



November 17, 2016

Ontario College of Pharmacists
Re: Open Consultation Feedback
483 Huron Street
Toronto ON M5R 2R4

e-mail: consultations@ocpinfo.com

Attention: Ms. Anne Resnick, Acting Interim Registrar

Dear Ms. Resnick:

RE: NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations

The Ontario Pharmacists Association ('OPA' or the 'Association') welcomes the opportunity to comment on the *Model Standards for Pharmacy Compounding of Non-Sterile Preparations* ('model standards') as proposed by the National Association of Pharmacy Regulatory Authorities ('NAPRA').

The Ontario Pharmacists Association represents the interests of Ontario's pharmacists, pharmacists-in-training and pharmacy technicians. Our more than 9,800 members work in a wide variety of settings, including but not limited to traditional community pharmacies, compounding pharmacies, hospitals, long-term care, family health teams, and industry. The Association maintains as a key element of its mandate the support for pharmacists in the delivery of the highest quality of care for all Ontarians.

Another important tenet within the Association's mandate is the pursuit of practice excellence, and it is on that basis that we offer our support of the proposed NAPRA standards along with some additional commentary and/or recommendations to various clauses as a means of contributing to improved clarity and facilitated adoption and implementation by our members and by their employer pharmacies and institutions. We recognize the critical importance of practice standards as they pertain to the safety of both the patient, who requires a compounded preparation, and the pharmacy professional who is tasked with preparing it. Aside from the essential development of these robust standards that protect the patient and the practitioner, implementation of these proposed standards must be done in a way that is both rational and pragmatic, allowing for a reasonable rate of adoption and the full acknowledgement of the challenges toward that adoption. To that end, OPA offers its support and collaboration with the Ontario College of Pharmacists ('OCP' or the 'College') in the implementation and support of the final OCP-approved standards.

Whereas the NAPRA document is quite lengthy, we will be restricting our commentary solely to those sections where additional clarity might be needed or where a recommendation can be offered to ease eventual adoption and implementation.

Section 6.1.1 – Roles and Responsibilities

It is noted that the model standards exclude “mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on the label of a drug approved by Health Canada within the normal practice of pharmacy.” Examples might include very common preparations of amoxicillin paediatric suspension or dilution of Methadose™ Oral Concentrate. The Ontario Pharmacists Association accepts that identification of a preparation as being “very common” does not constitute an exemption. As such, other very common preparations, such as the equal mixture of clotimazole cream and hydrocortisone 1% cream, may fall under Level ‘A’ compounding; it is reasonable to assume that every pharmacy will encounter at least one prescription for a simple and very common compound. For this reason, if and when OCP adopts and implements the model standards, **OPA recommends that all pharmacies in Ontario should be required to appoint and identify their non-sterile compounding supervisor on the College Register** regardless of their practice model or their stated intent not to compound. **This would require the compounding supervisor to be a member of the College.**

Section 6.1.2 – Training and Assessment

In section 6.1.2.2, the model standards state that a skills assessment program must be established for all pharmacists, and technical and cleaning personnel who are directly or indirectly involved in non-sterile compounding. As protocols and formulations change frequently, **OPA recommends that reassessments be required for all involved personnel on a three-year interval (minimum).** The model standards also state that the results of staff evaluations be noted in the employee’s file, and **OPA recommends that documentation of the dates of staff assessments should also be recorded in the maintenance log.**

Section 6.3 – Facilities and Equipment

In section 6.3.1, the model standards state that “areas reserved for compounding must only be used by staff authorized to compound non-sterile preparations” and that “this space must be reserved for compounding but may also be used in preparing or reconstituting marketed products.” Section 6.3.2 continues by stating that “all compounding must be performed in a separate space specifically designated for compounding of prescriptions.” While OPA understands the intent and value of sections 6.3.1 and 6.3.2, it may be impractical, if not impossible, for some pharmacies to designate a specific area reserved solely for compounding, as space limitations and/or lease restrictions may prevent such modifications to the practice site. **The Association requests that if and when OCP approves and adopts the NAPRA standards, it exercises discretion and flexibility for those pharmacies who may be unable to meet this standard, and suggests changing the word “must” in sections 6.3.1 and 6.3.2 to “should”.**

