Compounding

Intent

To advise Registrants who incorporate the controlled act of compounding in their naturopathic practice of the requirements to perform the procedure safely, ethically and competently.

Definitions

Cold Chain Management: A temperature, humidity and light-controlled supply chain for products that require a specific temperature range during distribution and storage.

Compounding: The process by which a Registrant creates a prescribed substance or non-prescription substance of unique properties by combining two or more existing prescribed substances and/or non-prescription substances.

Prescribed Substance: For the purpose of this standard, is anything referred to in Table 1, 2 or 5 of the *General Regulation*.

Manufacturer: A company or person who produces or processes a natural health product for sale. This does not include a health care professional who compounds a substance for sale to a patient.

Non-Prescription Substance: Anything publicly available and not listed in the *General Regulation*. This may include botanical tinctures, botanical powders or loose herbs, fluid/solid extracts, base creams, salves and ointments, homeopathic remedies, pharmaceutical-grade ethyl alcohol, vitamins, minerals and amino acids. A non-prescription substance also includes any item listed on the National Association of Pharmacy Regulatory Authorities (NAPRA) schedules 2, 3 or U.

STANDARD 1

The Registrant who compounds within the context of their naturopathic practice has acquired and maintains the knowledge, skill and judgment necessary to compound prescribed substances or non-prescription substances safely, ethically, and competently.

A Registrant demonstrates the standard by:

- Having met the College's requirements for compounding prescribed substances through successful completion of the College approved prescribing and therapeutics course and examination, when compounding prescribed substances listed on Table 1, 2 or 5 of the General Regulation.
- maintaining competency for performing the procedure by engaging in continuing education and/or incorporating compounding as a regular part of their practice, and
- ensuring that they are appropriately trained and competent in relevant emergency procedures and appropriate risk management processes are in place to assist in managing any adverse reactions or complications resulting from the administration or use of the compounded prescribed substance or non-prescription substance.

STANDARD 2

The Registrant minimizes the risks to the patient, self and others that are associated with the compounding of prescribed substances and non-prescription substances, before, during and after the procedure.

A Registrant demonstrates the standard by:

- having a naturopathic doctor-patient relationship with the patient for whom the compounded prescribed substance or non-prescription substance is being made,
- considering the patient's condition, the risks and benefits and any other relevant circumstances specific to the patient before compounding,
- ensuring the quality of the ingredients by using substances approved for use in Canada,
- ensuring that no prescribed substance or non-prescription substance is made available for sale unless the expiry date for each prescribed substance or non-prescription substance is at least 1 month past the date on which the patient is expected to finish taking the prescribed substance or non-prescription substance.
- ensuring that compounding is performed in an aseptic preparation area using aseptic techniques based on current evidence-based infection control protocols to minimize the risk of contamination,
- ensuring cold chain management, as appropriate,
- ensuring that all prescribed substances and non-prescription substances used for compounding are stored in a controlled-access area,
    - all prescribed substances and non-prescription substances to be compounded for injection and require refrigeration are stored in a dedicated refrigerator that contains only these prescribed substances and non-prescription substances.
- ensuring the tools and receptacles with which prescribed substances or non-prescription substances are compounded are designed, constructed, maintained, arranged, and used in a manner that:
    - permits the effective cleaning of all surfaces using appropriate cleaning agents, and
    - limits potential contamination of prescribed substances or non-prescription substances.
- ensuring all packaging and containers used for prescribed substances and non-prescription substances are free of identified toxic substances food-grade, appropriate to maintain the preparation's stability, integrity, and storage conditions, and stored in such a way as to avoid contamination,
- providing the compounded prescribed substance directly to the patient or the patient's authorized representative, and
- ensuring documentation in the patient record in accordance with the *Standard of Practice: Record Keeping*.

STANDARD 3

The Registrant complies with the rules and regulations applicable to compounding for Naturopathic Doctors in Ontario.

A Registrant demonstrates the standard by:

- using only the prescribed substances listed on Table 1, 2 or 5 in the *General Regulation*, subject to any limitations, routes of administration and dosages set out in the table, when compounding with one or more prescribed substances,
- advising the patient that the a Health Canda approved product or substance may be alternatively compounded at a pharmacy,
- ensuring that the compounded prescribed substance provides a customized therapeutic solution for patient care and does not duplicate an approved prescribed substance except to provide access to a necessary commercially prepared prescribed substance during periods of reduced or no supply,
- complying with College regulations, policies and standards of practice when compounding a prescribed substance for injection,
- ensuring that the compounded product complies with all relevant sections of the Food and Drugs Act including section 3 – prohibited advertising; 8 – prohibited sales of drugs; 9 – deception regarding drugs and 11- unsanitary manufacture of drugs (Appendix IV), and

- not using the authorized act of compounding as a means to bypass the federal drug review and approval system.

STANDARD 4

The Registrant ensures that all required information is included with the compounded product.

A Registrant demonstrates the standard by:

Including the following information with all products they have compounded. This information may be included on a label affixed to the product, or where space is limited, provided on an accompanying sheet.

