Association of Compounding Pharmacists of Canada
ACPC
Association des Pharmaciens Préparateurs du Canada

June 2016

Dear Pharmacist:

The National Association of Pharmacy Regulatory Authorities (NAPRA) has created two "Standards" documents regarding compounding of sterile preparations:

- Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations
- Standards for Pharmacy Compounding of Hazardous Sterile Preparations

Both documents went through four (4) drafts before reaching what is now a "final" version. NAPRA is optimistic that pharmacy Provincial Regulatory Authorities (PRA) will adopt these as Standards of Practice within the various provinces/territories.

The ACPC provided comments as a stakeholder concerning both documents (non-hazardous v.2A dated July 2014; hazardous v.2A dated August 2014). One significant area of concern was regarding Section 3 (Regulatory Framework), which stated (in part):

> *The preparation of medications...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)...*
>
> *In situations involving requests to compound preparations outside an individual physician-patient-pharmacist relationship, without a prescription, the compounding activities fall under the federal legislative framework.*[1]

By version 3, this content was changed and in fact the final versions of both documents now read as follows:

> *The preparation of medications (pharmacy compounding)...must always be carried out within a prescriber-patient-pharmacist relationship. [DELETED: "i.e., in the form of a patient-specific prescription" and "or within a pharmacist-patient relationship for a specific need (e.g., with over-the-counter preparations)"].*
>
> *In situations involving requests to compound preparations outside of a prescriber-patient-pharmacist relationship, in the absence of a patient-specific prescription, the preparation activities fall under the federal legislative framework.*[2]

[1] Underscores added
[2] Underscore added to illustrate changes

The ACPC submitted comments prior to version 3 being released, that urged the use of "healthcare professional-patient-pharmacist" terminology, consistent with what is found in Health Canada's POL-0051 document ("*Policy on Manufacturing and Compounding Drug Products in Canada*"). It did NOT endorse the use of "patient-specific" which appears to have arrived in version 3 after review by an American USP consultant. As we all should know by now, "office-use" is not considered legitimate in the USA by the FDA, which has been trying to eliminate this aspect of pharmacy practice.

Version 2A would, as written, not have prevented/outlawed any "office-use" dispensing since a "prescription" (by definition) included cases where a practitioner ordered drugs for his/her own use within the practice of that practitioner. (Example: narcotic office-use procurements are to be "sales-reported" in the name of the prescriber as patient and prescriber). Office-use procurements are acceptable in various professions across Canada per standards established by individual PRAs of medicine, dentistry, and veterinary medicine, in order to better serve patients of the practitioner. The Ontario College of Pharmacists published an article in its winter, 2016 "Pharmacy Connection" edition about the *Narcotic Safety and Awareness Act* (NSAA) that explained to pharmacists about how monitored drugs for "office-use" should be captured in the reporting system. Many other Canadian references abound that recognize the practice of "office-use" and the ACPC emphasized this point.

It cannot be emphasized strongly enough how the term "patient-specific" now being used in the two documents being considered by provincial colleges of pharmacy to be adopted as is, thus setting a "practice standard" to be adhered to, will eliminate any pharmacy under the jurisdiction of such colleges from being able to legally fill office-use prescription orders. The term is not defined in either document, also the case for the term "patient-specific." Yet these are critical terms now incorporated into both documents which pharmacy PRAs are considering adopting without further modifications to the documents. (One suggested change was to incorporate in writing--not by a general website statement that says "office-use will be permitted" without specifying so within the documents--a statement that indicates that if the current terms are to be retained, then "patient-specific" shall include "office-use" prescription orders from a practitioner entitled to prescribe in a province/territory of Canada).

This significant inclusion of American-based terminology in the two documents is consistent with the FDA using the same terminology to disqualify "office-use" orders since they are not "patient-specific."

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