In section 6.3.2, the model standards stipulate the use of “purified water” for compounding non-sterile drug preparations when formulations indicate the inclusion of water. There are various grades of water for pharmaceutical purposes, and notwithstanding the fact that there is a USP monograph for Purified Water, the term is vague. Therefore, for purposes of non-sterile compounding, **OPA requests that NAPRA and/or the College specify that the use of distilled water is the minimum standard for purified water.**

Section 6.3.3 addresses standards related to balances and weights. The Ontario Pharmacists Association believes that the minimum standard for validating the balance should be immediately prior to use, not every day. On the matter of certified weights, it is impractical to require that weights be certified annually by a qualified firm. Unless there is documented wide variations in weight calibrations on an annual basis, **OPA recommends that weight recertification be conducted at a minimum of every five (5) years.**

Section 7.2 – Master Formulation Record

The Ontario Pharmacists Association is supportive of the concept of pharmacies maintaining a master formulation record as a means of ensuring that all pharmacy staff have access to the complete set of information related to compounded formulations. This will ensure that product consistency can be more easily maintained. There is some concern, however, with the requirement to include sample labelling information, and specifically:

- the generic name and quantity or concentration of each active ingredient,
- the assigned beyond-use date (BUD), and
- the storage conditions.

While we agree that this information is important, we are concerned with the capabilities of pharmacy software systems to incorporate this, and other mandated information, onto the pharmacy label. Therefore, **OPA requests that the full set of business specifications be outlined for pharmacy software providers with sufficient lead time prior to implementation.**

Section 7.3.4 – Quality of Ingredients

The Association agrees that the quality of the product is directly correlated with the quality of the product's individual ingredients. However, the model standards state that "reasonable means must be taken to determine the purity and safety of the ingredients used for compounding. These means may include analyzing the batch and verifying the manufacturer's reputation and the supplier's reliability." **The Ontario Pharmacists Association requests additional clarity as to what constitutes "reasonable means" to determine purity and safety of the ingredients,** as pharmacies do not typically have the relationships with qualified laboratories that would be needed to analyze the products or ingredients.

Section 7.5 – Conduct of Personnel in Compounding Areas

The Association acknowledges the rationale applied, and policies proposed for minimizing the risks of product contamination and staff exposure to potentially hazardous substances. However, **OPA requests that compounding staff be given the discretion to apply professional judgment, and that latitude be applied by the College in inspections with regard to staff gowning, capping and masking when dealing with simple compounds** such as the mixture of two topical agents in a defined ratio. Risks of contamination and of exposure will already be stipulated in the Master Formulation Record and can direct the compounder as to the appropriate level of protection required. To require compounding staff to don gowns, caps and masks for the preparation of every single compound may be deemed excessive and costly.

Section 7.5.1 states that compounding personnel are required to “assess the final preparation using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate.” **The Association requests additional clarity on the meaning of “as appropriate”, and suggests that direction be stipulated on the Master Formulation Record as to whether the compound in question requires specific assessments including analytical testing.**

Section 7.6 – Labelling and Packaging

Under section 7.6.1.1, there appears to be a typographical error in the last paragraph on page 31. This reads verbatim as follows:

“As required by the respective provincial/territorial regulatory authority, another label must be added at the pharmacy where the compounded non-sterile preparations will be dispensed to the patient. Both labels must be retained on the preparations.”

The Association is working on the assumption that this paragraph refers to situations where a non-sterile preparation is prepared by another pharmacy on behalf of the dispensing pharmacy, where permitted by the provincial/territorial regulatory authority. In this type of scenario, **OPA asks that the requirement for double labelling be removed or, at a minimum, revisited.** When read in conjunction with section 7.6.1.2 (Label and Insert), OPA understands the intent as being a matter of full transparency; however, there are a number of challenges that are introduced with this protocol.

