ONTARIO PHARMACISTS ASSOCIATION

February 7, 2014

Ms. Judy Chong
Manager, Hospital and Specialized Practice
Ontario College of Pharmacists
Via email: jchong@ocpinfo.com

Dear Ms. Chong:

The Ontario Pharmacists Association (OPA or the "Association") welcomes the opportunity from the Ontario College of Pharmacists (OCP or the "College") to comment on the proposed supplement to the National Association of Pharmacy Regulatory Authorities' (NAPRA) Pharmacy Practice Management Systems (PPMS): Requirements to Support NAPRA Standards of Practice.

The Ontario Pharmacists Association is committed to evolving the pharmacy profession, and advocating for excellence in practice and optimum health care for all Ontario patients. As the largest advocacy organization, continuing education, and drug information provider for pharmacy professionals in Canada, the association represents pharmacists, pharmacy students, and pharmacy technicians across Ontario. By leveraging the unique expertise of pharmacy professionals, by enabling them to practice to their fullest potential, and by making them more accessible to all Ontarians, OPA and its more than 8,200 members are working to improve the efficiency and effectiveness of the province's healthcare system.

The Association would like to provide some comments, recommendations, and suggestions on the proposed supplement for the College's consideration.

The Ontario Pharmacists Association appreciates that the intent of the new requirements is to apply consistently across all provinces and territories, and recognizes that currently there are differences in provincial labelling standards. As such, if NAPRA were to adopt these requirements, OPA recommends that the provincial and territorial regulatory authorities work collectively to standardize a pan-Canadian direction to the existing labelling requirements.

Consistent with the Association's advocacy for excellence in practice and care and promotion of patient safety, the Association appreciates the overarching principle behind the proposed amendments to support the ability to effectively trace recalled medications to a specific patient. However, the Association questions the assumption that such traceability would necessitate changes to the labelling of a prescription provided by the pharmacy to the patient. Furthermore, section 156 (3) of the *Drug and Pharmacies Regulation Act* (DPRA) outlines the identification markings that need to be included on a container in which a drug is dispensed:

(a) the identification number that is on the prescription;
(b) the name, address, and telephone number of the pharmacy in which the prescription is dispensed;
(c) the identification of the drug as to its name, its strength, and its manufacturer, unless directed otherwise by the prescriber;
(d) the quantity where the drug dispensed is in solid oral dosage form;
(e) the name of the owner of the pharmacy;
(f) the date the prescription is dispensed;
(g) the name of the prescriber;
(h) the name of the person for whom it is prescribed;
(i) the directions for use as prescribed. R.S.O. 1990, c. H.4, s. 156 (3).

…../cont'd

Accordingly, amendments to the DPRA would ultimately be needed to allow for the enactment of the proposed labelling requirements in outpatient and community pharmacies. Given that the needs in homecare and hospital settings are different, as the medication administration to the patient is conducted through another healthcare professional, OPA recommends that the proposed requirements be amended to further reflect the different needs of community and outpatient dispensing in comparison to inpatient and homecare dispensing.

The Association supports the necessity of having Global Trade Item Numbers (GTINs) for any drug or compound provided to a pharmacy. However, it is OPA's view that:

1) GTINs should not be required on the labelling of products compounded and dispensed by a pharmacy directly to the patient.

   The PPMS is capable of storing the appropriate GTINs used to prepare the finished prescription product, and since patients cannot interpret GTINs, their inclusion on the label would clutter it unnecessarily.

2) The recommendations in the OCP supplement should come into effect only once GTINs are required and implemented on all products.

   The Association supports the notion that traceability of lot numbers and expiry dates through bar code scanning is of great value as a means of reducing risks associated with potential data entry errors. OPA suggests that a timeline be set for all drug manufacturers to start using GTIN technology to support such traceability on their products. While NAPRA has proposed that the original 35 requirements should come into effect January 1, 2016, it is OPA's recommendation that implementation of these additional PPMS requirements be deferred until such time whereby standardized GTIN protocols becomes a requirement for all manufacturers. If this standard is not upheld, the PPMS will not be able to reliably interpret information via a barcode scanner.

In addition, OPA questions how the assignment of GTINs to pharmacy-prepared compounds would be implemented and operationalized in practice. For instance:

- Appendix (I) implies that a pharmacy can create their own GTIN; however, the details must be recorded in the ECCnet registry, and the Association is unclear as to how such access would be operationalized in practice (i.e., web-based via a browser or integrated with the PPMS via a suite of messages). The Association would appreciate hearing GS1 Canada's perspective on this and other GTIN related matters.
- Will standard or commonly used mixtures have GTINs pre-assigned, or will GTINs be individualized per compound per pharmacy?
- Will there be an impact on prescription adjudication? For instance, will adjudicators continue to utilize PINs and pseudo-DINs for adjudication of prescription compounds, or will they adopt the National e-Claims Standards (NeCST) which would support all levels of GTINs.

