Ontario Regulation Module

Prescribing, Dispensing, Compounding, Selling, Administering by Injection or Inhalation

TRANSITIONAL COUNCIL OF
The College of Naturopaths of Ontario

1. Overview

The purpose of this presentation is to provide NDs with an overview of the drugs that they can prescribe, dispense, compound, sell and administer by injection or inhalation under the General Regulation.

2. Prescribing a Drug

2.1 Prescribing Drugs and Recommending NHPs

- A ND in Ontario, who has met the Standard of Practice for Prescribing, can provide a patient a prescription for any of the drugs listed in Table 3 to the General Regulation.
- The prescription allows a patient to “access” that drug, either through a pharmacy or through the ND’s dispensary.
- In some limited cases, a ND may write a prescription for a drug in order to be able to obtain that drug for resale from their dispensary, or for in-office administration (i.e. emergency drugs).

2. Prescribing a Drug

- Where a **drug** is not listed in Table 3 to the Regulation, e.g. Ativan, it is because NDs are not authorized to prescribe that drug to patients.
- Where a **substance** is not listed in Table 3, e.g. Vitamin C, it is because it is a natural health product, and is available without a prescription.
- Where a patient is expected to take a substance (i.e. as part of their treatment plan) which is not listed in Table 3 due to it being a natural health product (NHP), a prescription is not required. In this instance, the ND is “recommending” the substance as opposed to prescribing it.
- It is the responsibility of the ND to know when a prescription is required.

2. Prescribing a Drug

2.2 Relevant Standards of Practice

- Section 9(2) of the General Regulation outlines the standard of practice that applies when a ND is going to prescribe a drug on Table 3. These general requirements include, but are not limited to:
  - the ND must have a naturopath-patient relationship with the individual receiving the prescription;
  - the drug must be prescribed for therapeutic purposes only;
  - the ND must notify the other primary health care providers of the prescription unless the patient does not consent to the notification.

2. Prescribing a Drug

- Another relevant standard appears in section 9(3) of the Regulation. This standard details the information that must appear on the prescription and includes:
  - Name and address of the patient;
  - Name, strength and quantity of the drug prescribed;
  - Directions for use, etc.

2. Prescribing a Drug

- Finally, Section 9(4) of the General Regulation outlines the record-keeping requirements for a member who is writing a prescription for a patient.
- NDs who intend to prescribe the drugs on Table 3 are required to review, be familiar with and operate within these sections of the Regulation.

2. Prescribing a Drug

2.3 Table 3, Its Limitations and Intricacies

- Table 3 lists the drugs a ND can prescribe and the specifics around drug limitations, routes of administration and dosages.
- The “limitations, routes of administration and dosages” will provide NDs with:
  - Information about limits on the amount of the drug that can be prescribed; or
  - Circumstances about when a substance is considered a drug (i.e. due to route of administration, specific treatment indication or dosage amount).

2. Prescribing a Drug

- For example, podophyllum is a drug on Table 3 and in order to prescribe it to a patient, a prescription is always necessary. There are no limitations on the dosage so dosage amounts are left to the knowledge, skill and judgment of the member.
- On the other hand, digitalis purpurea (and its glycosides) is also a drug on Table 3, also requires a prescription whenever it is being prescribed to a patient but also carries a limitation that a ND 'must monitor the patient's serum level.' If a member will not or cannot monitor the serum levels, they may not prescribe this drug.
- Folic Acid and Vitamin A are two examples of where the limitations outline when a substance becomes a drug due to dosage amounts. Folic Acid under 1 mg per dose or where the total dosage per day is less that 1 mg is not a drug and does not require a prescription. The moment the ND increases the dosage or daily dosage above 1 mg, Folic Acid becomes a drug and a prescription is required. The same applies to Vitamin A with a dosage or daily dosage of 10,000 IU.