1. The package/container size may not lend itself to having two labels. For example, 15gm, 30gm and 60gm ointment pots can only accommodate a single label.
2. Potential patient confusion with double labels.
3. Access by the dispensing pharmacy to a label from the compounding pharmacy.
4. An auxiliary insert, generated when the label is deemed too small, becomes a non-affixed document which might get lost or misplaced by the patient/caregiver.

We believe that the Compounding Record should be sufficient for recording the compounding pharmacy and names of staff involved. We also believe that the patient or prescriber should only be contacting the dispensing pharmacy for questions related to the compound in question or in the event of an emergency; the compounding pharmacy information can be provided on request. With respect to the vast amounts of information proposed for inclusion on the label as a minimum standard, OPA requests that NAPRA reconsiders these elements with the goal of including only that information which a patient/caregiver absolutely needs to know. For example, we would suggest that inclusion of the “preparation batch number” is unnecessary for the label, so long as it is included in the patient’s medication profile and the Compounding Record, as it means nothing to the patient/caregiver on a day-to-day basis. As we stated under section 7.2 (Master Formulation Record), **OPA recommends that a full set of business specifications be outlined for pharmacy software providers with sufficient lead time prior to implementation to facilitate the generation of appropriate compound-specific labelling.**

It should also be noted that under section 7.6.1.2, the fifth bullet reads, “date when the sterile preparation was compounded.” **We believe this a typographical error and should refer to a “non-sterile preparation.”**

Given the volume of information that must be recorded and provided to the patient/caregiver, even after relegation of some elements to the Compounding Record, OPA recognizes that it may still be necessary to distribute the insert. If this is the case, **OPA recommends that there be a minimal amount of duplication of information between the insert and the label, and that there is an acknowledgement that the label be the primary source of information for the patient/caregiver.**

Section 7.8 – Labelling and Packaging

The Ontario Pharmacists Association suggests that development of a return and disposal policy for expired, partially used or unused compounded non-sterile products, is unnecessary as there are already policies in place for return and disposal which are no different than those used for traditional manufactured pharmaceuticals, including post-consumer waste of both hazardous and non-hazardous products.

Section 8.3 – Quality Assurance of Personnel and Processes

The model standards state that “compounding personnel need to be trained/certified and their work routinely observed with procedures/standards and maintenance of competency” and that “more frequent observations may be needed in cases such as return from extended leaves.” **The Association seeks additional clarity from NAPRA and/or OCP on the following:**

- a) **Whether specific competencies will be developed alongside the model standards** (separate and distinct from the training elements outlined in Appendix 4);
- b) **Whether mandatory credentialing or certification will be required in order to participate in non-sterile compounding activities; and**
- c) **If (b) is in place, whether there will be a defined time associated with credentialing or certification, after which re-credentialing or re-certification is required.**

Section 10.3 – Facilities and Equipment for Handling Hazardous Products (Level C)

The Association recognizes and welcomes the model standards related to the compounding of hazardous non-sterile preparations as these products can pose a significant risk to both patients and compounding staff. That said, **OPA requests that sufficient time be allocated to pharmacies to enable them to fully meet and comply with the model standards (once approved by the College) in terms of the physical requirements for compounding rooms.**

General Commentary

Throughout the *NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations*, references are made to pharmacists, pharmacy technicians, pharmacy assistants, and cleaning personnel. As such, **OPA requests that the Glossary on page 53 of the document include and define “registered pharmacy student” and “intern” and include them among eligible compounding personnel pursuant to them receiving the appropriate levels of training and orientation.**

