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**NAPRA MODEL STANDARDS FOR PHARMACY COMPOUNDING OF NON-
HAZARDOUS STERILE PREPARATIONS**
****POTENTIAL ELIMINATION OF "OFFICE-USE" PRESCRIPTIONS IN CANADA****

By using the term 'Patient-Specific' in the context of "prescriber-patient-pharmacist" relationship in the NAPRA Compounding Standards, there is a potential for the elimination of 'Office-Use' prescriptions in Canadian pharmacy.

Our specific concern is the change in wording in the final draft of the NAPRA Standards in that they appear to essentially eliminate 'Office-Use' compounded prescriptions. We have set out the specific wording from Draft 2A compared to Draft 3 and 4 (final) with the areas of concern highlighted. The wording that follows in the document reflects this change in position and is also of concern.

The Association of Compounding Pharmacists of Canada is advocating to preserve the right to dispense compounds for 'Office-Use'. Please review the information; we suggest you contact your Pharmacy Regulatory Authority to discuss the impact on your own practice and the risks to your patients.

Draft 2A [Sec 3.1]

"The preparation of medications has always been an integral part of the practice of pharmacy. It is essential to the delivery of health care and allows for personalized therapeutic solutions to improve patient care. However, it must always be carried out within an individual physician-patient-pharmacist relationship (i.e., from a prescription) or within a pharmacist-patient relationship for a specific need (e.g., with over-the-counter preparations). Provincial/territorial pharmacy regulatory authorities are responsible for verifying a pharmacy's preparation services in these situations."

Final Draft Version [Sec 3]

"The preparation of medications (pharmacy compounding) has always been an integral part of the practice of pharmacy. It is essential to the delivery of health care and allows for personalized therapeutic solutions to improve patient care. However, pharmacy compounding must always be carried out within a prescriber-patient-pharmacist relationship. Provincial/territorial pharmacy regulatory authorities are responsible for regulating a pharmacy's compounding services in these situations."

The proposed wording is not only in direct contradiction with Health Canada policy (POL-0051) and current OCP policy but will also have an enormous impact on those professions that rely on 'office-use' compounded prescriptions to provide quality care to their patients, notably physicians, dentists and veterinarians.

In our opinion the wording in Draft 3 and 4 (final) will impose an arbitrary and completely unnecessary restriction on a legitimate pharmacy practice that many prescribers and their patients rely upon. We also feel that it is entirely inappropriate for a NAPRA model standard to seek to limit or restrict the practice of physicians, dentists and veterinarians. These regulated professionals make use of 'office-use' compounded prescriptions to address the needs of their patient population and their permitted use of 'office-use' compounded prescriptions is endorsed and monitored by their own regulatory bodies.

It is not clear why the revision in wording is being proposed or whether NAPRA has consulted with prescribers and their regulatory bodies to appreciate the risks associated with eliminating 'office-use' compounded prescriptions.

The document should be revised to allow for the continued appropriate use of 'office-use' compounded prescriptions. The art of compounding is a professional practice area skill wherein pharmacists have the most skill and training of any healthcare professional, to ensure that it is done in a manner consistent with recognized international standards (e.g., USP)--standards which, when adhered to, ensure patient safety foremost, but also the safety and efficacy of the compounded preparation employed to treat the patient.

Putting practitioners in a situation of having to attempt to compound in their office because pharmacists cannot provide them with office-use preparations they require, and trying to do so under less than standardized conditions and procedures, does not protect the patient. Ironically, patient risk increases due to the practitioner not having properly compounded preparations at their disposal--all due to the elimination of office-use compounds. This makes a mockery of the very "standards" created allegedly to protect the patient, which themselves read "It is essential to the delivery of health care..." that pharmacy compounding be an integral part of the practice of pharmacy.

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