The College of Naturopaths of Ontario

Standard of Practice:

Compounding

Introduction

The intent of this standard is to advise Members of the requirements to compound drugs or substances listed on Table 5 of the General Regulation safely, ethically and competently.

Compounding is a component of the controlled act: "Prescribing, dispensing, compounding or selling a drug designated in the regulations." *(Regulated Health Professions Act, 1991, S.O. 1991, CHAPTER 18, s. 27).*

Members are authorized to compound drugs or substances under the *Naturopathy Act, 2007, S.O. 2007, CHAPTER 10, Sched. P, s. 4.1.*

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 member creates a drug or substance of unique properties by combining two or more existing drugs and/or substances.

Drug: For the purposes of this Standard of Practice, a drug 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 the purpose of sale. This does not include a health care professional who compounds a substance for the purpose of selling to a patient.

Substance: For the purposes of this Standard of Practice a substance is anything that is publicly available without a prescription and not listed on Tables 1, 2 or 5 of the General Regulation. This may include botanical tinctures, botanical powders or loose herbs, fluid/solid extracts, base creams, salves and ointments, homeopathic remedies, blank homeopathic pellets, pharmaceutical grade ethyl alcohol.

1. Competency

The Member has the knowledge, skill and judgment to compound drugs or substances safely, ethically and competently.

The Member does not use the authorized act of compounding as a means to bypass the federal drug review and approval system.

Performance Indicators

Prior to compounding drugs, the Member is in compliance with the Standard of Practice for Prescribing.

2. Safety Considerations

The Member will minimize the risks to the patient, self and others that are associated with the compounding of drugs and substances, before, during and after the procedure.

Performance Indicators

The Member:

- develops and applies current evidence-based infection control protocols to minimize risk factors for infection or contamination when compounding;
- when compounding a drug for injection, does so in accordance with applicable regulations, College policies and guidelines;
- when compounding drugs ensures the quality of the ingredients by using products produced from an authorized drug or active pharmaceutical ingredient approved for use in Canada;
- ensures 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 drug;
- ensures that he/she is appropriately trained and competent in relevant emergency procedures and has appropriate risk management processes in place to assist in managing any adverse reactions or complications;
- ensures that no drug or substance is made available for sale unless the expiry date for each drug or substance is at least 1 month past the date on which the patient is expected to finish taking the drug or substance;
- ensures that no expired drug or substance is made available for sale;
- ensures that the compounding is performed in an aseptic preparation area using aseptic techniques to minimize the risk of contamination;
- ensures cold chain management, where appropriate;
- ensures that the drugs or substances used have been obtained and stored in accordance with applicable laws; and
- ensures that all drugs and substances which are open and being used for the purposes of compounding are stored in a controlled-access area.

The Member has a Naturopathic Doctor-patient relationship with the patient for whom the compounded drug or substance is being made.

3. Compounding

The Member ensures good compounding practices are in place.

Performance Indicators

Before compounding a drug or substance, the Member considers the patient's condition, the risks and benefits and any other relevant circumstances specific to the patient.

The Member advises the patient that the drug may be compounded at a pharmacy.

The Member:

- ensures that the compounded drug provides a customized therapeutic solution for patient care and does not duplicate an approved drug. However, when there is a shortage or no supply of a commercially available drug and the Member determines the need for this drug, the drug may be compounded during the period of shortage;
- ensures that no drugs or substances are compounded in order to be sold to third parties;
- ensures that all drugs included in a compound for the purposes of inhalation are listed, and are in accordance with any limitations, on Table 1 of the General Regulation;
- ensures that all drugs included in a compound for the purposes of injection are listed, and are in accordance with any limitations, on Table 2 of the General Regulation;
- ensures that all drugs included in a compound for the purposes of oral or topical use are listed, and are in accordance with any limitations, on Table 5 of the General Regulation;
- ensures the tools and receptacles with which drugs or 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;
    - limits potential contamination of drugs or substances.
- ensures all packaging and containers used for drugs and substances are free of identified toxic substances (i.e. PVC or BPA), food grade, and stored in such a way as to avoid contamination; and
- provides the compounded drug directly to the patient or the patient's authorized representative.

4. Labeling

The Member ensures that all required information is included with all drugs or substances that are compounded.

Performance Indicators

The following information is included with all drugs or substances that are compounded. 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.

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

Related Standards & Guidelines

Consent
Delegation
Dispensing
Infection Control
Injection
IV Infusion Therapy
Prescribing
Record Keeping
CONO Policy on AED
CONO Policy on Laminar Air Flow Hood

Legislative Framework

General Regulation
Naturopathy Act, 2007
Professional Misconduct Regulation
Quality Assurance Regulation
Regulated Health Professions Act, 1991
Food and Drug Act
Occupational Health and Safety Act
Health Products and Food Branch Inspectorate Policy on Manufacturing and Compounding Drug Products in Canada POL-0051
Health Canada Drug Product Database
Environment Canada Toxic Substances List

Disclaimer
In the event of any inconsistency between this standard and any legislation that governs the practice of Naturopathic Doctors, the legislation shall govern.