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STANDARDS AND GUIDELINES

TITLE:	COMPOUNDING
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Note to Readers: In the event of any inconsistency between this document and the legislation that affects homeopathic practice, the legislation governs.

College publications contain practice parameters and standards which should be considered by all Ontario homeopaths in the care of their patients and in the practice of the profession. College publications are developed in consultation with the profession and describe current professional expectations. It is important to note that these College publications may be used by the College or other bodies in determining whether appropriate standards of practice and professional responsibilities have been maintained.

POLICY

Registrants who compound substances into medicines[1] on their premise for dispensing to their individual patients are expected to follow the Standards of Practice for Compounding to ensure patient protection through safe, ethical and competent practices.

INTENT

The intent of this standard is to provide guidance to Registrants, who compound substances into medicines for their individual patients, on how to perform the procedure safely, ethically and competently.

PREAMBLE

College Standards

The College of Homeopaths of Ontario has set standards to ensure the public that the process of compounding substances into medicines for individual patient use is performed safely, ethically and competently. The key elements of good compounding include qualified and trained personnel, adequate premises and space,

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[1] Medicine: Refers to homeopathic medicine, homeopathic remedy, homeopathic preparation and homeopathic drug as per the Evidence for Homeopathic Medicines Guidance Document (Health Canada, 2007) as well as products that the homeopath may compound, dispense or recommend for the individual use of the patient.

In the context of this standard the term "medicine" (as defined above) is not considered to have the same definition as "drug" is defined in the Drug and Pharmacies Regulation Act, Ontario Regulation 58/11.

The Canadian Food and Drug Act (R.S.C., 1985, CF-27) clarifies the use of language of homeopathic medicine in relation to natural health products. Portions of the Natural Health Products Regulations are included at the end of this document. For more information visit the Health Canada website at www.hc-sc.gc.ca or contact Health Canada Natural Health Products Directorate.

appropriate compounding procedures and instructions, suitable equipment, labels and containers, and accurate documentation. If a Registrant is compounding individual or small batch medicines for their own patient they are exempt from the Natural Health Products Regulation.

In addition to College standards homeopaths must, in the course of their practice, refer to and adhere to: Health Canada's Policy on Compounding, the Food and Drug Act, and the Drug and Pharmacies Regulation Act. Additional information is also available on Health Canada's Natural Health Product Raw Material Policy[2].

On the matter of compounding, drugs and the dispensing of drugs there are federal and provincial responsibilities as noted below.

Federal Responsibilities

As part of the Health Products and Food Branch of Health Canada, the Natural Health Products Directorate (NHPD) is the regulating authority for natural health products (NHPs) for sale in Canada.

NHPs are regulated under their own specific regulations, the Natural Health Products Regulation (NHPR), which take into account the unique nature and properties of these products.

The NHPR set out the standards and requirements that must be met by all companies wishing to market NHPs in Canada. Health Canada assesses each NHP for quality, safety and efficacy before it is issued a product licence.

Health Canada is also responsible for issuing site licences to Canadian sites that manufacture, package, label and import large quantities of NHPs.

The NHPD recognizes the need to clearly define what is meant by compounding and to outline the implications and scope of this concept. The NHP Compounding Policy[3] clarifies the distinction between the manufacturing and compounding of NHPs, including whether or not a site licence is required for a particular activity.

Provincial/Territorial Responsibilities

The practice of homeopathy falls within provincial/territorial jurisdiction. The province is responsible for developing standards for the practice of health professionals, including the practice of homeopathy. The practice of compounding is also within provincial/territorial jurisdiction.

