Feedback on Draft Clinical Practice Standards: Allergy Testing and Injectable Therapies

Context

BCND is providing feedback on the draft clinical practice standards for allergy testing and injectable therapies. These are established components of naturopathic scope of practice in British Columbia. Standards in these areas must protect patient safety without narrowing scope through unclear language, subjective interpretation, or operational requirements that are difficult to implement in community practice while still recognizing the need for professional clinical judgment. These comments are intended to clarify interpretation of the standards, not to prescribe detailed clinical protocols or limit appropriate clinical discretion.

The same structure is used below for each draft standard.

1. **Comments on the Standard:**
   Observations on clarity, interpretation, enforceability, and unintended consequences. The observations below identify areas where wording may lead to inconsistent interpretation. They are not intended to establish minimum thresholds or limit appropriate clinical decision-making.
2. **Implementation Considerations:**
   Operational issues that may arise in real clinical settings and areas where guidance or clarification will be required.

The goal is to identify gaps and risks so expectations are clear, consistent, and workable across solo, group, and multidisciplinary clinics, without creating overly prescriptive requirements that may limit appropriate clinical decision-making.

BCND's intent is to support standards that are clear and workable in real clinical settings while recognizing that naturopathic physicians are trained professionals who must apply clinical judgment to individual patients.

BCND supports standards that centre patient safety and public protection and seeks clarity on how expectations will be interpreted in practice.

Draft Clinical Practice Standard- Allergy Testing and Treatment

What already exists

Allergy testing and desensitization have been provided by naturopathic doctors in British Columbia for decades. Existing practice expectations include:

- Appropriate clinical training
- Emergency preparedness and life support certification
- Informed consent and documentation
- Appropriate patient screening and contraindication review
- Post treatment monitoring
- Maintenance of emergency medications and equipment

These services are routinely delivered in community clinics, integrative clinics, and multidisciplinary settings using professional clinical judgment within existing scope.

What is changing or being clarified

The draft replaces detailed profession-specific guidance with high-level language such as:

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- Additional training
- Clinically appropriate
- Appropriate life support certification

These terms are not defined and may be interpreted differently across professions, regulators, insurers, and investigators.

Comments on the Standard

Undefined competence thresholds

The standard refers to additional training but does not clarify what level or type of training would generally be considered sufficient or how competence may be evaluated over time. It is unclear how the following may be interpreted in complaints, QA reviews, or audits:

- Training obtained through different educational pathways
- Expectations around documenting competence over time
- How competence may be assessed in complaints or QA processes
- How recency of training may be considered

Without this clarity, expectations may vary across cases and enforcement may appear inconsistent.

Ambiguity in patient selection

Allergy testing carries known risks, including anaphylaxis. The standard does not clarify how patient selection decisions may be evaluated in complaints or QA reviews.

Experience with current regulatory language in allergy testing and desensitization shows that provisions intended to clarify scope can still be interpreted differently in clinical and regulatory contexts. Clear guidance on how standards will be applied would help ensure consistent expectations while supporting patient safety.

It is unclear how the following factors may be interpreted in assessing clinical judgment:

- Screening Practices
- Contraindication Review
- Use Of Medications Such As Beta Blockers Or ACE Inhibitors
- Consideration Of Higher-Risk Patient Populations
- Post-Treatment Observation Practices

Without guidance on how these considerations may be interpreted, expectations may vary across cases and create uncertainty for both patients and licensees.

Emergency preparedness language is incomplete

The standard references emergency readiness but does not clarify how preparedness may be evaluated across different clinic environments or practice settings. It is unclear how the following elements may be interpreted in complaints, inspections, or QA reviews:

- Emergency Medication Readiness
- Equipment Availability And Maintenance
- Staff Training And Role Clarity
- Emergency Response Planning Or Practice
- Documentation Of Emergency Preparedness

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Without clarity on how readiness may be assessed, expectations may vary across settings and create uncertainty for licensees.

