



SASKATCHEWAN  
COLLEGE OF PHARMACY  
PROFESSIONALS

# MicroSCOPE

March 26, 2019

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CompEX – Compounding  
Excellence

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## Continuing Education

### Treating Patients with Opioid Use Disorder

March 29, 2019 - Webinar

[More info](#)

### CAPhO Conference “Personal Medicine”

April 25-28, 2019 - Halifax

[More info](#)

### Oncology Conference

May 11, 2019 - Saskatoon

[More info](#)

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information, news and  
events, visit the homepage of  
the SCPP website:

[www.saskpharm.ca](http://www.saskpharm.ca)

## SCPP Officially Launches CompEX Implementation Program

**SCPP is pleased to officially launch CompEX**, the *NAPRA Model Standards for Pharmacy Compounding implementation program*. This edition of *MicroSCOPE* will lay out the steps and procedures, assessments and deadlines, that need to be met during Phase One, for you to achieve the new minimum standard requirements of Non-Sterile Pharmacy Compounding.

[Welcome to CompEX video link](#)

## Is Your Pharmacy Currently Involved in Compounding?

Compounding is defined by Health Canada as the following:

“The combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing. It can involve raw materials or the alteration of the formula and strength of commercially available products. It can include reformulation to allow for a novel drug delivery. Compounding does not include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on an approved drug’s labelling material.”

## Phase One Overview: March – September 2019

### Step One - Read

Review the *NAPRA Model Standards for Pharmacy Compounding* that are applicable to your pharmacy’s practice.

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

- [Model Standards for Pharmacy Compounding of Non-Sterile Preparations](#)
- [Guidance Document for Pharmacy Compounding of Non-Sterile Preparations](#)

MicroSCOPE is published by the Saskatchewan College of Pharmacy Professionals (SCPP) and is emailed to all active members of the College. As the newsletter includes decisions on matters such as regulations, drug schedule changes, etc., SCPP expects all members are aware of these matters.

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

- [Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations](#)

NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations:

- [Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations](#)

## **Step Two – Determine Level of Non-Sterile Compounding**

Section 4 of the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations Guidance Document lays out factors to consider and a decision algorithm for completing a Risk Assessment to determine what level of non-sterile compounding that your pharmacy's practice falls into.

A common request has been to have a list provided of what compounds are considered Level A and what fall into Level B classification. This cannot be provided as two pharmacies can prepare the same compounds, however, with the completion of a risk assessment evaluating the exposure risks associated with the drugs that are being compounded based on the frequency and volumes that are being prepared, some pharmacies could fall into a Level B classification while others can perform the same compounds within Level A. An example of this can be diclofenac as the frequency and volumes that your pharmacy prepares this compound can differentiate when you will need to meet either Level A or Level B compliance.

Understanding that completing a risk assessment can be complex, if you and your pharmacy team are struggling to determine where your practice lies, watch for a video to be released in mid-April providing more guidance on how to complete a risk assessment.

### Methadone Level B Statement:

The compounding of Methadone poses many exposure risks to the pharmacy staff who are performing the compounding activities as well as risks to patients and the rest of the pharmacy team when these activities are performed on a counter within the dispensary. These exposure risks have been reviewed by SCPP, as well as various regulatory and compounding groups and it has been concluded that based on a risk assessment, Methadone pharmacies must be compliant with Level B requirements.

## **Step Three – Completion of Gap Analysis**

A gap analysis checklist will be released in April that will assist you in assessing your areas of compliance through the implementation period. A gap analysis will be completed for the first time prior to the end of May 2019, and following the end of each implementation phase. The completion of this checklist will allow you to identify areas that you may like a little more guidance from your Compounding Field Officer, Brittany Sharkey, on how to meet compliance.

## Step Four – Phase One Completion Areas

A gap analysis checklist will be released in April that will assist you in assessing your areas of compliance through the implementation period. The implementation schedules outline the areas to begin reviewing and implementing as you begin your path to full compliance. Review the applicable sections in the NAPRA Model Standards for Pharmacy Compounding documents applicable to your practice for full details on the requirements to be compliant in each area.

Phase One focus areas include:

- Begin reviewing and revising existing beyond-use dates and dating methods, compounding procedures and compounding records
- Training and Assessment for staff involved in compounding activities
- Personnel conduct education and validation on handwashing, applying personal protective equipment, compounding techniques, cleaning and disinfecting, verification and labelling

## Implementation Schedules

- [Non-Sterile Compounding Implementation Schedule](#)
- [Non-Hazardous Sterile Compounding Implementation Schedule](#)
- [Hazardous Sterile Compounding Implementation Schedule](#)

## Resources To Assist You

### WEBSITE

- You will find a CompEX section through the Professional Practice tab on the SCPP website, [www.saskpharm.ca](http://www.saskpharm.ca)

### Other Channels

- A Webinar date and time is being determined. Stay tuned for further details
- FAQ Sheet will be posted to the website
- Your implementation coach, Brittany Sharkey, is just a phone call or email away to assist you, [Brittany.Sharkey@saskpharm.ca](mailto:Brittany.Sharkey@saskpharm.ca) or phone at 306-584-4330

Welcome to officially beginning Phase One on the road to NAPRA Model Standards for Pharmacy Compounding compliance! This implementation program has been designed with careful consideration and feedback from the SCPP Professional Practice Committee, SCPP Council and the Regulatory National Compounding Implementation Working Group. We look forward to working through this implementation process as a team to ensure full compliance can be met by all pharmacies by the December 2020 deadline.