Compounding is a process whereby a health care practitioner mixes or prepares health products to an exact specification tailored to a patient's needs. Compounding is an activity performed by a health care practitioner in the context of a practitioner-patient relationship. The activity of compounding and the product resulting from it are a provincial/territorial responsibility. A site licence is therefore not required to compound, and the compounded

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[2] Health Canada website at https://www.canada.ca/en/health-canada.html

[3] Health Canada's Natural Health Products Compounding Policy: Describes how a homeopath compounds. Available at https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/policies/compounding-policy.html

product does not require a product licence to be sold. Responsibility for the safety, efficacy and quality of the compounded product is assumed by the health care practitioner.

The practice of compounding is excluded from the scope of NHP Regulations through the manufacturer definition.

Natural Health Products Regulation

Federal legislation under the Canadian *Natural Health Products Regulations* was created after many consultations with Canadian consumers, academics, health care practitioners and industry stakeholders. They address Canadians' concerns about Natural Health Products (NHPs) availability and safety.

To be legally sold in Canada, all natural health products must have a product licence, and the Canadian sites that manufacture, package, label and import these products must have site licences.

To get product and site licences, specific labelling and packaging requirements must be met, good manufacturing practices must be followed, and proper safety and efficacy evidence must be provided.

The licensing requirements of the *Natural Health Products Regulations* apply to any person or company that manufactures, packages, labels and/or imports NHPs for commercial sale in Canada. These requirements do not apply to health care practitioners who compound products on an individual basis for their patients, or to retailers of NHPs.[4]

For more information on the NHPs regulations contact the Natural Health Products Branch of Health Canada.

DESCRIPTION OF STANDARD

1. Competence
   - 1.1 The Registrant shall have the knowledge, skill and judgment to compound.
   - 1.2 The Registrant ensures that every person to whom they assign the compounding of substances into medicines has the necessary knowledge, skill and judgment.

2. Compounding
   - 2.1 The Registrant ensures every person who compounds substances into medicines follows the College's Standard on Infection Control which includes:
     - 2.1.1 Cleaning procedures for the area, tools and receptacles where substances are compounded into medicines;
     - 2.1.2 Instructions for the compounding of substances into medicine and proper sanitary handling of materials;
     - 2.1.3 Minimum requirements of health and hygienic behaviour; and
     - 2.1.4 Utilizing readily disinfected, non-porous containers for storage.

[4] Health Canada website at https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/policies/compounding-policy.html

2.2 The principles of compounding contained in these standards relate for single and complex compounds and medicines.

3. Premises

3.1 The compounding area shall be clean, sanitary, orderly and of sufficient space to perform the compounding activity involved.
3.2 Premises shall permit effective cleaning of all surfaces.
3.3 Premises shall prevent contamination of substances or medicines and the inadvertent addition of extraneous material to the medication.

4. Equipment

The tools and receptacles with which medicines are compounded are designed, constructed, maintained, arranged, and used in a manner that:
4.1 Permits the effective cleaning of all parts and surfaces.
4.2 Limits potential contamination of substances or medicines.
4.3 All packaging and containers used for substances or medicines are inert food-grade containers complying with Health Canada standards and guidelines, and stored in such a way as to avoid contamination.

5. Personnel

5.1 Registrants that compound or assign compounding activities to technical staff shall have the knowledge, skill, and judgment to be responsible for the preparation of the product.
5.2 Registrants shall act within their skills and competencies and use their professional judgment when deciding whether they have the expertise to compound a specific medicine and shall be aware of good compounding principles.
5.3 Registrants lacking the resources to compound substances into medicine may order product for the patient or may direct the patient to obtain product from another Registrant or appropriate source.
5.4 The Registrant shall gather sufficient information to make knowledgeable decisions regarding the formulation and process of compounding. Formulations shall be accessed from a reputable source. If no formulation is available, a formula shall be completed using the Registrant's knowledge, training, and judgment.