No clarity on shared clinic environments

Many naturopathic doctors practise in multidisciplinary or shared clinic settings. The standard does not clarify how requirements will be interpreted where equipment, staff, or policies are shared across providers or tenants. It is unclear how the following situations may be assessed in complaints, inspections, or QA reviews:

- Shared Emergency Equipment Such As Crash Carts
- Shared Clinic Policies Or Protocols
- Responsibility When Equipment Is Owned Or Maintained By Another Provider
- Emergency Response Planning In Multi-Tenant Or Leased Spaces

Without clarity on how shared environments will be evaluated, expectations may vary across practice settings and create uncertainty for licensees.

Interaction with other standards

Consent, documentation, infection prevention and control, and practice environment requirements appear across multiple standards. The draft does not clarify how overlapping expectations may be interpreted where standards intersect or appear to conflict. This may create uncertainty in complaints, audits, or QA reviews about which expectations apply in specific clinical situations.

Risk of indirect scope narrowing

High-level language without defined thresholds may be interpreted differently by insurers, hospitals, or auditors when assessing competence or coverage. Inconsistent interpretation in external systems can affect patient access to care and create uncertainty for licensees.

Implementation Considerations for this Standard

Consider providing non-binding examples or guidance that illustrate how expectations may be interpreted in different practice environments, including:

- Emergency Preparedness In Community And Shared Clinic Settings
- Documentation Approaches That Demonstrate Training And Ongoing Competence
- Post-Treatment Monitoring And Observation Practices
- Consent Approaches Specific To Allergy Testing And Desensitization
- Responsibilities In Multidisciplinary Or Shared Clinic Environments
- Considerations When Introducing New Desensitization Techniques Within Scope

Draft Clinical Practice Standard- Injectable Therapies

What already exists

Injectable therapies are an established part of naturopathic scope in British Columbia. Existing expectations include:

- Clinical training and competence
- Prescribing authority within scope
- Patient selection and screening
- Emergency preparedness
- Documentation of indication, dose, and follow up

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Injectable therapies are provided in solo practices and multidisciplinary clinics across the province, across a range of clinical indications and practice settings.

What is changing or being clarified

The draft replaces more detailed guidance with high-level language about competence and training without clarifying how these expectations may be interpreted in practice.

Comments on the Standard

No defined competence framework

Injectable therapies vary widely in complexity and risk. The draft standard requires "additional training" but does not indicate how competence may be interpreted across different types of injectable procedures or practice settings.

Without clarification, it is unclear how the following factors may be considered in complaints, inspections, or quality assurance reviews:

- Training obtained through different educational pathways
- Experience with different types of injectable procedures
- Supervised or mentored practice where applicable
- Ongoing competence and recency of practice
- Documentation that demonstrates training and competence

BCND recognizes that the College appropriately avoids prescribing specific clinical protocols. However, additional guidance on how competence may be demonstrated in principle would help ensure consistent interpretation across complaints, QA reviews, insurers, and multidisciplinary practice settings.

Without guidance, expectations may evolve into informal thresholds around training hours or case numbers. Clarification on principles for assessing competence would help avoid inconsistent or overly prescriptive interpretations.

For example, clarification could include non-binding examples such as:

- Documentation that demonstrates structured training or mentorship
- Approaches to documenting ongoing competence or recency of practice
- Considerations when licensees adopt new techniques within an existing therapeutic category

This type of guidance would support consistent expectations without limiting appropriate professional judgment.

No restatement of scope boundaries

The standard does not clarify how scope considerations will be interpreted for injectable therapies, particularly as techniques and products evolve. It is unclear how the following external stakeholders may interpret expectations in the absence of clear alignment with existing scope regulations:

- Insurers
- Hospitals
- Employers
- College Investigators

Without clarity on how scope is understood in applying the standard, there is a risk of inconsistent interpretation that may affect patient access and clinical practice.

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Device licensing requirement lacks clarity

Item 1.6 requires that devices used for procedures have an active Health Canada medical device licence. The draft does not clarify what is meant by "devices used for procedures" or how this requirement will be interpreted across different types of equipment.

