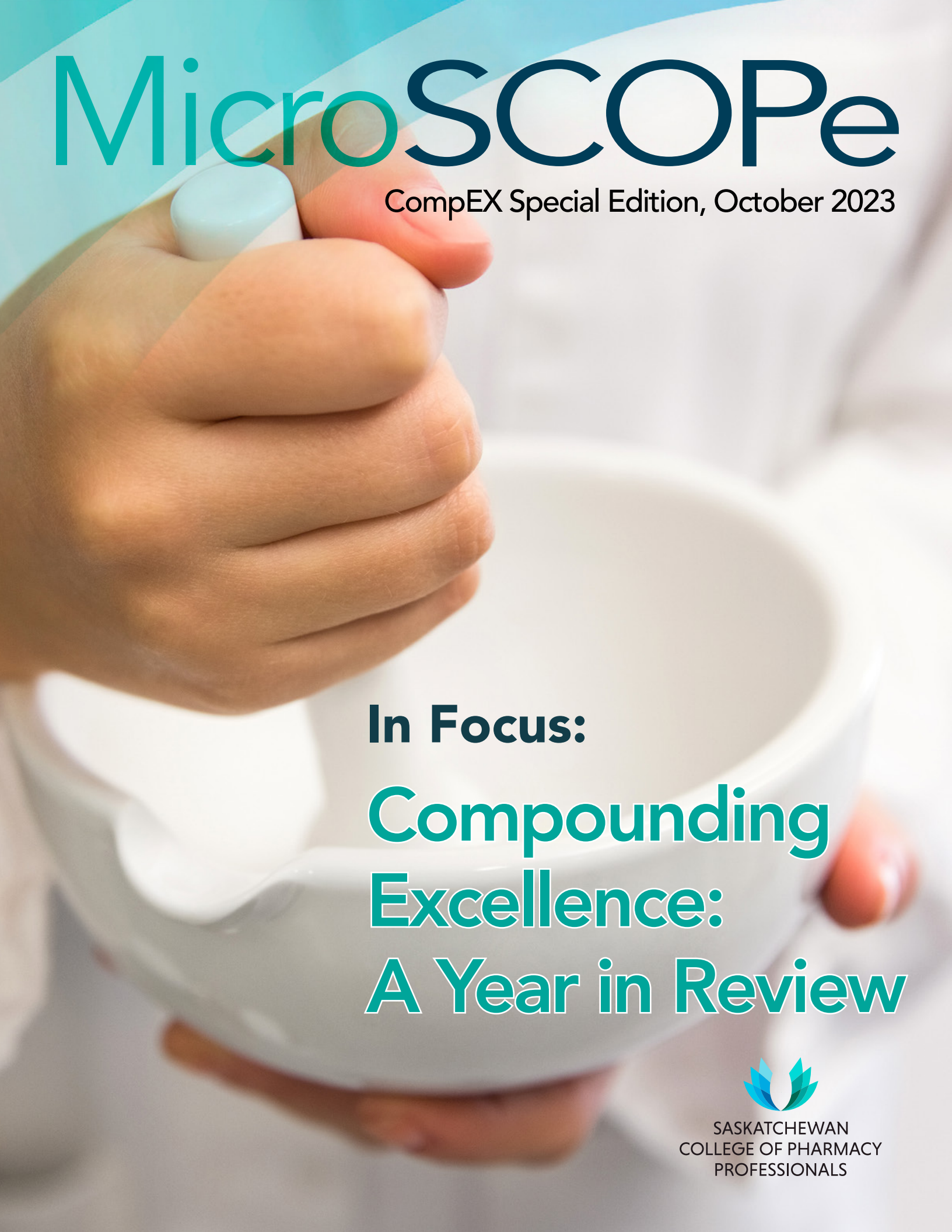
MicroSCOPe

CompEX Special Edition, October 2023



In Focus:

Compounding Excellence: A Year in Review

SASKATCHEWAN
COLLEGE OF PHARMACY
PROFESSIONALS

A Year in Review

- Following the announcement of the adoption of the NAPRA (National Association of Pharmacy Regulatory Authorities) Model Standards for Pharmacy Compounding in February 2019, all Saskatchewan pharmacies began a multi-year implementation process with full compliance by the Council-determined deadline of Aug. 31, 2022.
- Since the compliance deadline, the Field Operations team has been working through assessing facility and documentation compliance with all pharmacies through QIRs (Quality Improvement Reviews), renovation inspections and compounding specific follow up communication and visits.
- Trending areas of deficiency among Level A pharmacies are:
  - Documented Standard Operating Procedures (SOPs)
  - Cleaning logs and cleaning documentation
  - Documented in-house training and assessment programs, with documentation verifying training of pharmacy assistants prior to delegation of compounding duties. For a comprehensive outline of requirements in these areas, review NAPRA Non-Sterile Guidance Document.
- By Dec. 31, 2022, all pharmacies actively involved in Level C non-sterile compounding and sterile compounding had received compliance inspections and were either deemed compliant or required to suspend specific compounding activities until deficiencies were rectified. All Level B pharmacies had facility reviews prior to Dec. 31, 2022, with documentation reviews ongoing as part of the QIRs.
- The SCPP website now offers the ability to looks up a pharmacy's compounding level as part of the information provided under 'Pharmacy Services' through the Find a Pharmacy quick link.
- Level B Pharmacies – 50
- Level C Pharmacies – 7
  - 5 pharmacies are compliant
  - 2 pharmacies in the progress of addressing deficiencies
- Sterile Compounding Pharmacies – 5
  - 3 pharmacies compliant
  - 2 pharmacies with sterile operations in the progress of addressing deficiencies

