



Clinical Practice Standard: Designing, Compounding and Dispensing Herbal Medicines and Natural Health Products

This Clinical Practice Standard applies to:

- traditional Chinese medicine and naturopathic medicine licensees who design, compound, dispense and/or recommend herbal medicines and/or natural health products as outlined in Principles 1, 2, 3, 4 and 5;
- chiropractic licensees who may recommend and dispense natural health products as adjuncts to treatment within their authorized scope of practice as outlined in Principles 1, 2 and 3.

This Clinical Practice Standard does not apply to Indigenous cultural, ceremonial, or traditional healing practices.

Principle	Outcome Statement
As a CCHPBC licensee, you must meet the following Principles within the Clinical Practice Standard: Designing, Compounding and Dispensing Herbal Medicines and Natural Health Products	People receiving health services from CCHPBC licensees expect that their health care practitioner will:
Principle 1: Licensees must meet all ethical, legal and professional standards related to herbal medicines and/or natural health products	Incorporate the use of herbal medicines and/or natural health products safely and ethically and in compliance with all requirements.



Principle 2: Licensees must provide patients with sufficient information about herbal medicines and/or natural health products to support informed decision making, collaborative care and safe use.	Provide clear, understandable, accurate and relevant information about herbal medicines and/or natural health products to support safe use, informed decision making and collaborative care.
Principle 3: Licensees who dispense or store herbal medicines and/or natural health products must establish and maintain quality assurance processes that support safety throughout sourcing, storage, and dispensing.	Dispense herbal medicines and/or natural health products that meet established standards for quality and safety.
Principle 4: Licensees who design herbal medicines and/or natural health products for compounding must provide clear, complete and accurate instructions to support safe preparation, dispensing and use.	Ensure that instructions for herbal medicines and/or natural health products are written accurately and completely with ingredients clearly listed to support safe preparation and use.
Principle 5: Licensees who compound herbal medicines and/or natural health products must establish and maintain quality assurance processes that support the safe preparation, packaging, and use of compounded products.	Prepare herbal medicines and/or natural health products in a hygienic environment that prioritizes safety.

Definitions

additional training: refers to structured education with an objective assessment of knowledge and skill beyond entry-level competency that includes both theoretical and practical components including:

- theory and principles of the technique and/or approach
- assessment and diagnosis
- treatment
- proper handling, including storage and preparation, of substances when applicable
- risk and management as applicable



compound: means

- (a) with respect to an herb, to mix the herb and/or natural health product with a least one other ingredient, and
- (b) in any other case, to mix two or more ingredients

continuing professional development: means an activity or program undertaken for the purpose of ensuring that professional knowledge, skills and abilities remain current

design: with respect to herbal medicine and natural health products, includes to determine:

1. the appropriate herb, formulae and/or natural health product including the proportions of those ingredients.
2. the method of preparation, route of administration and frequency of delivering the ingredient(s)

dispense: with respect to herbal medicine and natural health products, includes:

- (a) to prepare and/or sell herbal medicine and/or natural health products referred to in the design and/or recommendation of an herb, herbal formulae and/or natural health product,
- (b) to provide herbal medicine and/or natural health products to a person for the purpose of self-administration or administration to or by another person,
- (c) to take steps to ensure the therapeutic suitability of an herbal medicine and/or natural health product for its intended use, and
- (d) to take steps to ensure an herb, herbal formulae and/or natural health product's proper use

health care team: refers to regulated or unregulated health care practitioners as well as traditional and cultural practitioners

herbal medicine: a single herb or an herbal formula containing two or more herbal ingredients, used in whole, processed, or extract forms for the prevention, treatment, or management of diseases, disorders, and conditions, and for the maintenance or promotion of health



natural health product: a product that has been licensed for sale by Health Canada with a Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) on the label

recommend: with respect to natural health products means:

- a) to provide advice regarding the suitability of a Health Canada licensed natural health product including vitamins and minerals, as adjuncts to treatment.

substance: includes air and water, but does not include a drug

Principle 1: Licensees must meet all ethical, legal and professional standards when related to herbal medicines and/or natural health products

To meet this standard, licensees must:

- 1.1 Hold one (or more) of the CCHPBC licence classes of: Doctor of Traditional Chinese Medicine: Full, Traditional Chinese Medicine Practitioner: Full, Traditional Chinese Medicine Herbalist: Full, Naturopathic Medicine: Full, or Chiropractic: Full.
- 1.2 Comply with all relevant laws and legislation; including:
 - 1.2.1 The *Natural Health Products Regulations* ;
 - 1.2.2 The *Food and Drugs Act*;
 - 1.2.3 The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); and
 - 1.2.4 The *Complementary Health Professionals Regulation* (including with respect to limits and conditions set out by the College).
- 1.3 Design and/or recommend only those herbal medicines and/or natural health products that are authorized within the licensee's scope of practice and within the licensee's individual competence.
- 1.4 Maintain competence to support safe practice through continuing professional development, including obtaining additional training when required.
- 1.5 Design and/or recommend herbal medicines and/or natural health products in consideration of:
 - 1.5.1 diagnosis and/or patient condition;
 - 1.5.2 patient age;
 - 1.5.3 dosage and duration;



- 1.5.4 contraindications;
- 1.5.5 precautions and interactions;
- 1.5.6 adverse effects; and
- 1.5.7 toxicity.
- 1.6 Document in the patient health care record:
 - 1.6.1 the name(s) of the herbs, herbal formula(e) and/or natural health product(s) designed and/or recommended;
 - 1.6.2 the dose, frequency, timing and duration of the herbs, herbal formula(e) and/or natural health product(s) designed and/or recommended;
 - 1.6.3 the patient's response to the herbal medicines and/or natural health products, as appropriate; and
 - 1.6.4 follow-up recommendations.
- 1.7 Where the documentation in the patient health care record uses the botanical and/or Latinate names of the herbs, or the Pinyin, botanical and/or Latinate names of traditional Chinese medicine herbs as per the Chinese pharmacopoeia, ensure that record entries are produced in English upon request by a patient, College or third party.
- 1.8 Participate in required provincial and/or national reporting programs (e.g. Canada Vigilance Program).

Principle 2: Licensees must provide patients with sufficient information about herbal medicines and/or natural health products to support informed decision making, collaborative care and safe use.

To meet this standard, licensees must:

- 2.1 Hold one (or more) of the CCHPBC licence classes of Doctor of Traditional Chinese Medicine: Full, Traditional Chinese Medicine Practitioner: Full, Traditional Chinese Medicine Herbalist: Full, Naturopathic Medicine: Full, or Chiropractic: Full.
- 2.2 Provide patients with sufficient information to do their own research and discuss with other health care practitioners or members of their health care team to make an informed decision, including:
 - 2.2.1 For herbal medicines, the name of each herb or ingredient in English, Pinyin, botanical and/or Latinate name, as appropriate;
 - 2.2.2 The expected action of the herbal medicine(s) and/or natural health product(s);



- 2.2.3 The toxicity of the herbal medicine and/or natural health product, as appropriate;
- 2.2.4 The dosage, frequency, timing and duration of the herbal and/or natural health product therapy;
- 2.2.5 Directions for use including route of administration as appropriate;
- 2.2.6 Specific precautions or instructions related to the therapy including potential side-effects and/or adverse reactions (e.g. allergic reactions) and action to take if they occur;
- 2.2.7 Potential interactions between the herbal medicine(s) and/or natural health product(s) including but not limited to:
 - 2.2.7.1 foods,
 - 2.2.7.2 other herbs and/or natural health products, and
 - 2.2.7.3 drugs and/or other substances.

Principle 3: Licensees who dispense and/or store herbal medicines and/or natural health products must establish and maintain quality assurance processes that support safety throughout sourcing, storage, and dispensing.