6. Ingredients

6.1 All substances are stored in a controlled-access area and in such a way as to avoid contamination.
6.2 No contaminated, disintegrated or decomposed substances may be used.
6.3 The Registrant shall be able to distinguish materials that require specialized handling and storage and demonstrate safe handling techniques.
6.4 The Registrant shall ensure the quality of the ingredients by using products with a standard designation or equivalent pharmacopoeia standard.[5]

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[5] Sales of 94% overproof alcohol is "restricted solely to those who require ethyl alcohol of that strength for research, experimental, scientific, chemical, therapeutic or commercial manufacturing purposes" and is available in from the Liquor Control Board of Ontario (LCBO). For more information regarding the Purchasing Requirements of Global Alcool-94 (LCBO #378323) please call the helloLCBO team by phone at 1-800-668-5226 or (416) 365-5900 or by webform.

7. Sanitation

7.1 The practice shall have available a written sanitation program consistent with the College's Standard of Practice on Infection Control to include cleaning requirements for the premises and equipment as well as the safe disposal of consumables pursuant to prevailing environmental guidelines.

7.2 No person who is infected with or is a carrier of a disease in a communicable form[6], or who has an uncovered, open lesion on any exposed surface of the body, shall have access to any area where a substance is being compounded into a medicine.

7.3 Written procedures detailing the minimum requirements for health and hygienic behaviour of individuals performing compounding activities shall be documented. This shall include, but not be limited to:

a. Suitable dress (e.g. masks, gloves, footwear);
b. Hand washing; and
c. Open sores.

8. Record Keeping

8.1 All records shall be maintained in accordance with the College's Guideline on Record Keeping and Privacy of Information.

8.2 Every Registrant who compounds product shall maintain a log containing a record of the distribution of each medicine compounded that enables the Registrant to issue a recall if necessary. The record shall include the manufacturer's name, name of the original substance(s) used, potency, and lot number. These records shall be retained for a minimum of ten years from the date of the prescription.

8.3 Where a complaint respecting the quality of a medicine is received, a record of the complaint and action taken is retained by the Registrant for a period of at least ten years in an incident file and a copy placed in the patient chart.

9. Packaging

9.1 The packaging shall be appropriate for the stability of the product and proper patient use.

10. Labeling

10.1 Product labels shall follow all federal and provincial requirements.

10.2 Information on the container must include:

10.2.1 The Registrant's name and telephone number;
10.2.2 Patient's name;
10.2.3 Name of the medicine;
10.2.4 Date the medicine was compounded;
10.2.5 Potency;
10.2.6 Directions for the proper use of the substance; and
10.2.7 Any cautionary information about the substance.

10.3 This information may be included in a label affixed to the product, or where space is limited, information may be provided on an accompanying sheet.

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[6] As listed in the Health Protected and Promotions Act, Ontario Regulation 135/18.

RELEVANT COMPETENCIES

Note to Readers: The performance indicators listed below each competency are examples of the possible indicators which demonstrate performance consistent with the competency. The list of performance indicators is not exhaustive. For complete information please refer to College documents *Competency Profile for Entry-to-Practice Homeopaths Practising in Ontario* (February 27, 2012) and *Performance Indicators* (March 2012).

2.23 Understand handling, dispensing and storage of medicines as set out in the professional practice guidelines. (S)
RELEVANT PERFORMANCE INDICATORS
1. Identify factors that may inactivate medicines.
2. Identify factors that may contaminate medicines.
3. Explain the process of grafting.
4. Explain the process of compounding.
5. Identify types of storage materials that may be used to contain medicines.

DEFINITIONS

For the purpose of this standard the following definitions apply:

Compounding

"Compounding" is generally understood as a process whereby a health-care practitioner mixes or prepares health products (natural, medicinal, etc.) to an exact specification tailored to a patient's needs, and in a vehicle desired (cream, lotion, gel, drops, capsules, pellets, etc.). Compounding is generally used to:

1. Provide products unavailable or not readily available in the specifications needed by a practitioner (e.g., strength) to address the specific health concerns, symptoms and needs of a particular patient, and/or to meet the specific requirements of a particular health care practice;
2. Provide products free of preservatives, dyes and chemical allergens; and
3. Prepare palatable flavoured dosage forms.
   (Health Canada, Natural Health Products Directorate, October 2006)

Grafting

"Grafting" is a process of medicating blank pellets. (Yasgur, 1998)

Homeopath

"Homeopath" means a registrant of the College of Homeopaths of Ontario.