- an identification number, if applicable,
- Registrant's name, title, address, and telephone number,
- name of the person who compounded the product,
- patient's name,
- name and strength of the prescribed substances or non-prescription substances, and any other ingredients used, and manufacturer where applicable,
- date the prescribed substances or non-prescription substances were compounded,
- amount or percentage of each prescribed substance, non-prescription substance, and any other ingredients,
- quantity of the compounded product in the container,
- expiration date based on known sterility and stability data,
- directions for the proper use of the compounded product including its dose, frequency, route of administration and any special instructions,
- directions for proper storage of the compounded product, and
- any cautionary information about the compounded product.

APPENDIX I

TABLE 1
PRESCRIBED SUBSTANCES THAT MAY BE ADMINISTERED BY INHALATION

Substance	Limitations
Acetylcysteine	No limitation specified.
Glutathione	No limitation specified.
Ipratropium Bromide	Administered to a patient by the member in his or her office only in emergency circumstances. In an emergency, administer a maximum daily dose of 0.5 mg but only after the member has administered Salbutamol to the patient.
Salbutamol	Administered to a patient by the member in his or her office only in emergency circumstances. In an emergency, administer a maximum of two doses, each dose 2.5 mg.
Saline	No limitation specified.
Therapeutic Oxygen	No limitation specified.

APPENDIX II

TABLE 2
PRESCRIBED SUBSTANCES THAT MAY BE ADMINISTERED BY INJECTION

Substance	Route of Administration	Limitation
Acetylcysteine	Intravenous	Must be in combination with other amino acids.
Adenosine triphosphate	Intravenous	No limitation specified.
Alanine	Intravenous	Must be in combination with other amino acids.
Alpha Lipoic Acid	Intravenous	Maximum daily dose of 600 mg for racemic form or 300 mg for R form.
Arginine	Intravenous	Must be in combination with other amino acids.

Aspartic Acid	Intravenous	Must be in combination with other amino acids.
Atropine	Intravenous	Administered to a patient by the member in his or her office only in emergency circumstances. In an emergency, administer 0.5-1 mg q3-5 min. Dose must be 0.5 mg or higher but must not exceed 2 mg.
Biotin	Intravenous	No limitation specified.
Calcium Chloride	Intravenous	No limitation specified.
Calcium Gluconate	Intravenous	No limitation specified.
Calcium Glycerophosphate	Intravenous	No limitation specified.
Carbohydrates in sodium chloride solution	Intravenous	No limitation specified.
Chromium	Intravenous	No limitation specified.
Copper Sulfate	Intravenous	No limitation specified.
Cupric Chloride	Intravenous	No limitation specified.
Dextrose Injection	Intravenous	No limitation specified.
Diphenhydramine Hydrochloride	Intravenous, Intramuscular	Administered to a patient by the member in his or her office only in emergency circumstances with a maximum dose of 100 mg.
Epinephrine Hydrochloride	Intramuscular	Administered to a patient by the member in his or her office only in emergency circumstances with a maximum dose of 1.5 mg.
Ferrous Sulphate	Intramuscular	Must be administered by z-track only.
Folic Acid	Intravenous, Intramuscular	No limitation specified.
Glutamine	Intravenous	Must be in combination with other amino acids.
Glutamic Acid	Intravenous	Must be in combination with other amino acids.
Glycine	Intravenous	Must be in combination with other amino acids.
Glutathione	Intravenous, Intramuscular	No limitation specified.
Histidine	Intravenous	Must be in combination with other amino acids.
Hydrochloric Acid	Intravenous	In ratio of 1:1000 or 1:500.
Isoleucine	Intravenous	Must be in combination with other amino acids.
L-Tryptophan	Intravenous	No limitation specified.

Lactated Ringer's Solution	Intravenous	No limitation specified.
Leucine	Intravenous	Must be in combination with other amino acids.
Levocarnitine and its salts	Intravenous	No limitation specified.
Lysine	Intravenous	Must be in combination with other amino acids.
Magnesium Sulfate	Intravenous, Intramuscular	Must never be administered by the member for the treatment of eclampsia or pre-eclampsia.
Magnesium Chloride	Intravenous, Intramuscular	Must never be administered by the member for the treatment of eclampsia or pre-eclampsia.
Manganese	Intravenous	No limitation specified.
Methionine	Intravenous	Must be in combination with other amino acids.
Molybdenum	Intravenous	No limitation specified.
Ornithine	Intravenous	Must be in combination with other amino acids.
Phenylalanine	Intravenous	Must be in combination with other amino acids.
Potassium Chloride	Intravenous	In dosage form not more than 0.3 mEq/kg/hr. Must never be administered as a single agent or by intravenous push.
Potassium Phosphate	Intravenous	In dosage form not more than 0.3 mEq/kg/hr. Must never be administered as a single agent or by intravenous push.
Proline	Intravenous	Must be in combination with other amino acids.
Ringer's Solution (sodium, chloride, potassium and calcium)	Intravenous	No limitation specified.
Saline Solution	Intravenous, Intramuscular	No limitation specified.
Selenium	Intravenous	No limitation specified.
Serine	Intravenous	Must be in combination with other amino acids.
Sodium Bicarbonate	Intravenous	No limitation specified.
Sodium Iodide	Intravenous	Must be in combination with other minerals.
Sterile Water	Intravenous, Intramuscular	Must be in combination with other substances.
Strontium and its salts	Intravenous	No limitation specified.

