes advertising through any medium and includes the publication, display, distribution or use of an advertisement;

“advertisement” includes an announcement, directory listing or other form of communication similar to an advertisement.

Advertising requirements

29. (1) No person shall advertise or permit, directly or indirectly, another person to advertise a pharmacy or its services in a manner that,

- (a) is false, misleading or deceptive, including as a result of the inclusion or omission of information;
- (b) is not dignified and in good taste;

- (c) contains anything that cannot be verified;
- (d) contains testimonials, comparative statements or endorsements relating to the quality of drugs or services provided in the pharmacy or in any other pharmacy;
- (e) inappropriately uses a term, title or designation to indicate or imply that a member practising in the pharmacy has a specialization in the profession; or
- (f) contains any representations as to the safety or effectiveness or an indication for use of a Schedule I drug.

(2) Where an advertisement includes price information relating to a Schedule I drug, the advertisement shall contain sufficient information to enable a reasonable member of the public to understand the price of the drug having regard to its quantity, strength, dosage, the fee for dispensing it, and the length of time the advertised price will be available.

(3) No person shall advertise the price of a Schedule I drug unless the advertisement also contains prices of a sufficient number of other drugs such that members of the public are not encouraged to obtain pharmacy services from a pharmacy, or to transfer their prescriptions between pharmacies, solely or principally on the basis of the price of a Schedule I drug.

ODBA information

30. Nothing in this Part prohibits the advertising of the co-payment or dispensing fee charged 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.

PART VI PROPRIETARY MISCONDUCT

Definition

31. In this Part, “prescription information” means information that relates to the prescribing and dispensing of drugs pursuant to prescriptions in a pharmacy.

Acts of proprietary misconduct

32. The following are acts of proprietary misconduct for the purpose of section 140 of the Act:

CERTIFICATES AND STANDARDS OF ACCREDITATION

1. Contravening a term, condition or limitation imposed on a certificate of accreditation.
2. Failing to maintain any of the standards of accreditation.

RELATIONSHIP WITH THE COLLEGE

3. Failing to reply within a reasonable time to a written or electronic inquiry or request from the College.
4. Failing to co-operate with an inspector or investigator of the College.
5. Failing to comply with an order of a Committee or a panel of a Committee of the College.
6. Failing to carry out or abide by an undertaking given to the College or breaching an agreement with the College, a Committee or a panel of a Committee of the College or the Registrar.

RECORDS AND INFORMATION PRACTICES

7. Failing to keep records as required respecting the operation of the pharmacy or the patients or practice of members practising in the pharmacy.
8. Falsifying a record relating to the pharmacy or a patient's health record.
9. Signing or issuing a document that contains a false or misleading statement.
10. Failing to keep confidential personal health information or other personal information concerning a patient, except with the consent of the patient or the patient's authorized representative or as otherwise permitted or required by law.
11. Disclosing prescription information to another person unless:
 - (i) the disclosure is made in accordance with a written agreement between the owner and the person to whom the disclosure is made, and that agreement requires that any prescription information that is disclosed will not include anything that would be reasonably expected to identify a patient; and
 - (ii) the designated manager or contact person of the pharmacy, as applicable, is aware of the existence of the written agreement referred to in subparagraph (i).
12. Failing to respond, or to respond accurately, to an inquiry about whether or not prescription information in the pharmacy is disclosed to third parties, or, where there is a response, failing to provide to the person making the inquiry either the nature of the information that is disclosed to third parties, or to whom such information is disclosed.

BUSINESS PRACTICES

13. Operating a pharmacy while in a conflict of interest as defined by sections 34 of this Regulation.
14. Submitting an account or charge that is false or misleading.
15. Charging a fee or an amount that is excessive in relation to the service or product provided.
16. Charging a person, including the executive officer under the *Ontario Drug Benefit Act*, more for a Schedule I drug than what was advertised, pursuant to subparagraph 29(2)(a)(ii), as the total cost for the drug including any dispensing fee.
17. Soliciting or permitting the solicitation of an individual unless,
 - (i) the person who is the subject of the solicitation is advised, at the earliest possible time during the communication, that the purpose of the communication is to solicit use of the pharmacy's services, and
 - (ii) the communication ends immediately if the person who is the subject of the solicitation so elects.
18. Entering into any agreement that restricts a person's choice of a pharmacy or pharmacist without the consent of that person.

PHARMACY SERVICES AND PROFESSIONALISM MATTERS

19. In a pharmacy that is accredited as a community pharmacy, returning to stock or selling or dispensing again a drug that was previously sold or dispensed, except that it will not be proprietary misconduct to
 - (i) return to stock or re-sell or re-dispense a drug that does not require refrigeration, that is listed on Schedule II or Schedule III and that is in its original, unopened packaging, or
 - (ii) accept the return of a drug from a patient for purposes of re-packaging and re-dispensing the drug to the same patient, as long as that the drug is suitable for re-packaging.
20. In a pharmacy that is accredited as a hospital pharmacy, returning to stock or selling or dispensing again a drug, that was previously sold or dispensed, except that it will not be proprietary misconduct to return to stock or re-sell or re-dispense a drug

- (i) that is returned to the pharmacy in a sealed dosage unit or container as originally dispensed,
 - (ii) that is returned with the labelling intact and includes a legible drug lot number and expiry date, and
 - (iii) the integrity of which can be verified.
21. Dispensing, selling or compounding a drug, or administering a substance, that is not of good quality or does not meet the standards required by law, or, in the case of a drug, does not contain a substance that the drug is meant to contain.
 22. 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.
 23. Permitting, counselling or assisting a person who is not a member to represent himself or herself as a member or to perform a controlled act that the person is not authorized to perform.
 24. Inappropriately using a term, title or designation in respect of the practice of a member practising in the pharmacy.
 25. Inappropriately using a term, title or designation indicating or implying that a member practising in the pharmacy has a specialization in the profession.

