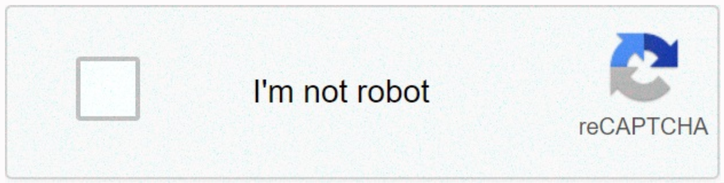

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Ocp guidelines for sterile compounding

Approval Date: March 28, 2018 NAPRA's suite of model standards for pharmacy compounding includes three model standards, with one pertaining to non-hazardous sterile preparations, one to hazardous sterile preparations, and one to non-sterile preparations. The implementation of model standards is under the direction of the respective provincial, territorial or Canadian Armed Forces pharmacy regulatory body. These bodies each establish their own process for the implementation of the standards in their jurisdiction. The guidance document has been developed to provide more information on how to achieve the standards described in model standards for Pharmacy Compounding of Non-sterile Preparations. In addition, the guidance document provides direction and assistance in the implementation of model standards. The model standard for pharmacy compounding of non-sterile preparations, published with this guidance document, is available below and on our website. The model standard document effectively replaces NAPRA's Pharmacicompounding Guidelines (2006). Audience: General Practice Resources It is the responsibility of the appointed managers and pharmacists to ensure that they stay up to date by reviewing this page and College communications regularly. If the standards implementation and adherence to these standards are an important way that pharmacists can protect patients, increase patient safety and protect pharmacists. Model standards represent the minimum requirements that must be met by all pharmacists and pharmacy technicians as composite non-sterile preparations. All internships must meet this standard and the performance of pharmacy professionals engaged in the use of non-sterile preparations will be measured by these standards. These standards have replaced the 2006 College Guideline for compounding preparations. Implementation In recognition of the changing COVID-19 pandemic situation and the need for pharmacists to focus on continuity of care and minimise general risk, the Council approved on 23 March 2020 an extension of deadlines for pharmacies to meet standards. The updated timelines for the completion of each phase are: Phase 1: 1 January 2020 – Assessing risks and gaps phase 2: 1 July 2021 – Staff training and quality assurance phase 3: 1 January 2022 – Facilities and equipment In phase 1, evaluation of the pharmacy's current training environment is a priority, with the aim of implementing appropriate procedures and quality controls to protect patients and compounding staff. For more information on Assessing Risks and Gaps, see the Pharmacy Connection Article Implementation Timeline for Non-Sterile Compounding Standards. In phase 2, the priority will be the training and assessment of all staff involved in non-sterile compounding. Quality assurance processes need to be to monitor compliance with the standards and safety of the system. In phase 3, the focus will be on ensuring that the plant and equipment for the preparation of hazardous and non-hazardous non-sterile compounds are in compliance with the standards. A quality assurance programme will have to deal with facilities, equipment, personnel, composite non-sterile preparations and documentation. It is the College's expectation that pharmacies are currently engaged in preparing for the implementation of the standards by 1 January 2022. Important resources from the College To assist pharmacy professionals as they work to implement the standards, the college has provided: In addition, see the assessment criteria document and list of relevant Pharmacy Connection articles below. Assessment criteria The College has produced a document on assessment criteria for non-sterile preparations. This document is intended to be used by pharmacists to assess the gaps between current processes/practices at the pharmacy and the requirements of the standards. The document sets out each standard and accompanying section of the guidance document to illustrate specific insights or activities required to ensure compliance with the standard. Pharmacy professionals can tick off any standard as it is met and track their progress on meeting standards. However, this document is not intended to replace the standards. As described above, it is the College's expectation that pharmacies will have assessed their risks and gaps by 1 January 2020 to prepare for the implementation of the staff training and quality assurance components by 1 July 2021. Pharmacy Connection Articles Previously Shared in Pharmacy Connection are expected to fully comply with all parts of the standards by January 1, 2019. Take the time to review the college's sterile compounding key initiative and FAQs to ensure your pharmacy is prepared. If a pharmacy needs additional time to ensure compliance with standards, it is the college's expectation that these pharmacies will prioritize their work to ensure that they comply with all critical elements of the standards by January 1, 2019 and submit a detailed action plan with risk mitigation strategies to the college outlining the steps the pharmacy will take, with timelines, toward full compliance. As the college concludes its visits to all pharmacies engaged in sterile compounding, it is clear that there has been a tremendous amount of hard work put in by pharmacies throughout the province as they prepared for the implementation of these important patient-safety standards. For pharmacies that have submitted action