2. Prescribing a Drug

Professional Practice Scenarios- Prescribing vs Administering

Scenario #1

- A patient consults with a Naturopathic Doctor and has been determined through blood laboratory testing to be Vitamin D deficient. To correct this deficiency, a dosage of Vitamin D that is greater than 1000 IU is required. The ND therefore must write a prescription for the patient and inform them that the prescription may be filled at a pharmacy, or via the ND's dispensary (if available). The appropriate guidelines for prescription sales are outlined in Section 12 of the General Regulation.

2. Prescribing a Drug

Professional Practice Scenarios- Prescribing vs Administering

Scenario #2

- A patient arrives after lunch at their Naturopath's office and begins to experience chest pain. Although the patient experiences angina regularly, they have forgotten to bring along their nitroglycerine patches. The Naturopathic Doctor may prescribe sublingual doses of nitroglycerine to the patient in order to administer it from their emergency kit if needed. However, the ND cannot dispense more for the patient to take home after the conclusion of the patient visit. If the Naturopathic Doctor did not meet the Standard of Practice for Prescribing, the appropriate measure would be to call for emergency assistance by dialing 911. A call to emergency services would be appropriate in either case if the symptoms did not alleviate.

2. Prescribing a Drug

Professional Practice Scenario - Prescribing vs Administering

Scenario #3

- A post menopausal patient attends your clinic, and with recent testing has been diagnosed with osteoporosis. Alongside her pharmaceutical prescription, you prescribe 120mcg of Vitamin K2. She is unwilling to stop taking her self prescribed multivitamin and calcium supplement that contain 40mg of Vitamin K2. The prescribing Naturopathic Doctor must have met the Standard of Practice for Prescribing to prescribe the Vitamin K2, and is also required, with the patient's consent, to notify the patient's other primary health care provider(s) of the prescription.

3. Dispensing a Drug

3.1 What is dispensing?

- Dispensing is a controlled act when a ND dispenses a drug that is listed in Table 4 of the General Regulation.
- Where a **drug** is not listed in Table 4 to the Regulation, e.g. Ativan, it is because NDs are not authorized to dispense that drug to patients.
- Where a **substance** is not listed in Table 4, e.g. Vitamin C, it is because it is a natural health product that is available without a prescription. In such instances a ND may provide that substance to his/her patient, but are not legally dispensing it.
- The General Regulation makes an important distinction between “dispensing” or handing out of a drug, and “administering” a drug, which is not handed out per se but is given to a patient in-office by inhalation or injection.

3. Dispensing a Drug

3.2 Relevant Standards of Practice

There are a number of relevant standards of practice in the General Regulation that pertain to the controlled act of dispensing.

- Section 10(2) of the Regulation establishes the primary standards of practice that a member must follow when dispensing. These include but are not limited to:
  - Unless the exception outlined in subsection 10(3) applies, the ND must have a patient-ND relationship with the person to whom they are dispensing the drug;
  - The drug must be dispensed for therapeutic purposes;
  - The ND must advise the patient or their authorized representative that the drug may be available in a pharmacy;
  - The ND must comply with any of the limitations, route of administration or dosage information that appears in Table 4.

3. Dispensing a Drug

- Standards of practice relating to labeling of a dispensed drug appear under paragraph 11 of section 10(2) of the Regulation, and include:
  - The NDs name and title,
  - The name, address and telephone number of the place from which the drug is dispensed
  - The identification of the drug, its name, strength and manufacturer
  - The quantity of the drug etc.
- NDs who intend to dispense the drugs on Table 4 are required to review, be familiar with and operate within these sections of the Regulation.

3. Dispensing a Drug

3.3 Dispensing a Drug to Non-patients

- Subsection 10(3) is unique to the Naturopathic Profession. It allows a ND to dispense a drug to a person who is **NOT** a patient provided certain conditions apply. Those conditions are:
  - The ND has the prescription for the drug in their possession;
  - The prescription is from another ND (and not from any other regulated health professional)
  - The prescription contains all of the necessary information required under the prescribing provisions of the Regulation;
  - The ND retains a copy of the prescription in their records.

