



## Commentary: Assessing Knowledge and Technique when Compounding

*Companion document to the NAPRA Model Standards for Pharmacy Compounding of Non-sterile Preparations*

### Introduction

Compounding has historically been an integral part of pharmacy practice in New Brunswick. While modern manufacturing processes have largely supplanted the pharmacist's need to individually prepare every prescription, compounded medications are still required to meet individual needs for some specialized products.

Health Canada's Policy on Manufacturing and Compounding Drug Products in Canada<sup>1</sup> describes their interpretation of compounding as:

*"The combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing. It can involve raw materials or the alteration of the form and strength of commercially available products. It can include reformulation to allow for a novel drug delivery. Compounding does not include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on an approved drug's labelling material."*

Recognizing that the quality of the final product and patient safety is always the focus, and that consistency of practice and a greater awareness of risk to pharmacy personnel must be addressed, the National Association of Pharmacy Regulatory Authorities (NAPRA) developed the new Model Standards for Pharmacy Compounding of Non-sterile Preparations (the Standards)<sup>2</sup>. The Council of the New Brunswick College of Pharmacists adopted the Standards at their regular meeting in February, 2019 and implementation will be carried out over a period of time beginning on July 1, 2019.

A working group of New Brunswick practitioners participated in a review of the Standards, as well as the comments submitted during the member consultation and subsequently recommended they be adopted by Council as published by NAPRA. The working group felt strongly that the College draft this Commentary in order to address some of the concerns raised through consultation and as a caution to members to some of the risks they felt may not be adequately addressed in the Standards.

### Requirements

The Standards are now the **minimum requirements for all members of the College involved in non-sterile compounding**. All pharmacy practice sites (hospital, community, specialty, etc.) must meet these Standards, as laid out in the timeline [\[LINK\]](#). The College recognizes that significant changes may be required in some practice environments, and encourages all pharmacy teams to work diligently to comply with the Standards, even ahead of the required schedule.

*“There are known knowns. These are things we know that we know. There are known unknowns. That is to say, there are things that we know we don’t know. But there are also unknown unknowns. There are things we don’t know we don’t know.” (Rumsfeld)*

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## Over-arching Principles

The working group prioritized the following topics as needing to be brought to the attention of members through this Commentary:

1. Practitioners must recognize changes in knowledge and techniques in compounding in recent years. If gaps in knowledge and techniques are **not even known**, then final products will not meet the expected outcomes of treatment. For some examples, compounding transdermal products requires micelle formation, or some compounds require pH adjustment (litmus paper testing), or a proper choice of wetting agents requires additional knowledge. As a further example, many pharmacies are currently compounding what they think are transdermal formulations, using basic mixing technique on a paper ointment slab; this is an example of “not knowing what you do not know.” Sometimes, compounding is undertaken simply because a prescription for a compound is received in the pharmacy, without researching if there is an indication for that product. During gap analysis, and whenever creating master formulation sheets, research must be done to answer all these types of questions; if answers cannot be found, the patient(s) must be referred to an appropriate practice site.
2. While specific tasks in the standards may be delegated to pharmacy technicians and appropriately supervised unregulated personnel, it remains the **pharmacist’s responsibility to assess and ensure that the compound is therapeutically appropriate for the patient**. Refer to page three of the Standards<sup>1</sup>: *“As for all prescriptions, it is expected that a pharmacist will review the prescription for each non-sterile preparation and use personal expertise to determine whether the compounded preparation is appropriate for the particular patient. In addition, the pharmacist and/or pharmacy technician who is designated as the compounding supervisor must determine whether the appropriate knowledge and resources to develop the formulation and/or the appropriate equipment and competency to compound the preparation are available... Once a determination has been made that it is appropriate to compound the preparation, these Model Standards must be applied.”*
3. After assessing clinical appropriateness, **and** whether or not the practice environment is in possession of the appropriate knowledge and resources, if the required facilities, knowledge and/or ingredients are not in place, then the pharmacist must not permit preparation of the compound in question. The patient(s) should be referred to an appropriate practice site.
4. Pharmacists must acquire or develop a formula/process which has reputable references (see Standard 6.2 and accompanying Guidelines<sup>3</sup>). If there isn't a formula available that has reputable references, and development of such a formula/process is too onerous, the pharmacist must not permit preparation of the compound, and should refer the patient(s) to an appropriate practice site.
5. There is a need for compounding training for all personnel involved, which meets or exceeds requirements, commensurate with the complexity and risk level of the compound being prepared. Subsequently, there must be ongoing assessment of compounding personnel’s technique and understanding.

6. There is a need for a designated, clean, uncluttered space for storage of all necessary supplies, including appropriate personal protective equipment, and then, an area appropriate for preparation of the compound, dependent on the complexity and risk level of that compound.
7. All compounding personnel must understand risks and hazards inherent in the particular compound they are making, as well as methods to mitigate risk. If there is uncertainty as to the level of risk, then personnel **shall defer to the higher standard**. Risk assessments must be done for all existing formulas, as well as any new compounds presented by patients.
8. Assigning beyond use dating must be done using evidence-based materials. Dating must be determined by regulated pharmacy personnel with adequate experience and broad scientific knowledge. When required, dating must be assigned after consulting the manufacturer and literature on the stability, compatibility and degradation of ingredients.
9. Creation of a quality assurance process is not optional. See Section 7 of the Standards<sup>1</sup> and the Guidelines<sup>3</sup>. This must include facilities, equipment and personnel, as well as the final product. Quality assurance must be ongoing; for example, Master Formulas must be regularly reviewed/documentated to ensure current and evolving standards are being applied.

Finally, the working group recommended a *Frequently Asked Questions (FAQ)* document be developed in conjunction with this document. It will include a list of questions members should ask themselves in assessing whether or not they have the knowledge, competency, and tools to compound specific compounds, or compound in particular therapeutic areas. The FAQ will be updated as necessary as concerns and questions are raised by members while they are working through the process.

## References:

1. <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/policy-manufacturing-compounding-drug-products.html>
2. <https://napra.ca/general-practice-resources/model-standards-pharmacy-compounding-non-sterile-preparations>
3. <https://napra.ca/general-practice-resources/guidance-document-pharmacy-compounding-non-sterile-preparations>