Dispensing and Selling

Intent

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

This standard applies to:

a) Dispensing and selling prescribed substances included in Table 4 (dispensing) and Table 6 (selling) of the *General Regulation*, or non-prescription substances or devices to a patient, or someone who is not a patient when filling a prescription or recommendation from another Registrant.

Definitions

Dispensing: To provide prescribed substances, non-prescription substances, or devices for specific treatments. This includes the packaging, labeling and security necessary to safeguard the prescribed substances, non-prescription substances, or devices provided.

Prescribed Substance: For the purpose of this standard is anything referred to in Table 4 (Appendix I) or 6 (Appendix II) 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 to sell to a patient.

Recommendation: An advised course of treatment using non-prescription substances.

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 dispenses or sells prescribed substances, non-prescription substances or devices within the context of their naturopathic practice has acquired and maintains the knowledge, skill, and judgment necessary to perform the procedure safely, ethically, and competently.

A Registrant demonstrates the standard by:

- having the necessary knowledge, skill and judgment when dispensing or selling non-prescription substances,
- meeting the College's requirements for dispensing and selling prescribed substances listed in Tables 4 or 6 of the *General Regulation* through successful completion of the College approved prescribing and therapeutics course and examination, and
- maintaining competency for performing the procedure by engaging in continuing education and/or incorporating dispensing and selling as a part of their practice.

STANDARD 2

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

A Registrant demonstrates the standard by:

- having a naturopathic doctor-patient relationship with the patient. If no such relationship exists:
    - the Registrant possesses the prescription/recommendation from another Registrant for the prescribed substance, non-prescription substance or device,
    - verifies and documents the accuracy and validity of the prescription/recommendation before dispensing and selling the prescribed substance, non-prescription substance or device, and
    - retains a copy of the prescription/recommendation.
- only dispensing and selling a compounded prescribed substance or non-prescription substance directly to their patient or patient's authorized representative,
- ensuring that the prescribed substances, non-prescription substances, and devices dispensed and sold have been obtained and stored in a controlled-access area and in accordance with the manufacturer's recommendations,
- ensuring that the prescribed substances or non-prescription substances dispensed and sold have not expired and will not expire before the date on which the patient is expected to use the last of the product,
- dispensing and selling prescribed substances, non-prescription substances, or devices in accordance with any limitations listed in the *General Regulation*,
- not dispensing or selling prescribed substances, non-prescription substances, or devices while being in an unmanaged conflict of interest,
- not selling a prescribed substance for a profit or a direct or indirect personal or financial benefit, and
- when selling a prescribed substance or non-prescription substance, ensuring that the patient is aware that they may choose to purchase the prescribed substance or non-prescription substance from another location.

STANDARD 3

The Registrant ensures that all required information is included with all prescribed substances, non-prescription substances, or devices that are dispensed.

A Registrant demonstrates the standard by:

ensuring that the following information is included with all prescribed substances or non-prescription substances that are dispensed. This information may be included on a label affixed to the product, or where space is limited, on an accompanying sheet:

- an identification number, if applicable,
- dispensing Registrant's name and title,
- the clinic name, address, and telephone number from which the product was dispensed,
- patient's name,
- name of product, strength, quantity, and manufacturer if available,
- date the prescribed substances, non-prescription substances, or devices were dispensed,
- expiration date,
- directions for the proper use of the prescribed substance, non-prescription substance or device including dose, frequency, route of administration and any special instructions, and
- any cautionary information about the prescribed substance or non-prescription substance.

Where the information is already present on the label of a finished product it need not be duplicated.

APPENDIX I

TABLE 4
DRUGS THAT MAY BE DISPENSED

Drug	Limitations, routes of administration, dosages
Colchicine	Must not be dispensed unless the drug is botanical colchicine, compounded from the corm of the colchicum autumanle.
Digitalis Purpurea and its glycosides	Only if dispensed in conjunction with monitoring of patient's serum level by the member.
Estrogen (bioidentical)	Only if dispensed in topical or suppository form.
Folic Acid	Only if dispensed 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 dispensed 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.
Levocarnitine and its salts	Only if dispensed for the treatment of primary or secondary levocarnitine deficiency.
Pancreatin	Only if dispensed in a dosage form 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 dispensed in a dosage form 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 dispensed unless, 1. the dispensed drug botanical pilocarpus compounded from the leaves of pilocarpus microphyllus, 2. the member monitors his or her patient's drug levels during treatment with the drug and, 3. the drug is never dispensed to treat a patient with glaucoma.
Podophyllotoxin	Must not be dispensed unless, 1. the dispensed drug is botanical podophyllotoxin compounded from podophyllum peltatum and, 2. the drug is never dispensed to treat a patient with rheumatoid arthritis.
Progesterone (bioidentical form)	Only if dispensed in a topical or suppository form.
Rauwolfia	No limitation, etc., specified.

Thyroid	No limitation, etc., specified.
Vitamin A	Only if dispensed 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 dispensed 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 dispensed in oral dosage when the maximum daily dose is more than 0.120 mg.
Vitamin K2	Only if dispensed in oral dosage when the maximum daily dose is more than 0.120 mg.
Yohimbine and its salts	Must not be dispensed unless the dispensed drug is botanical yohimbine compounded from the bark of pausinystalia yohimbine.

APPENDIX II

TABLE 6
DRUGS THAT MAY BE SOLD

Drug	Limitations, routes of administration, dosages.
Colchicine	Must not be sold unless the drug is botanical colchicine, compounded from the corm of colchicum autumnale.
Digitalis Purpurea and its glycosides	Only if sold in conjunction with monitoring of the patient's serum levels by the member.
Estrogen (bioidentical)	Only if sold in topical or suppository form.
Folic Acid	Only if sold 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 sold 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 three to four equally divided doses.
Levocarnitine and its Salts	Only if sold for the treatment of primary or secondary levocarnitine deficiency.

Pancreatin	Only if sold in a dosage form 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 sold in a dosage form 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 sold 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 sold to treat a patient with glaucoma.
Podophyllotoxin	Must not be sold unless, 1. the drug is botanical podophyllotoxin, compounded from podophyllum peltatum and, 2. the drug is never sold to treat a patient with rheumatoid arthritis.
Progesterone (bioidentical form)	Only if sold in topical or suppository form.
Rauwolfia	No limitation, etc., specified.
Thyroid	No limitation, etc., specified.
Vitamin A	Only if sold 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 sold 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 sold in oral dosage where the maximum daily dose is more than 0.120 mg.
Vitamin K2	Only if sold in oral dosage where the maximum daily dose is more than 0.120 mg.
Yohimbine and its salts	Must not be sold unless the drug is botanical yohimbine compounded from the bark of pausinystalia yohimbine.