In Appendix 2, which identifies an algorithm to determine the requirements for non-sterile compounding, there may be some confusion with the text box that reads: “Do these ingredients require greater precautions to protect the patient or staff?” **The Association requests greater clarity on the term “greater precautions” as well as on the decision algorithm.** As an example, if an ingredient has the potential to increase one’s risk of birth defects, the compounding supervisor might want to exercise a greater degree of precaution which in turn might shift the compounding requirements from Level A to Level B, thereby necessitating a separate compounding room. For an otherwise simple compound, such a precautionary approach may seem excessive. **OPA also asks for greater clarity and delineation between the three levels of compounding (A, B and C), so that compounding personnel are clear on the requirements associated with them.**

In Appendix 3, which presents a summary chart of the required conditions for non-sterile compounded preparations, the second row under “Training” states: “Has been trained in techniques appropriate for the compounding of Complex preparations and some hazardous products.” A checkmark (denoting that it is mandatory) is included for Level B compounding, but **OPA believes that this would also be a requirement for Level C compounding and that a checkmark should be added in its column.**

With Appendix 4, which outlines the training of compounding and cleaning personnel, we question the reliance on the training of a pharmacy assistant (“PA”) on matters of a more clinical nature. These would include:

- Knowledge of pharmaceutical and medical abbreviations (Element 1.4)
- Knowledge and good command of the pharmaceutical calculations required to compound non-sterile preparations (Element 1.10)
- Knowledge and understanding of the importance of and use of accurate measurements (Element 1.11)
- Knowledge of drug delivery systems (Element 1.18)
- Knowledge of levels of risk and beyond-use dates (Element 1.19)

Based on the clinical background associated with many of these elements, **OPA suggests that there is a big difference between knowing these elements and being competent in them. Therefore, the compounding supervisor will need to exercise discretion when asking a PA to obtain this level of training. Ultimately, the onus should fall to a regulated health professional trained in compounding (i.e., pharmacist, pharmacy student, intern, or regulated pharmacy technician) to validate the work of a PA.**

For Appendix 5, under Quality Assurance Program, Policy C.1, **OPA recommends that this should also include verification of the storage of products/ingredients,** so that there is an assurance that the products used in compounding are being stored appropriately in order to protect potency and stability.

With respect to Appendix 8:

- **OPA recommends that Compounding Step #2 should stipulate that all pharmaceutical calculations must be verified by a regulated health professional trained in compounding (i.e., pharmacist, pharmacy student, intern, or regulated pharmacy technician).**
- **OPA recommends that for Compounding Step #7, it should be made clear that compounding personnel are to compound only one preparation at a time in the designated compounding area.**
- **OPA recommends that for Compounding Step #17, verification of product conformity should be performed by a regulated health professional trained in compounding (i.e., pharmacist, pharmacy student, intern, or regulated pharmacy technician).**

With respect to Appendix 10, OPA acknowledges the intent of the process algorithm as a means of protecting staff. However, this algorithm poses a challenge as in most cases, hazardous products are often shipped and arrive in the pharmacy in the same shipping container as all other pharmaceutical products. Furthermore, receiving staff would need to know in advance that a hazardous product is in the shipment. Therefore, **OPA recommends that NAPRA engage with distributors, either individually or through the Canadian Association for Pharmacy Distribution Management (CAPDM), to establish protocols for the safe shipping of hazardous materials from the warehouse to the pharmacy.**

Conclusion

The Ontario Pharmacists Association thanks OCP and NAPRA for the opportunity to comment on the proposed *Model Standards for Pharmacy Compounding of Non-Sterile Preparations*. The Association would also like to acknowledge the pioneering work undertaken by the Ordre des pharmaciens du Quebec that led to this development of NAPRA's draft model standards document. The model standards, while extremely robust and contingent on strong documentation standards, will go a long way toward instilling public trust and confidence in the work that goes into pharmaceutical compounding. We look forward to ongoing feedback, dialogue and collaboration with our members and with the College on this matter. Should you have any questions or concerns with regard to this submission, please do not hesitate to contact the undersigned at your convenience.

Respectfully submitted,



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SVP, Professional Affairs

c.c. Sean Simpson, Chair of the Board, Ontario Pharmacists Association
Dennis A. Darby, CEO, Ontario Pharmacists Association
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