Hygiene

"Hygiene" means the conditions or practices conducive to maintaining health and preventing disease, especially through cleanliness.

Medicine

"Medicine" refers to homeopathic medicine, homeopathic remedy, homeopathic preparation and homeopathic drug as per the Evidence for Homeopathic Medicines Guidance Document (Health Canada, 2007) as well as products that the homeopath may compound, dispense or recommend for the individual use of the patient.

Registrant
A Registrant is a member of the College of Homeopaths of Ontario.

Sanitary
"Sanitary" means hygienic; free from or designed to kill or protect against germs, infection, etc.[7]

Sanitation
"Sanitation" is a process that reduces micro-organisms on an inanimate object to a safe level (e.g., dishes and eating utensils are sanitized).

Scope of Practice
"Scope of Practice" encompasses the services that its practitioners are educated, competent and authorized to provide. (National Physiotherapy Advisory Group, 2009) In the *Homeopathy Act, 2007* a registrant's scope of practice is defined as "the assessment of body system disorders and treatment using homeopathic techniques to promote, maintain or restore health."

Substances
"Substances" may include, but is not limited to, raw materials, ingredients and vehicles, medicinal and non-medicinal, mother tinctures, powders, fluid/solid extracts, base creams, salves, and ointments, blank homeopathic pellets, alcohol.

RELEVANT DOCUMENTS
#1 Guideline on Record Keeping and Privacy of Information

LEGISLATIVE CONTEXT
Regulated Health Professions Act, 1991 (RHPA), S.O. 1991, CHAPTER 18, s. 27
Health Protection and Promotions Act, Ontario Regulation 135/18, Ontario Regulation 501/17 and Ontario Regulation 557 (143/18) Communitable Diseases General
Homeopathy Act, 2007, Ontario Regulation 315/12 Professional Misconduct:

23. Failing to keep records in accordance with the standards of the profession.

Health Canada
Natural Health Products Regulations
SOR/2003-196 - Food and Drug Act - Registration 2003-06-05
Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1) of the *Food and Drugs Act*, hereby makes the annexed *Natural Health Products Regulations*.

[7] Canadian Oxford Dictionary, 2nd Edition, 2004. Oxford University Press.

INTERPRETATION

1. (1) The following definitions apply in these Regulations.

"natural health product"

"natural health product" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in

(*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
(*b*) restoring or correcting organic functions in humans; or
(*c*) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Food and Drug Regulations under the *Food and Drugs Act* (Canada)

91. Every product number required by these Regulations to be shown on a label of a natural health product shall

(*a*) in the case of a homeopathic medicine, be preceded by the designation "DIN-HM"; and
(*b*) in any other case, be preceded by the designation "NPN".

SCHEDULE 2(Subsection 1(1))
Excluded natural health product substances

ITEM	SUBSTANCES
1.	A substance set out in Schedule C to the Act
2.	A substance set out in Schedule D to the Act, except for the following: (*a*) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and (*b*) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy
3.	[Repealed, SOR/2018-132, s. 3]
4.	A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*
5.	A substance that is administered by puncturing the dermis
6.	An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic
7.	*Cannabis* as defined in subsection 2(1) of the *Cannabis Act*, except for a derivative or a product made from a

ITEM	SUBSTANCES
	derivative that is exempt from the application of the *Cannabis Act* under the *Industrial Hemp Regulations* and that does not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid
8.	Anything referred to in Schedule 2 to the *Cannabis Act* that contains more than 10 µg/g THC, an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid

SOURCE

College of Naturopaths of Ontario
Ontario College of Pharmacists