…../cont'd

Furthermore, since identifiers (such as GTINs, lot numbers, serial numbers, etc.) are of no direct value to the patient, OPA recommends that PPMS's instead store this information and trace it back to the correct patient and prescription, eliminating the need for its inclusion on the label. Pharmacy staff can subsequently retrieve this information directly from the PPMS as required.

Recognizing that label space is generally limited, OPA reasons that adding additional information which is neither directly relevant nor beneficial to patients' understanding of their prescription product will create an unnecessarily cluttered label. This in turn would require the use of either larger labels or smaller font sizes to accommodate the new information. This is especially problematic for prescriptions for small products, such as eye drops, or for compounds that have multiple ingredients, resulting in multiple expiry dates and lot numbers being recorded.

The Ontario Pharmacists Association is also concerned that recording expiry dates on a label may incorrectly skew the patient's perception of the effectiveness of the medication, as these dates would not reflect the impact of real-life handling and storage conditions on the stability of the product. Moreover, once opened some medications such as eye drops have a much shorter shelf-life than the expiry date printed on the actual product. In such instances, a question arises as to which expiry date a pharmacist or a pharmacy technician should input on the label, particularly in common situations where such products might not be used immediately.

Therefore, it is the Association's view that the proposed changes in the supplement be considered as guidelines for pharmacists rather than as requirements. The onus would fall to the designated manager to ensure the pharmacy has the appropriate operational policies and/or software management systems in place to comply with the NAPRA standards of practice. As an example, some pharmacies voluntarily track expiry dates and lot numbers for all dispensed prescriptions. However, in the event of a recall, this documented information is not usually relied on solely to contact patients as there might be a potential for error in the manual recording of the lot number or expiry date. Hence, such a potential error could place a patient at risk should this information be the sole source of data relied upon to filter those patients who are to be contacted as a result of the recall. Therefore, operational best practices would suggest that the pharmacy should contact all patients who have received the medication during the time period when the recalled product was available within the pharmacy distribution network.

Given that the potential for recording a lot number in error would still exist with an electronic solution (e.g., two stock bottles with different lot numbers and expiry dates used to fill a prescription), the proposed amendments would create additional labour to capture information that may ultimately not be used. In addition, during the prescription filling process, pharmacy staff can input such information directly into the PPMS, which could store lot numbers, expiry dates, and other identifiers. Consequently, if a lot number is required for traceability, pharmacy staff can instantly identify all prescriptions related to that identifier directly from the PPMS. This scenario would be further exacerbated in cases of medication dispensing using compliance packaging, either through compliance cards or pouch packaging. This would affect both community and long-term care practice, particularly in instances where medications are dispensed as pouches generated by automated packagers that have the capabilities to automatically track medications by lot numbers and expiration dates through bar-code verification. As such, requiring inclusion of this information on each pouch would be unnecessary.

…../cont'd

It is also of OPA's opinion that the requirement for a separate machine-readable patient identifier would be un-necessary in community practice, as most PPMS's already identify prescriptions uniquely via a prescription/transaction number or a barcode, which in turn automatically identifies the correct patient. Furthermore, with regards to the requirement for the PPMS' capability to generate a label to identify a patient by a patient number, it seems that this would be more applicable for hospital practice than for community practice; OPA recommends that this requirement be clarified as such. Finally, the requirement of having the notation "exact volume" or "overfill" printed on the label seems to be more relevant to hospital, specialty pharmacy, or drug preparation premises than to retail community practice. The Association suggests the inclusion of sample practice examples for clarification and guidance on how such a requirement would be implemented in those various practice settings.

The Ontario Pharmacists Association appreciates the opportunity to comment on the proposed OCP supplement on Traceability and Labelling Requirements to NAPRA's Pharmacy Practice Management Systems Requirements to Support Standards of Practice. Should you require any additional information or clarification on any of the elements identified in this submission, please do not hesitate to contact me at your convenience.

Yours truly,

Allan H. Malek
Senior Vice President, Professional Affairs

cc Carlo Berardi, Chair, Board of Directors, Ontario Pharmacists Association
Dennis Darby, CEO, Ontario Pharmacists Association
Jim Gay, Chair, e-Health working group, Ontario Pharmacists Association
Sherif Guorgui, Vice President, Pharmacy, Ontario Pharmacists Association