Understanding Your Pharmacy's Compliance Level and Risk Assessment

The determination of your pharmacy's compounding compliance level occurred through the completion of a risk assessment of the compounds prepared by the pharmacy. The risk assessment involved reviewing the frequency and volume in which compounds are prepared, in conjunction with assessing the cumulative risk of all compounds.

The risk assessment of all compounds individually, and the cumulative risk, must be reviewed on an annual basis to ensure no changes to the compounding level (e.g., increased to level B or C or decrease from level B to A) has occurred. If a change has occurred, please contact the SCPP's Certified Compounding Inspector.

When receiving a prescription for a compound which the pharmacy has not made before, the first step should be to identify the risks which would be associated with the preparation of the compound. This might include, but not be limited to, drug exposure risk to pharmacy personnel, required equipment, and the pharmacy's compliance level. Based upon the risk assessment the pharmacy can then determine whether to transfer the prescription to a pharmacy who is able to safely prepare the compound (see SCPP's website under Find a Pharmacy) or prepare the compound with the appropriate supporting documentation as per the Standards.

A decision of professional judgement needs to be made and documented, with rationale supporting the determination to either transfer the prescription to a pharmacy of a higher level of compounding compliance or supporting the decision to prepare the compound.

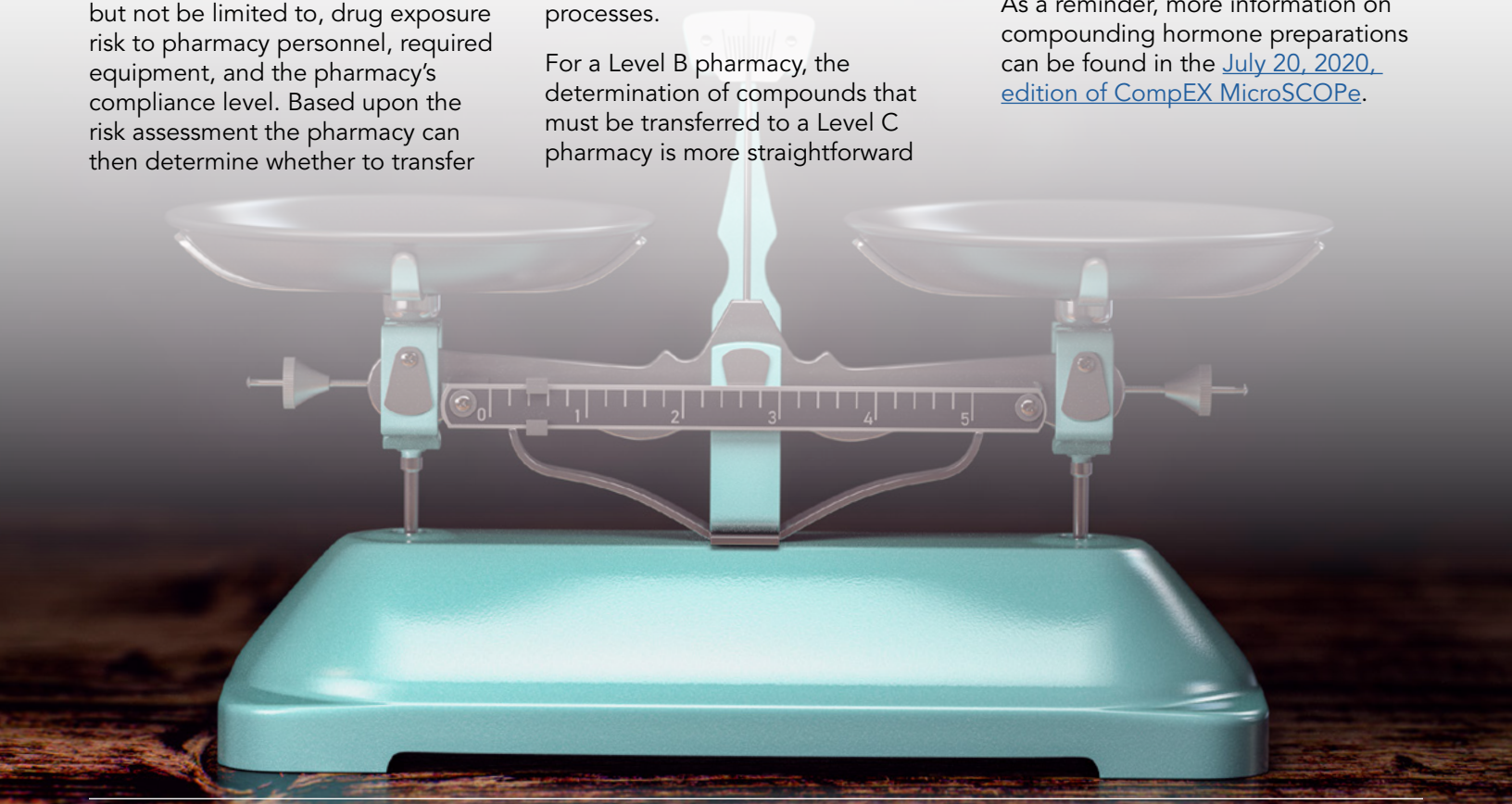
The differentiation between level A and level B compounding relies upon risk assessment. The assessment must include the drugs/active pharmaceutical ingredients/excipients utilized, the amount prepared and the frequency at which the compound is prepared. Pharmacy professionals are required to utilize up to date resources and to document any decisions to compound a product outside normal processes.