3. Dispensing a Drug

3.4 Table 4, Its Limitations and Intricacies

- Table 4 lists the drugs a ND can dispense and the limitations, routes of administration and dosages that apply.
- The “Limitations, routes of administration and dosages” will provide NDs with:
  - Information about limits on the amount of a drug that can be dispensed;
  - Information about a substance being a drug only when dispensed over certain dosages; or
  - Circumstances about when a substance being dispensed is considered a drug.
- Table 4 is very similar to Table 3 in this regard, however, there are several substances that appear on Table 3 (Prescribing) that do not appear on Table 4 (Dispensing) because they allow a ND to access the drug for use but do not allow the ND to dispense the drug. For example, Calcium gluconate must be prescribed if being administered in an injectable form however, as it is being administered in office by the ND, the substance would not be dispensed and therefore does not appear on Table 4.

3. Dispensing a Drug

Dispensing- Professional Practice Scenario #1

- Following a patient check-up, you determine that your patient requires 10,000 IU of Vitamin D and 175 mg of Vitamin K2, both of which need to be prescribed. You inform the patient that they may have the prescription filled at your clinic dispensary or at a local pharmacy. The patient opts to purchase the prescriptions from you. In dispensing these two substances you ensure that the product labels contain all of the dispensing information requirements outlined in Section 10 (2) of the General Regulation, a copy of this information is put into the patient's file, and that the dosage instructions are reviewed with the patient.

3. Dispensing a Drug

Dispensing – Professional Practice Scenario #2

- A patient of another ND is on vacation in your city, and forgot to bring her Bio-Identical Estrogen and Progesterone creams with her. The patient inquires whether it is possible to purchase a re-fill from your office for her month away from home. As the dispensing ND, you would be expected to contact the patient's primary ND and obtain a new prescription for the patient. Once obtained, you would then be able to dispense the required prescription from your office, making sure that all required labeling information is included and that a copy of this information is retained on file at your office.

4. Selling a Drug

4.1 What is Selling a Drug?

- Selling a drug is a controlled act when a ND sells a drug that is listed in Table 6 of the General Regulation.
- Where a **drug** is not listed in Table 6 to the Regulation, e.g. Ativan, it is because NDs are not authorized to sell that drug to patients.
- Where a **substance**, is not listed in Table 6, e.g. Vitamin C, it is because it is a natural health product that is available without a prescription and an ND may provide that substance to his/her patient. While a patient may purchase a publicly available product/NHP from a ND, the controlled act of selling a drug applies only to the substances listed on Table 6.

4. Selling a Drug

- *4.2 Relevant Standards of Practice*
- There are a number of relevant standards of practice in the General Regulation that pertain to the controlled act of selling a drug.
- The standards of practice for selling a drug may be found in Section 12(2) of the Regulation. Examples of the standards include:

    - Unless subsection 12(3) applies, a ND must have a patient-ND relationship with the person for whom the drug is sold and must only sell a drug to the patient or their authorized representative;
    - The drug must be sold only for therapeutic purposes;
    - The drug must be sold in accordance with any limitations set out in table 6;
    - The ND must not sell the drug for a profit or where they receive a direct or indirect personal or financial benefit.

- NDs who intend to sell the drugs on Table 6 are required to review, be familiar with and operate within these sections of the Regulation.

4. Selling a Drug

4.3 Selling to Non-patients

- Subsection 12(3) is unique to the Naturopathic Profession. It allows a ND to sell a drug to a person who is **NOT** a patient provided certain conditions apply. Those conditions are:
  - The ND has the prescription for the drug in their possession;
  - The prescription is from another ND (and not from any other regulated health professional)
  - The prescription contains all of the necessary information required under the prescribing provisions of the Regulation;
  - The ND retains a copy of the prescription in their records.

4. Selling a Drug

4.4 Table 6, Its Limitations and Intricacies

- Table 6 lists the drugs a ND can sell and the limitations, routes of administration and dosages that apply.
- The “Limitations, routes of administration and dosages” will provide NDs with:
  - Information about limits on the amount of drug that can be sold;
  - Information about a substance being a drug only when sold over certain dosages; or
  - Circumstances about when a substance being sold is a drug.
- Table 6 is very similar to Table 3 in this regard, however, there are several substances that appear on Table 3 (Prescribing) that do not appear on Table 6 (Selling). For example, in an emergency, a ND may prescribe nitroglycerin; however, because the circumstances are emergency, a member may not “sell” this drug.