MISCELLANEOUS MATTERS

26. Contravening the Act, the *Pharmacy Act, 1991*, the *Regulated Health Professions Act, 1991*, the *Narcotics Safety and Awareness Act, 2010*, the *Drug Interchangeability and Dispensing Fee Act*, the *Ontario Drug Benefit Act* or the regulations under those Acts.
27. Contravening any federal, provincial or territorial law or any municipal by-law,
 - (i) with respect to the distribution, purchase, sale, or dispensing or prescribing of any drug product, the administering of any substance, or the piercing of the dermis,
 - (ii) the purpose of which is to protect or promote public health, or
 - (iii) that is otherwise relevant to the operation of the pharmacy or the provision of pharmacy services.
28. Using, or knowingly permitting the premises in which a pharmacy is located, or the area adjacent to such a premise to be used, for unlawful purposes.
29. Permitting, consenting to, approving, counselling or assisting, whether expressly or by implication, the commission of an offence against any Act relating to the practice of pharmacy or the sale of drugs.
30. Engaging in conduct or performing an act relevant to the operation of a pharmacy that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional.

Conflict of interest, definitions

33. In this section, and in sections 34 and 35,

“benefit” means any incentive or inducement of more than nominal value, whether direct or indirect, and includes a rebate, credit or gift;

“child” means a child within the meaning of the *Family Law Act*;

“non-arm's length relationship” means a relationship between two parties such that one party has the ability to exercise, directly or indirectly, control or significant influence over the operating and financial decisions of the other party and includes a relationship between a responsible person and a related person or a related corporation;

“parent” means a parent within the meaning of the *Family Law Act*;

“related corporation” means a corporation wholly or substantially owned or controlled, whether directly or indirectly, by the responsible person or a related person of the responsible person;

“related person” means any person who has one of the following relationships to the responsible person or to the spouse of the responsible person, whether based on blood, marriage, common-law or adoption:

- (a) A child or the spouse of a child.
- (b) A grandchild or the spouse of a grandchild.
- (c) A parent or the spouse of a parent.
- (d) A grandparent or the spouse of a grandparent.
- (e) sibling or spouse of a sibling;

“responsible person” means the designated manager and the owner of the pharmacy;

“spouse” means,

1. a spouse as defined in section 1 of the *Family Law Act*, or
2. either of two persons who live together in a conjugal relationship outside marriage.

Conflict of interest

34. It is a conflict of interest for a responsible person to do, or to cause or permit another person to do, directly or indirectly, any of the following:

- (a) refer a patient to another person if the responsible person, or a person in a non-arm’s length relationship with the responsible person, requests, accepts or receives a benefit by reason of the referral;
- (b) offer, make or confer a benefit to a person by reason of the referral of a patient to a pharmacy with which the responsible person is associated;
- (c) offer, make or confer a benefit to a patient in relation to the sale of a drug or the provision of pharmacy services other than,
 - (i) an adjustment in the fee or amount that would otherwise be charged with regard to that patient for that drug or that professional pharmacy service, or
 - (ii) the provision to a patient, at no charge, of an item of a nominal value, to be used in maintaining or promoting well-being or health;
- (d) enters into any agreement or arrangement that influences or encourages, or appears to influence or encourage, a prescriber to promote the services of the pharmacy with which the responsible person is associated;
- (e) enters into any agreement or arrangement that adversely influences or appears to adversely influence the exercise of professional expertise or judgment or the ability of a member working in the pharmacy to engage in the practice of the profession in an ethical manner or in accordance with the standards of practice of the profession.

Examples of not being in conflict

- 35.** (1) No conflict of interest arises under subclause 34 (a) or (b),

- (a) solely as a result of a referral to a person who is in a non-arm's length relationship with the responsible person where,
 - (i) no direct benefit is received by the responsible person, and
 - (ii) before making the referral, the nature of the relationship between the responsible person and the person in the non-arm's length relationship is disclosed to the patient; or
- (b) solely as a result of a referral from a person who is in a non-arm's length relationship with the responsible person where,
 - (i) no direct benefit is received by the responsible person, and
 - (ii) before any pharmacy services are provided, the nature of the relationship between the responsible person and the person in the non-arm's length relationship is disclosed to the patient.

(2) No conflict of interest arises under section 34 in connection with the paying of rent with respect to premises leased for the purposes of operating a pharmacy if the rent reflects the normal rent payable for the same type of premises in the same geographical area.

(3) No conflict of interest arises under section 34 in connection with a responsible person or a related person or a related corporation having a financial interest in the manufacturer, vendor or supplier of a drug or substance if,

- (a) before any pharmacy services are provided in relation to the drug or substance, the fact of the financial interest is disclosed to the patient; or
- (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 none of the responsible person, a related person, a related corporation, or any combination thereof, wholly or substantially owns the corporation, or has the ability to exercise, directly or indirectly, control or significant influence over its operating or financial decisions.

**PART VII
EXAMINATION AND AUDIT**

Examination and audit

36. (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 owner, the designated manager, or anyone acting on their behalf is correct.

(2) Where the Registrar appoints a person under subsection (1), the owner and the designated manager shall co-operate fully and shall provide to the person appointed all evidence, vouchers, records, books, documents and papers that may be 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.

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.	Attapulgate (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.	Guaiifenesin
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

SCHEDULE B

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 tetrachlorohydrate glycine
14.	Aluminum zirconium trichlorohydrate glycine
15.	Ammonium bicarbonate
16.	Ammonium carbonate
17.	Ammonium chloride
18.	Ammonium hydroxide (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.	Bioflavonoids
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.	Pyrimidine 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