plans, it is important that this work continues and that risk mitigation strategies are in place until a pharmacy's full compliance with the standards has been achieved. It is also important that the College continues to provide support and guidance to pharmacies for help them them complete compliance. Practice advisors will continue to provide support and support to pharmacies with action plans after the implementation deadline and the College will continue to provide information and resources to pharmacies to support their ongoing efforts to meet standards. In the meantime, the college has posted Frequently Asked Questions on our website. Be sure to check them out. Questions in the frequently asked questions online are: What is required for January 1, 2019? What happens if our pharmacy is unable to meet the critical elements by January 1, 2019? What are the next steps for organizations that are not fully compliant with NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations by January 1, 2019 but have met the critical elements? Who can be a Sterile Compounding Supervisor (CS) and what are they responsible for? Where can I find a third party evaluator to evaluate sterile compounding supervisors? Do you have any suggestions or recommendations to assist us in requests for potential capital projects required to meet the standards by January 1, 2019? Are there opportunities for regional models? Who should I contact about specific questions I have about operational procedures and police? What are the college's expectations for Beyond-Use-Dating, (BUD)? What training and certification programs are recommended? What is required when organisations/pharmacies respond to assessment report action plans? How do I submit and respond to an action plan? What are the requirements for environmental testing? Does our hospital need to be concerned about the sterile implementation guidelines if there is no pharmacy in place? Sterile compounding is a high risk activity and the preparation of sterile compounds requires comprehensive standards to ensure quality and safety. Knowledge of the environment in which these preparations are prepared, training of staff, policies and procedures, as well as quality assurance procedures, as well as facilities and equipment standards, are required to ensure public safety. The college's mandate is to serve and protect the public. In line with the expectations of the public and the patient, these standards are important and must be in place to protect patients. Patient safety will be our top priority in the work with pharmacies that implement the standards. Requirements for January 1, 2019 We recognize the work and efforts that have been completed so far among pharmacies and institutions to meet the standards and provide safe, high-quality medications to patients. We also recognise that some pharmacies may need additional time to implement the necessary infrastructure changes to meet the requirements for facilities and equipment. Consequently, the College expects that by 1 January 2019: (a) All pharmacies will be fully compliant with all critical elements of the standards, as specified in the hazardous sterile preparations and non-hazardous sterile preparations Pharmacies that require additional time to achieve full compliance on all parts of the standards, including plant or equipment upgrades, will have a full compliance action plan, including timelines and risk reduction strategies that are satisfactory to the college on site and submitted to us within 30 days of their assessment in 2018. College Practice Advisors will work with pharmacies to review and complete action plans and remain available to help meet standards. How can you prepare for implementation? Since it is our expectation that pharmacies are currently engaged in the preparation for the implementation of the standards within the deadline, your pharmacy is encouraged to: a) review the hazardous sterile preparations and non-hazardous sterile preparation assessment documents. (b) carry out a gap analysis, if not already done, to compare against the standards, and in particular the critical elements, to assess gaps in pharmacy infrastructure, equipment, training, policies, procedures and practices; Once the gaps have been identified, resources should be directed to address these gaps; and c) Check the College's website and communication tools regularly for updates and resources to support pharmacies in preparing for the implementation of the new standards. d) Collaborate with your LHIN and other hospitals to identify regional solutions to meet standards. The college has been working with northeastern LHIN to develop a regional pharmacy strategy, which can be used by LHINs and hospitals to guide regional planning for decisions related to sterile compounding. The overall goal of the strategy is to support hospitals in an LHIN to consistently provide medication management services according to standards, with an immediate focus on standards related to sterile compounding. The strategy has been designed to be flexible and can be adapted to suit the needs of different LHINs. The college has sent letters to all pharmacies that perform sterile compounding to highlight these expectations. A copy of each letter is available below: Ultimately, these standards are an important way to protect patients and increase patient safety. It is the College's expectation that pharmacies are currently engaged in preparing for the implementation of the standards by 1 January 2019. Safe Compounding: It all starts with you! You!