4. Selling a Drug

- As mentioned in previous examples highlighting nitroglycerine and salbutamol, these substances are within the scope of a ND (who has met the Standard of Practice for Prescribing) to use with their patients in an emergency situation in clinic, but they may not be sold to patients. This would require a referral to a Medical Doctor for a prescription, or a prescription refill.
- Nitroglycerin – It is allowed for emergency use only. It is on the Prescribing table to allow a ND to purchase from a Pharmacist for in-office use and to keep in their crash cart. It is not on Table 4 (drugs that may be dispensed), as a ND cannot dispense the drug to a patient to take home, but would use it only in an emergency situation in clinic. It is not on Table 5 (drugs that may be compounded) as it may not be compounded. It is not on Table 6 (drugs that may be sold), as even when given in an emergency, it is not expected that a ND would charge a fee for providing it to the patient.

4. Selling a Drug

Selling – Professional Practice Scenario

- A patient is diagnosed with a Vitamin D deficiency, and is prescribed a dose of 10,000 IU QD for 1 month by the ND. The ND may dispense and sell Vitamin D, or refer the patient to a local pharmacy to have the prescription filled, depending on the patient's preference. If the prescribed Vitamin D is sold to the patient from the ND's dispensary it is expected that the ND charges the patient only the cost of the drug. The ND may not sell a drug if the selling provides a profit.

5. Compounding a Drug

5.1 What is Compounding a Drug?

- Compounding a drug is a controlled act when a ND reconstitutes, dilutes, mixes, prepares or labels two or more drugs listed in Table 5 of the General Regulation to create a customized therapeutic product for the patient.
- Where a **drug** is not listed in Table 5 to the Regulation, e.g. Ativan, it is because NDs are not authorized to compound that drug for patients.
- Where a **substance** is not listed in Table 5, e.g. Vitamin C, it is because it is a natural health product that is available without a prescription and a ND may reconstitute, dilute, mix, prepare or label one or more of these substances without the process being considered a controlled act; however, the ND must still comply with the Colleges standard of practice for compounding (e.g. labeling requirements).

5. Compounding a Drug

- A ND compounds in a number of circumstances, including:
  - Compounding drugs for the purposes of prescribing, dispensing and selling the customized therapeutic product; (e.g. a mixed botanical tincture)
  - Compounding drugs for the purposes of administering the customized therapeutic product to a patient by inhalation; (e.g. 0.9% saline and glutathione compounded for nebulizing)
  - Compounding drugs for the purposes of administering the customized therapeutic product to a patient by injection; (e.g. Vitamin B12 and Folic Acid IM injection)
  - Compounding drugs for the purposes of administering the customized therapeutic product to a patient by intravenous infusion therapy (IVIT) (e.g. multi vitamin and mineral nutritional IV treatment)
- The premises where a ND compounds for IVIT is subject to inspection, under the Colleges Inspection Program (Regulation pending).
- Whenever a drug is reconstituted, diluted, mixed with another drug or substances, it is compounding. For example, a ND who mixes a drug (e.g. dextrose) with saline solution for the purposes of IVIT, he/she is compounding under the General Regulation.

5. Compounding a Drug

5.2 Relevant Standards of Practice

- Section 11(2) of the General Regulation establishes the standards of practice for compounding, which include, but are not limited to the following:
  - The ND must have a patient-ND relationship with the person for whom the drug is compounded;
  - The ND must have the knowledge, skill and judgment to compound the drug safely, competently, and ethically;
  - The ND must compound the drug in accordance with any limitations that appear in Table 5;
  - The ND may only compound a drug when a supply of a Health Canada approved, commercially available prepared product that meets the patient's needs is not reasonably available.

