



Guidelines for Pharmacists regarding the provision of Non-sterile compounding services

September 18, 2020

Introduction

The council of the College of Pharmacists of Manitoba approved the implementation schedule for the National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards for Pharmacy Compounding of Non-sterile preparations on December 10, 2018.

Pharmacists have a crucial role in health systems. Section 2(1) of The Manitoba Pharmaceutical Act states that the practice of pharmacy consists of the compounding, dispensing and retail sale of drugs. Pharmacists are educated and trained in the science of compounding and expected by patients and other healthcare professionals to provide this service. Pharmacists cannot simply choose to exclude this entirely from their practice.

However, the level to which a pharmacist engages in compounding must be considered. If the compounding is beyond the pharmacist's scope of practice, they must refer the patient to a pharmacy that is able to provide the service.

When deciding what level of compounding services to provide, there are a few things to consider:

1. Competencies necessary to compound at each Level
2. Facilities necessary to compound at each Level
3. Patient's access to medication

Pharmacies refusing to provide any compounding services at all would severely limit access to medications and ultimately put the public at risk, especially for remote or already underserved areas. It is in the patient's best interest to have their prescriptions processed in a timely manner by their community pharmacy and available for use, regardless of whether it is for a manufactured or compounded product. If a pharmacist cannot provide a compounded product due to unsuitable facilities or competency, they must refer patients to other health care providers whose expertise can best address the patient's needs.

Pharmacist's Role and Responsibilities in providing non-sterile compounding:

- In accordance with the pharmacy facilities practice direction, pharmacies must have the space and equipment necessary to provide compounding as part of the practice of pharmacy.
- Compounding personnel must maintain their competencies in order to provide non-sterile compounded drug products and services.

- Compounding personnel prepare compounded non-sterile products suitable to their level of competency and the facilities, equipment and training.
- A Pharmacy must make appropriate accommodations to obtain a compounded product or refer the patient to another pharmacy with appropriate facilities or competencies when the treatment required by the patient is beyond the scope of the member's professional practice or competence.

It is a reasonable expectation that a patient can receive a simple compounded product at any pharmacy in Manitoba.

Referring a patient:

Pharmacists referring patients to another pharmacy to obtain a compounded product should be familiar with the Practice Direction: referring a patient.

A licensed pharmacist must refer a patient to another appropriately qualified regulated health professional when:

2.3.1 the care or treatment required by the patient is beyond the scope of the member's professional practice or competence;

A licensed pharmacist who makes a referral to another health care professional must have reasonable arrangements in place to ensure continuity of care and follow-up with the patient when necessary. Pharmacists have the requisite knowledge and in most cases are already safely compounding simple, Level A compounds. They must consider a patient's access to care. Pharmacists are encouraged to consult the NAPRA Model Standards for Pharmacy compounding of Non-sterile products guidance document and seek out resources to assist them in providing the appropriate safe environment so they can provide a minimum level of care and not restrict access.

Resources

The following are a few resources that may be helpful to pharmacists preparing for non-sterile compounding:

- Quality Assurance Self Assessment Non-sterile compounding
- NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations
- NAPRA Guidance Document for Pharmacy Compounding of Non-Sterile Preparations
- Implementation Resources on the College Website