Without clarification, it is unclear how the following situations may be assessed in complaints, inspections, or QA reviews:

- Devices in direct contact with the patient, such as imaging or treatment equipment
- Equipment used to generate, prepare, or deliver substances administered to the patient
- Situations where no Health Canada-licensed device currently exists for a therapy within naturopathic scope
- Equipment historically used within established naturopathic therapies under previous regulatory frameworks

The standard also notes an exception for ozone in relation to Health Canada approval of injectable substances. Additional clarification would be helpful on how this interacts with the device licensing requirement and how licensees are expected to comply where no licensed device exists.

Clear guidance on these points would help ensure consistent interpretation across practice settings while supporting patient safety.

If interpreted narrowly, this requirement could effectively restrict established therapies through operational constraints where no licensed device exists, and clarification on intended scope and compliance expectations is therefore important.

Clarification on Health Canada approval for compounded injectable therapies

The draft standard states that injectable substances must be approved by Health Canada. Many injectable therapies within naturopathic scope involve compounded preparations where individual ingredients are Health Canada–approved but the combined formulation is not a separately approved product.

Clarification is needed on how this requirement will be interpreted where:

- Individual components are approved but the compounded preparation is not separately approved
- Preparations are compounded by licensed pharmacists
- Therapies have been historically provided within naturopathic scope using approved components
- Therapies involving off-label use of Health Canada–approved substances within existing scope

Without clarification, the standard may unintentionally restrict established therapies or lead to inconsistent interpretation by insurers, investigators, or auditors. Clarification is particularly important for therapies involving autologous products or off-label use of approved substances that are widely used within current authorized BC scope.

In particular, clarification is requested on whether the requirement refers to approved ingredients and pharmacy-compounded sterile preparations within authorized scope, rather than requiring a finished DIN product, so that longstanding therapies such as compounded or off-label use of approved substances are not unintentionally excluded.

Consistency between scope examples and Health Canada approval requirement

The draft standard lists categories of injectable therapies within scope while also requiring that injectable substances be approved by Health Canada. Some therapies commonly provided within existing naturopathic scope involve autologous products, compounded preparations, or combinations of Health Canada–approved components used within authorized scope under the Complementary Health Professionals Regulation.

Clarification is needed on how the Health Canada approval requirement will be interpreted in these situations so that the standard does not create unintended inconsistencies between listed scope activities and approval requirements, or lead to variable interpretation by insurers, investigators, or auditors.

In addition, clarification is requested where a substance is approved by Health Canada for one route of administration but is commonly used within authorized naturopathic scope through other routes that have historically been part of established clinical practice. Many injectable therapies rely on Health Canada–approved ingredients administered in different concentrations, volumes, or anatomical locations than those described in the product monograph. Many

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injectable therapies rely on Health Canada–approved ingredients administered in different concentrations, volumes, or anatomical locations than those described in the product monograph. Examples include established procedures that use approved solutions in different concentrations, anatomical locations, or therapeutic contexts within authorized scope. These uses may be supported by emerging or established clinical evidence and have been part of naturopathic and medical practice for many years.

Clarification is also needed where a substance is approved by Health Canada for one route, location, or therapeutic indication but has historically been used within authorized naturopathic scope through other routes or indications supported by clinical judgment and evolving evidence. Without this clarification, therapies that were previously within scope could be unintentionally excluded through interpretation rather than an explicit change to scope.

If the standard is interpreted to prohibit use outside the specific route or indication described in Health Canada approval, this could unintentionally remove established and lower-cost treatment options for patients and represent a material change to practice without an explicit scope amendment. Clarification is therefore requested on whether the requirement refers to use of approved ingredients within authorized scope and professional judgment, including off-label use within authorized scope where appropriate, rather than requiring route-specific approval of the final product.

Without this clarification, there is a significant risk of inconsistent interpretation by insurers, investigators, and quality assurance reviewers, and potential unintended impacts on patient access to care and continuity of multidisciplinary care.