5. Compounding a Drug

- Paragraph 12 of section 11(2) outlines the standards of practice for labeling a compounded drug. These requirements include, among other requirements:
  - The NDs name and title
  - The name, address, and telephone number of the location where the drug was compounded;
  - The percentage of each of the drugs or substances and other ingredients used to make the compounded product and the quantity of the compounding product in the container.
- NDs who intend to compound the drugs on Table 5 need to review, be familiar with and operate within these sections of the Regulation, as well as the College's standards of practice for compounding if intending to mix natural health products.

5. Compounding a Drug

5.3 Table 5, Its Limitations and Intricacies

- Table 5 lists the drugs a ND can compound and the limitations, routes of administration and dosages that apply.
- The “Limitations, routes of administration and dosages” will provide NDs with:
  - Information about limits on the amount of drug that can be compounded;
  - Information about a substance being a drug only when compounded over a certain dosage; or
  - Circumstances about when a substance being compounded is a drug.
- Table 5 is very similar to Tables 3, 4, and 6.

5. Compounding a Drug

- Adenosine triphosphate is considered a drug if being compounded for IVIT. If the substance was being mixed for oral use, the controlled act of compounding would not apply however, the College's standards of practice for compounding would still need to be adhered to.

- Rauwolfia may be compounded with other herbs to be prescribed and sold to a patient for oral use; however, it **cannot** be compounded for either inhalation or injection therapies as it does not appear on Tables 1 or 2.

5. Compounding a Drug

Compounding – Professional Practice Scenario

- A patient arrives for a follow-up visit with her ND to assess the effect of the cardiovascular tincture provided to her at a previous visit. After a consult and physical exam, the ND decides that Rauwolfia would be a beneficial addition to the patient's tincture. Initially, the tincture was a combination of botanicals that are within the general scope of Naturopathic medicine, but with the addition of Rauwolfia, the practitioner must have met the Standard of Practice for Prescribing to be able to prescribe this botanical, as it is classified as a drug. The patient also must continue to be monitored and assessed for response to treatment (both positive and for any adverse affects).

6. Administering a Prescribed Substance by Inhalation

6.1 What is Administering a Drug by Inhalation?

- Although the RHPA includes a controlled act of administering a substance by inhalation, the Act itself does not define what that is.
- The role of interpreting what constitutes inhalation is left up to the various health regulatory Colleges whose members are authorized to perform this controlled act.
- The College of Naturopaths of Ontario has interpreted this controlled act in the case of naturopathic practice to mean the administration of a substance using a mask, nasal cannula or aerosol inhaler.
- Any substance that a patient breathes in by any other means is not interpreted by the College to mean the controlled act of administering by inhalation, e.g. breathing in essential oils.
- A ND may administer by inhalation, that is, by means of a mask, nasal cannula or aerosol inhaler, only those substances listed in Table 1 of the General Regulation.

6. Administering a Prescribed Substance by Inhalation

6.2 Relevant Standards of Practice

- Section 5(2) of the General Regulation sets out the standards of practice for administration of a substance by both inhalation and injection. It notes that if a ND mixes, prepares, packages or labels two or more substances in Tables 1 or 2 for the purposes of administering a customized therapeutic product, they do so in compliance with all of the standards for compounding as set out in the Regulation.
- The standards of practice set out in Section 3(1) of the Regulation apply to this controlled act. These general requirements include but are not limited to:
  - The ND having a patient-ND relationship and having recorded the patient's health history;

6. Administering a Prescribed Substance by Inhalation

6.2 Relevant Standards of Practice

- Informing the patient before performing the controlled act of the purpose of the controlled act, the risks inherent in its performance and alternative treatments the ND knows or ought to know are available;
- Receiving informed consent
- Ensuring that appropriate infection control procedures are in place and that the controlled act is performed in a clean, safe, private and comfortable environment.

- NDs who intend to administer a prescribed substance by inhalation from Table 1 need to review, be familiar with and operate within these sections of the Regulation.

