Priority One: To be Complied with Prior to July 1, 2018

- Review NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations
- Identify risk level (complexity, volume) of compounded sterile preparations
- Perform a gap analysis by comparing the Model Standards with current pharmacy sterile compounding procedures and facilities
- Prioritize the gap analysis and develop an action plan for compliance with the Model Standards
- Initiate a quality assurance program, prioritizing:
    - Verification of equipment, including PEC
    - Verification of controlled areas (clean room and anteroom)
    - Development of a written sampling plan for controlled areas according to specifications of a recognized standard, such as CETA applications guide CAG-002, CAG-003, or CAG-008

Priority Two: To be Complied with Prior to January 1, 2019

- Meet or exceed core requirements for a sterile compounding service
    - Personnel – both compounding personnel and cleaning personnel
    - Policies and procedures
- Meet or exceed production preparation requirements
    - Compliance with beyond use dating and dating methods – including consideration of the requirements surrounding sterility and endotoxin testing
    - Compounded sterile preparation protocols
    - Compounded sterile preparation log
    - Patient file
    - Conduct of personnel in areas reserved for the compounding of sterile preparations
    - Aseptic compounding of non-hazardous sterile preparations – including, but not limited to, hand and forearm hygiene and garbing, cleaning and disinfection
    - Packaging
    - Storage
    - Transport and delivery
- Complete quality assurance program
    - Verification of equipment and facilities – certification and written sampling plan (Implementation Framework, step one)
    - Results and action levels
    - Quality assurance of personnel involved in aseptic compounding – Gloved fingertip sampling, media fill test
    - Quality assurance of compounded sterile preparations
    - Documentation of quality control activities

Priority Three: Date for Coming into Effect to be Determined

- Meet or exceed core requirements for a sterile compounding services
    - Facilities and equipment

A date for priority three to come into effect was deferred pending approval of complementary standards for Compounding Sterile Hazardous Preparations and the availability of additional information from key stakeholders and policy decisions in other provinces.