Taurine	Intravenous	No limitation specified.
Threonine	Intravenous	Must be in combination with other amino acids.
Tyrosine (L-tyrosine)	Intravenous	Must be in combination with other amino acids.
Vanadium	Intravenous	Must be in combination with other minerals.
Viscum Album	Intravenous, Subcutaneous	No limitation specified.
Vitamin A	Intravenous	Maximum daily dose of 10,000 International Units.
Vitamin B1	Intravenous, Intramuscular	No limitation specified.
Vitamin B2	Intravenous, Intramuscular	No limitation specified.
Vitamin B3	Intravenous, Intramuscular	No limitation specified.
Vitamin B5	Intravenous, Intramuscular	No limitation specified.
Vitamin B6	Intravenous, Intramuscular, Subcutaneous	No limitation specified.
Vitamin B12	Intravenous, Intramuscular	No limitation specified.
Vitamin C	Intravenous	Must administer no more than 15 g per day when patient's G6PD is deficient.
Vitamin D	Intravenous, Intramuscular	No limitation specified.
Vitamin E	Intravenous	No limitation specified.
Vitamin K1	Intramuscular	No limitation specified.
Zinc Chloride	Intravenous	No limitation specified.
Zinc Sulphate	Intravenous	No limitation specified.

APPENDIX III

TABLE 5
DRUGS THAT MAY BE COMPOUNDED

Drug	Limitations, routes of administration, dosages.
Adenosine triphosphate	Only if compounded for intravenous injection.

Colchicine	Must not be compounded unless the drug is botanical colchicine compounded from the corm of colchicum autumnale.
Dextrose Injection	Only if compounded when in concentrated solution for intravenous injection.
Digitalis Purpurea and its glycosides	Only if compounded in conjunction with monitoring of the patient's serum levels by the member.
Estrogen (bioidentical)	Only if compounded in topical or suppository form.
Folic Acid	Only if compounded in oral dosage containing more than 1.0 mg of folic acid per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 1.0 mg of folic acid.
L-Tryptophan	Only if compounded for patient's use in oral dosage form at a concentration of more than 220 mg per dosage unit or per daily dose. Recommended daily dose must not exceed 12g and must be provided in 3 to 4 equally divided doses. May also be compounded as a single ingredient intended for intravenous injection.
Levocarnitine and its Salts	Only if compounded for the treatment of primary or secondary levocarnitine deficiency.
Pancreatin	Only if compounded in a dosage that provides more than 20,000 USP units of lipase activity per dosage unit or for the treatment of pancreatic exocrine insufficiency.
Pancrelipase	Only if compounded in a dosage that provides more than 20,000 USP units of lipase activity per dosage unit or for the treatment of pancreatic exocrine insufficiency.
Pilocarpine and its salts	Must not be compounded unless, 1. the drug is botanical pilocarpine, compounded from the leaves of pilocarpus microphyllus, 2. the member monitors his or her patient's serum levels during treatment with the drug and, 3. the drug is never compounded to treat a patient with glaucoma.
Podophyllotoxin	Must not be compounded unless, 1. the drug is botanical podophyllotoxin, compounded from podophyllum peltatum and, 2. the drug is never compounded to treat a patient with rheumatoid arthritis.
Progesterone (bioidentical)	Only if compounded in topical or suppository form.
Rauwolfia	No limitation, etc., specified.
Thyroid	No limitation, etc., specified.
Vitamin A	Only if compounded in oral dosage containing more than 10,000 International Units of Vitamin A per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 10,000 International Units of Vitamin A.
Vitamin D	Only if compounded in oral dosage form containing more than 2,500 International Units of Vitamin D per dosage form or where the largest recommended daily dosage shown on the label would

	result in the daily intake by that patient of more than 2,500 International Units of Vitamin D.
Vitamin K1	Only if compounded in oral dosage where the maximum daily dose is more than 0.120 mg.
Vitamin K2	Only if compounded in oral dosage where the maximum daily dose is more than 0.120 mg.
Yohimbine and its salts	Must not be compounded unless the drug is botanical yohimbine, compounded from the bark of pausinystalia yohimbine.

APPENDIX IV

Foods, Drugs, Cosmetics and Devices

Prohibited advertising

3 (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.1.

Prohibited sales

(2) No person shall sell any food, drug, cosmetic or device if

- **(a)** it is represented by label as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.1; or
- **(b)** the person advertises it to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.1.

Prohibited sales of drugs

8 No person shall sell any drug that

- **(a)** was manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or
- **(b)** is adulterated.

Deception, etc., regarding drugs

9 (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Unsanitary manufacture, etc., of drug

11 No person shall manufacture, prepare, preserve, package or store for sale any drug under unsanitary conditions.