6. Administering a Prescribed Substance by Inhalation

6.3 Table 1, its Limitations and Intricacies

- Tables 1 and 2 are significantly different than Tables 3, 4, 5 and 6.
- Where Tables 3 through 6 inclusively list the “drugs” that may be prescribed, dispensed, compounded or sold, Tables 1 and 2 are the ”**Prescribed Substances**” that may be administered by Inhalation and Injection.
- In simple terms, this distinction means that a ND can only administer by inhalation, a substance listed on Table 1.
- Table 1 lists only 5 substances:
  - two of which are for use in an **emergency situation only** (Ipratropium bromide, Salbutamol)
  - therapeutic oxygen
  - saline (usually when compounded with another substance for administration by inhalation);
  - Acetylcysteine and glutathione.

6. Administering a Prescribed Substance by Inhalation

- No other substances may be administered by inhalation.

- It is important to note that therapeutic oxygen does not appear on Table 3 (Drugs that may be Prescribed). Therefore, while a ND may administer it in office, they may not provide a patient with a prescription for the use of oxygen in their home.

6. Administering a Prescribed Substance by Inhalation

Administering by Inhalation – Professional Practice Scenario

- A patient presents at your office with a chronic chest infection and difficulty expectorating mucous. The patient has been prescribed an antibiotic and after examining him you decide to recommend that he undergo a few nebulized glutathione treatments to support his lungs and facilitate mucous clearance. The patient inquires if it would also be ok to steam vaporize some eucalyptus essential oil when he returns home from your office, which you confirm would be fine. The recommendation to a patient to access nebulized glutathione can be made by any actively practicing registered Naturopathic Doctor however, administering the glutathione treatment is restricted to NDs who have met the Standard of Practice for Prescribing. The recommendation to vaporize essential oils does not fall within the controlled act of administering by inhalation and does not require the ND to have met the Standard of Practice for Prescribing.

7. Administering a Prescribed Substance by Injection

7.1 What is Administering by Injection?

- Administration of a substance by injection is the controlled act of injecting a substance by an intramuscular injection (IM), subcutaneous injection (SubQ), or by intravenous infusion (IV).
- A ND may only inject a substance that is listed on Table 2 of the General Regulation, subject to the route of administration and any limitations outlined on the table.
- For example, Sodium Iodide may only be administered by intravenous infusion and in combination with other minerals.
- Under Canadian and Ontario law, once a substance is administered below the dermis, it becomes a drug (e.g. saline solution once injected is a drug and as a result has been listed on Table 2).

7. Administering a Prescribed Substance by Injection

7.2 Relevant Standards of Practice

- Section 5(2) of the General Regulation sets out the standards of practice for administration of a substance by both inhalation and injection. It notes that if a ND mixes, prepares, packages or labels two or more substances in Tables 1 or 2 for the purposes of administering a customized therapeutic product, they do so in compliance with all of the standards for compounding as set out in the Regulation.
- The standards of practice set out in Section 3(1) of the Regulation apply to this controlled act. These general requirements include but are not limited to:
  - The ND having a patient-ND relationship and having recorded the patient's health history;
  - Informing the patient before performing the controlled act of the purpose of the controlled act, the risks inherent in its performance and alternative treatments the ND knows or ought to know are available;
  - Receiving informed consent
  - Ensuring that appropriate infection control procedures are in place and that the controlled act is performed in a clean, safe, private and comfortable environment.

7. Administering a Prescribed Substance by Injection

- NDs who intend to administer a substance by injection (Table 2) need to review, be familiar with and operate within these sections of the Regulation. **In addition to the Standard of Practice for Prescribing, NDs who wish to administer a substance intravenously must also meet the Standard of Practice for Intravenous Infusion Therapy (IVIT).**

7. Administering a Prescribed Substance by Injection

Administering by Injection – Practice Scenario #1

- A Naturopathic Doctor consults with a patient who has been recently diagnosed with Celiac disease. He has also been found to be deficient in Vitamin B12 by his Medical Doctor, and was referred to the ND for assistance. The ND explains to the patient that his best option for quick repletion would be an IM injection of Vitamin B12, but as the ND has not met the Standard of Practice for Prescribing, she is unable to administer IM injections. The ND makes a referral to a naturopathic colleague who has met the Standard of Practice for prescribing to administer the Vitamin B12 IM, and makes a recommendation to the patient to take a sublingual Vitamin B12 lozenge in the interim. The patient is also scheduled to re-test their Vitamin B12 blood levels in 2 months.