For a Level B pharmacy, the determination of compounds that must be transferred to a Level C pharmacy is more straightforward as all hazardous drugs classified by NIOSH on Table 1 or classified as hazardous by WHMIS must be compounded by a Level C pharmacy.

Hormones and NIOSH Table 2 and 3 drugs that will be compounded on a routine basis and with potentially larger quantities of active pharmaceutical ingredients (APIs) need to be compounded by a Level C pharmacy.

Infrequent hormone preparations (i.e. "one offs," or prescriptions that will not require routine, regular refills) can be compounded by Level B pharmacies, following the completion of an appropriate risk assessment and documenting additional protocols and procedures to follow for preparing that preparation; however, hormone preparations that are going to require the pharmacy to compound on a routine basis must be transferred to a Level C pharmacy.

As a reminder, more information on compounding hormone preparations can be found in the July 20, 2020, edition of CompEX MicroSCOPe.



I Received a Prescription for a Compound my Pharmacy Can't Prepare, Now What?

When a prescription is received for a compound that your pharmacy cannot prepare as per the above direction, that prescription must be either logged and transferred to a pharmacy of the compliance level necessary for preparing that compound or the patient must be provided with their prescription and directed to pharmacies that can are able to safely prepare the compound.

The patient's best interest must always be the first consideration in the provision of pharmaceutical care and every effort should be made to ensure that the patient is not unduly delayed in obtaining their prescription, including transferring the prescription to the closest/most convenient pharmacy for the patient.

The patient must always have the right to choose which pharmacy their prescription is transferred to.

If the pharmacy is going to log and transfer the prescription, the patient must be fully informed of the alternative pharmacies that can prepare and dispense the compound.

The patient must choose which pharmacy they would like the prescription transferred to on their behalf and proper documentation as per SCPP Regulatory Bylaws, Part N, must be included on the prescription transfer. In addition, documentation for the patients consent for the prescription to be transferred to the pharmacy of their choice must be completed.

The patient's best interest is of first consideration in the provision of pharmaceutical care and the patient must be fully informed of their options when they present a prescription for a compound that your pharmacy is unable to prepare and dispense.

Non-Sterile Compounding Across Canada

As with any transfer, the pharmacist must consider the patients' best interests as their first concern and that the protection of the patient is ensured.

Where a prescription is transferred to be filled out of province, the pharmacy the prescription is being transferred to is required to meet the same NAPRA Model Standards of Practice as that of Saskatchewan pharmacies.

The member transferring the prescription should be assured of the pharmacy's level of compliance with the NAPRA Model Standards for Pharmacy Compounding. The pharmacist should also ensure that the pharmacy has proper shipping and quality control measures to ensure safe transportation of the prescription to maintain the integrity of the compound.

As provinces have either adapted[i] or adopted[ii] the Standards and not all provinces have completed their implementation, it is essential to confirm that a patient's prescription is being filled by a pharmacy that meets the Standards in Saskatchewan in order to ensure the safety of the patient.

SCPP has completed a scan of most provinces and obtained the following information:

- PEI – Adopted with implementation deadline of Jan. 31, 2022.
- New Brunswick – Adopted with full compliance as of Oct. 1, 2022.
- Nova Scotia – Adapted, with adaptation published March 2021, full compliance expected Sept. 2023.
- Ontario – Adopted and implemented with full compliance currently expected.
- Manitoba – Adopted in 2018 with full compliance as of April 1, 2021.
- Alberta – Adapted in 2018 with full compliance expected as of July 1, 2021.
- British Columbia – Not fully implemented.

As outlined in previous communications, Saskatchewan adopted the NAPRA Model Standards for Pharmacy Compounding as announced in February 2019 with full compliance as of Aug. 31, 2022.

i Adopted – no modifications or changes to the Standards.
ii Adapted – modifications or changes were made to the Standards.