To meet this standard, licensees must:

- 3.1 Hold one (or more) of the CCHPBC licence classes of Doctor of Traditional Chinese Medicine: Full, Traditional Chinese Medicine Practitioner: Full, Traditional Chinese Medicine Herbalist: Full. Naturopathic Medicine: Full, or Chiropractic: Full.
- 3.2 Source herbal medicines and/or natural health products in a manner that ensures products are safe, accurately identified, and of acceptable quality.
- 3.3 Before dispensing take reasonable steps to verify the identity, quality and suitability of herbal medicines and/or natural health products.
- 3.4 Maintain records sufficient to support traceability of herbal medicines and/or natural health products that are dispensed.
- 3.5 Store herbal medicines and/or natural health products in conditions that preserve their quality, stability, and integrity, including by:
 - 3.5.1 Storing herbal medicines and/or natural health products in a manner that prevents contamination, deterioration, adulteration, and unauthorized access;
 - 3.5.2 Implementing measures to prevent contamination, cross-contamination, misidentification, and dispensing errors;



- 3.5.3 Removing from use any herbal medicine and/or natural health products that are expired, contaminated, deteriorated, or otherwise unsuitable for use; and
- 3.5.4 Ensuring equipment, utensils, containers, and surfaces are clean and suitable for their intended purpose.

Principle 4: Licensees who design herbal medicines and/or natural health products for compounding must provide clear, complete and accurate instructions to support safe preparation, dispensing and use.

To meet this standard, licensees must:

- 4.1 Hold one (or more) of the CCHPBC licence classes of Doctor of Traditional Chinese Medicine: Full, Traditional Chinese Medicine Practitioner: Full, Traditional Chinese Medicine Herbalist: Full, or Naturopathic Medicine: Full.
- 4.2 Provide herbal medicine and/or natural health product instructions that contain sufficient information to support accurate preparation and safe use including:
 - 4.2.1 Licensee's name, business address, telephone number and date of the prescription, including an expiration date;
 - 4.2.2 The name of the patient and parent/guardian where applicable;
 - 4.2.3 The name of each ingredient, including:
 - 4.2.3.1 For herbal medicines, the name of each herb and/ or natural health product ingredient;
 - 4.2.3.2 For traditional Chinese medicine herbs, the name of the herb in Chinese characters or Pinyin, and/or its botanical or Latinate name as identified in the *Chinese pharmacopoeia*;
 - 4.2.3.3 The part of the herb or plant to be used when applicable;
 - 4.2.3.4 The exact species, when multiple plant species share the same name;
 - 4.2.3.5 The form of processing, where applicable;
 - 4.2.3.6 Abbreviations only if they are well established and consistently understood by compounding facilities and/or dispensaries;
 - 4.2.4 The quantity of each ingredient with measurement units clearly indicated;
 - 4.2.5 The form of the herb and/or natural health product (whole/raw, powdered, granule, tincture, etc.);
 - 4.2.6 Special preparation instructions where applicable;
 - 4.2.7 Number of packets, bottles or doses including:
 - 4.2.7.1 frequency, interval or maximum daily dose;



- 4.2.7.2 number of refills where applicable; and
- 4.2.7.3 route of administration instructions and precautions.

Principle 5: Licensees who compound herbal medicines and/or natural health products must establish and maintain quality assurance processes that support the safe preparation, packaging, and use of compounded products.

To meet this standard, licensees must:

- 5.1 Hold one (or more) of the CCHPBC licence classes of Doctor of Traditional Chinese Medicine: Full, Traditional Chinese Medicine Practitioner: Full, Traditional Chinese Medicine Herbalist: Full, or Naturopathic Medicine: Full.
- 5.2 Compound herbal medicines and/or natural health products in a clean, sanitary, and appropriately maintained environment including:
 - 5.2.1 Implementing measures to prevent contamination, cross-contamination, misidentification, and compounding errors;
 - 5.2.2 Ensuring equipment, utensils, containers, and preparation surfaces are clean and suitable for their intended purpose;
- 5.3 Before compounding, take reasonable steps to verify the identity and quality of herbal medicines and/or natural health products;
- 5.4 Ensure compounded herbal medicine(s) and/or natural health products are appropriately prepared, packaged and labelled to support their safe use and storage including:
 - 5.4.1 the name of patient and compounding date;
 - 5.4.2 where multiple packages are compounded, label packages to ensure the patient can readily identify each package;
 - 5.4.3 where products are intended to be used, prepared or administered in a specific sequence, label packages and provide instructions sufficient to support appropriate use;
 - 5.4.4 appropriate route of administration instructions, precautions and storage instructions, where applicable.