Emergency preparedness is underspecified

Injectable therapies carry risks including anaphylaxis, vasovagal reactions, and dosing errors. The standard does not clarify how emergency preparedness expectations will be interpreted across different clinic environments or practice settings. It is unclear how the following elements may be assessed in complaints, inspections, or QA reviews:

- Emergency Medication Readiness And Accessibility Appropriate To The Procedures Performed
- Monitoring Equipment Availability And Use
- Post-Treatment Observation Practices
- Roles And Response Planning In Shared Or Multidisciplinary Clinic Environments

Without clarification on how preparedness will be evaluated, expectations may vary across settings and create uncertainty for licensees.

Documentation expectations are unclear

Injectable therapies require clear clinical documentation. While general record-keeping expectations already exist, the draft standard does not clarify how documentation specific to injectable procedures may be interpreted or assessed in complaints, inspections, or QA reviews:

- Clinical Indication
- Dose And Route Of Administration
- Batch Or Lot Number Where Relevant
- Monitoring And Follow-Up
- Documentation Of Patient Response

Without clarity on how documentation will be evaluated, expectations may vary across practice settings and create uncertainty for licensees.

Multidisciplinary clinic realities

Many naturopathic doctors practise in shared or multidisciplinary clinic environments. The standard does not clarify how expectations will be interpreted where facilities, staff, or policies are shared across providers. It is unclear how the following situations may be assessed in complaints, inspections, or QA reviews:

- Shared Infusion Or Treatment Rooms
- Shared Clinic Policies Or Procedures

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- Responsibility For Staff Training Or Supervision
- Storage And Handling Of Injectable Products In Shared Spaces

Without clarification on how shared clinic environments will be evaluated, expectations may vary across practice settings and create uncertainty for licensees.

Adoption of new techniques

Injectable therapies evolve quickly as new products and techniques become available. The standard does not clarify how competence may be assessed when licensees adopt new techniques within existing scope. It is unclear how the following factors may be interpreted in complaints, inspections, or QA reviews:

- Training Obtained For New Techniques Or Products Within An Existing Therapeutic Category
- Supervision Or Mentorship Where Applicable And Documentation Of Such Training
- Documentation Of Competence Over Time
- Recency Of Practice With Specific Techniques

Without clarity on how competence will be evaluated in these situations, expectations may vary across cases and create uncertainty for licensees.

Implementation Considerations for this Standard

Consider providing non-binding examples or guidance that illustrate how expectations may be interpreted across different clinic environments, including:

- Clinic Readiness In Solo And Shared Practice Settings
- Documentation Approaches That Demonstrate Training And Ongoing Competence
- Responsibilities In Multidisciplinary Or Shared Clinic Environments
- Monitoring And Follow-Up Practices For Injectable Therapies
- Considerations When Adopting New Injectable Techniques Within Existing Scope
- Interpretation Of The Health Canada Device Licensing Requirement, Including Whether It Applies Only To Devices In Direct Patient Contact Or Also To Equipment Used To Generate Or Prepare Therapeutic Substances
- Transitional considerations or compliance pathways where no Health Canada-licensed device currently exists for a therapy otherwise contemplated in the standard.

Non-binding examples may help illustrate how expectations could be applied in practice without creating overly prescriptive requirements.

Closing

Allergy testing and injectable therapies are established components of naturopathic practice in British Columbia. These standards will be applied in licensure decisions, complaints, audits, and insurance contexts. Where language is broad or undefined, interpretation may vary and create uncertainty for licensees and patients.

BCND has identified areas where the draft standards lack operational clarity, create ambiguity, or do not reflect common practice environments such as community clinics and multidisciplinary settings. These observations are provided so expectations can be understood consistently in the settings where naturopathic doctors provide care, without creating unintended limits on appropriate professional judgment.

These comments are offered so that standards can be implemented consistently across practice settings without unintended impacts on patient access to care.

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BCND will continue to monitor implementation and document impacts on naturopathic practice and patient access to care as these standards are finalized.

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