7. Administering a Prescribed Substance by Injection

7.3 Table 2, Its Limitations and Intricacies

- Similar to Table 1, Table 2 prescribes the substances that a ND may administer by Injection, including by IVIT. If the substance a ND wishes to inject is not on the list, then the ND may **not** inject that substance.
- Table 2 lists the substances that a ND can inject, the route of administration and the limitations and dosages that apply.
- The "Limitations, routes of administration and dosages" will provide NDs with:
  - Information about the route or routes of administration by which the substance may be injected;
  - Information about limits on the amount of drug that can be injected;
  - Information about combinations of substances that may be necessary.

7. Administering a Prescribed Substance by Injection

- Some minerals such as vanadium must only be administered with other minerals and not as a singular vitamin. The dosage amounts however are left up to the knowledge, skill and judgment of the ND.
- Other limitations include:
  - Specifics regarding technique, e.g. Ferrous sulphate must be administered by Z track only
  - Specifics regarding indication for use, e.g. emergency only substances

- Please refer to Table 2 of the General Regulation for the limitations and specifics with respect to prescribed substances that may be administered by injection.

7. Administering a Prescribed Substance by Injection

Administering by Injection – Practice Scenario #2

- A long standing hypertensive patient returns to your office for assistance as he has recently experienced a small elevation in his blood pressure. His cardiologist has recommended supportive treatment, but the patient has requested to consult with you for a second opinion. Since his blood pressure elevation is mild, and he is in robust health, you make a suggestion that he have a series of nutritional IVs to replete some vitamins and minerals known to support optimal heart function and then re-assess his blood pressure. The patient consents to the treatment and to having you notify his cardiologist of the treatment plan, which you do, advising the cardiologist that you will follow-up with a treatment update in an appropriate length of time. Alongside potassium chloride and magnesium sulphate, you also administer an amino acid combination containing Glutamine. As this amino acid being administered by injection carries a limitation that it “must be in combination with other amino acids” Glutamine cannot be administered as a singular amino acid. If the patient did not respond to treatment within a reasonable amount of time, a referral back to their cardiologist would be an appropriate course of action

8. What is a Natural Health Product and When Might it be a Drug?

- The Natural Health Products Regulation and the Schedule 1 attached to it identify that a natural health product (NHP) substance is:
  - A plant or plant material, an alga, a bacterium, a fungus or a non-human animal material
  - Any extract or isolate of the substances identified in the preceding bullet point;
  - Any of vitamins biotin, folate, niacin, pantothenic acid, riboflavin, thiamine, A, B6, B12, C, D, E, K1, K2
  - An amino acid
  - An essential fatty acid
  - A synthetic duplicate of a substance in bullets 2 to 5
  - A mineral
  - A probiotic.

8. What is a Natural Health Product and When Might it be a Drug?

- Typically, a NHP is not considered a drug; however, there are certain unique circumstances when a NHP becomes a drug, including but not necessarily limited to:
  - When the NHP is injected below the dermis (e.g. vitamin B12 injection);
  - When the NHP is listed on the Prescription Drug List from Health Canada (e.g. Vitamin A over 10,000 IUs);
  - When the NHP is a controlled drug or substance under the Controlled Drugs and Substances Act (e.g. homeopathic cannabis);
  - When the NHP is designed in the regulations made under the Drugs and Pharmacies Regulation Act as a drug.
- For NDs, it may not always be safe to assume that because a product is a natural health product it is available for recommendation to patients; a ND must be certain that the product has not been designated as a drug under statute and if it is, that it is authorized for use under the General Regulation.

Links/Resources

- CONO website
- General Regulation (http://www.ontario.ca/laws/regulation/150168)
- E-laws
- Prescription Drug List
- NAPRA
- *Drugs and Pharmacies Regulation Act*
- *Controlled Drugs and Substances Act*.