

[Pharmacy Name]
[Pharmacy Address]

February 16, 2018

Re: Implementation of Model Standards for Sterile Compounding

Dear Designated Manager/Director Liason,

In September 2016, the Ontario College of Pharmacists (the College) adopted the National Association of Pharmacy Regulatory Authorities (NAPRA) *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations* with an implementation date of **January 1, 2019**. These standards apply to all pharmacies which undertake sterile compounding.

In addition to regular pharmacy assessments and ongoing dialogue between College Practice Advisors and pharmacies, the College has also implemented a communication program to educate relevant pharmacies of their obligations under the new standards. As the implementation date is now just under a year away, this letter is intended to provide you with a reminder of the College's expectations in relation to these standards. All pharmacies engaged in sterile compounding will be completing an assessment in 2018.

Requirements for January 1, 2019

Sterile compounding is a high-risk activity and preparation of sterile compounds requires comprehensive standards to ensure quality and safety. Knowledge of the environment in which these preparations are prepared, training of personnel, policies and procedures, quality assurance procedures as well as appropriate standards for facilities and equipment are required to ensure public safety.

We acknowledge the work and efforts completed to date among pharmacies to comply with the standards and provide safe, high quality medications to patients. We also recognize that some pharmacies may need additional time to implement the needed infrastructure modifications in order to meet the requirements for facilities and equipment. Accordingly, the College expects that by **January 1, 2019**:

- a) All pharmacies will be fully compliant with all **critical elements** of the standards, as specified in the Assessment document (see Appendix A).
- b) Pharmacies that require additional time to achieve full compliance on all elements of the standards, including facility or equipment upgrades, will have an **action plan towards full compliance** –

including timelines and risk mitigation strategies satisfactory to the College – in place and submitted to us within 30 days of your 2018 assessment. Heather Arnott, College Practice Advisor, will work with pharmacies to review and finalize action plans and remain available to assist towards compliance with the standards.

Preparing for implementation

As it is our expectation that pharmacies are currently engaged in preparing for the implementation of the standards by the deadline, your pharmacy is encouraged to:

- a) Review the College's revised assessment document ([click here](#)) that identifies the critical elements that must be met by January 1, 2019 (see Appendix A for details).
- b) Conduct a gap analysis, if not already done, to compare against the standards, and particularly the critical elements, to assess gaps in pharmacy infrastructure, equipment, training, policies, procedures and practice. Once gaps are identified, resources should be directed to address those gaps; and
- c) Check the College's website and communication tools on a regular basis for updates and resources to support pharmacies in preparing for implementation of the new standards.

I am confident that together we can achieve our shared goals of quality and safe patient care. If you have any questions regarding the requirements for compliance, please reach out to Heather Arnott at harnott@ocpinfo.com.

Regards,



Tina Perlman, R.Ph., B.Sc.Pharm,
Manager, Community Practice

APPENDIX A

The following categories of standards from the *Model Standards for Pharmacy Compounding of Nonhazardous Sterile Preparations* and the *Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations* (NAPRA 2016) contain elements that are considered critical for the January 1, 2019, deadline. Identification and explanation of those critical elements can be found in the Assessment Report, [here](#). (insert Link) We also encourage you to review the Standards in their entirety to identify other areas that may require attention in order to develop your action plan to bring the pharmacy into full compliance.

Personnel

- The Pharmacy Manager or Pharmacy department head is responsible for developing, organizing and supervising all activities related to pharmacy compounding of sterile preparations.
- The sterile compounding supervisor develops, organizes and oversees all activities related to the compounding of sterile preparations.
- The compounding pharmacist or pharmacy technician performs or supervises compounding activities, ensuring compliance with policies and procedures related to the compounding of sterile preparations.
- The sterile compounding supervisor ensures policies and procedures are in place and adhered to for all compounded sterile preparations.
- All compounding personnel have received specific training and completed a competency assessment program in the workplace.
- All cleaning and disinfecting personnel have received initial training and completed a competency assessment program in the workplace.

Personnel Involved in Aseptic Compounding

- There is a quality assurance program in place that addresses the personnel involved in aseptic compounding.

Conduct of Personnel

- Conduct of personnel in controlled areas must meet NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations.

Compounded Sterile Preparation Protocols, Compounded Sterile Log Preparation & Patient File

- Effective documentation and record keeping processes are in place according to standards of practice and NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations.
- The Pharmacy has access to the current required references as listed in the NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations.

Facilities and Equipment

- The storage of non-hazardous drugs is in compliance with the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations.

- When a segregated compounding area is used, the specific conditions outlined in NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations standards must be met.
- Equipment for the compounding of sterile preparations is designed, built, and maintained in accordance with NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations. For example by January 1, 2019:
 - An appropriate Primary Engineering Control (PEC)/hood is certified and validated.
 - The refrigerator must be commercial, biomedical grade.
- There is a cleaning and disinfecting procedure in place that addresses all compounding areas.
- There is a cleaning, disinfecting, deactivating and surface decontamination procedure in place for compounding personnel that addresses all compounding areas.

Verification of Equipment and Facilities

- There is a quality assurance program in place that addresses the verification of equipment and facilities.

General Maintenance Log

- The general maintenance logs are complete, accurate and maintained as per standards of practice and NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations.

Beyond Use Date and Dating Methods

- The Pharmacy's operating procedures describe the risk assessment process used to establish the BUD and the storage conditions according to NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations. For example by January 1, 2019:
 - High risk preparations made from non-sterile ingredients or equipment must meet beyond use dates.
 - There must be a policy in place to specify beyond use dating of single dose vials.

Aseptic Compounding of Sterile Preparations

- There is a process in place to ensure aseptic compounding of sterile preparations meets the NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations.
- There is a process for verification of the final compounded sterile preparation.

Labelling

- Labelling of the final compounded sterile preparation meets NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations and provincial requirements.

Recall of Sterile Products or Final Compounded Sterile Preparations

- There is a process in place when a product or preparation does not meet requirements due to issues of internal control and/or a complaint or a product recall.

Quality Assurance Program

- There is a quality assurance program in place that addresses the content of the program itself, the results & actions taken, the product preparation process and documentation.

Packaging, Receipt & Transport and Delivery

- The Pharmacy has policies and procedures in place to ensure safe packaging, transport and receipt of compounded sterile preparations.

Incident and Accident Management

- The Pharmacy has policies and procedures in place to address incident and accident management with respect to sterile compounding.

Waste Management

The Pharmacy has a waste management process in place.