CONNECTICUT DEPARTMENT OF CONSUMER PROTECTION

DRUG CONTROL DIVISION

Connecticut Enforcement Policy and Emergency Authorization of Deviation from USP 797 Compounding Standards During Declared Public Health Emergency for COVID-19

For as long as the current public health emergency, declared by Governor Ned Lamont on March 10, 2020, remains in effect, hospital and health systems pharmacies located in Connecticut may deviate from the USP 797 standards related to the garbing requirements for non-hazardous compounding if the following conditions are met:

1. The hospital or health system pharmacy determines that deviation is necessary due to shortages in personal protective equipment (PPE) and such determination shall be documented.

2. The hospital or health system pharmacy notifies the Department of Public Health (DPH) and the Department of Consumer Protection Drug Control Division (Drug Control) by e-mail prior to the implementation of **any material deviation** from USP 797 garbing requirements and provides the assessment to support and outline the material deviation. The e-mail shall be sent to dph.flisadmin@ct.gov and DCP.DrugUSPCompounding@ct.gov.

3. A deviation from USP 797 garbing requirements may be implemented immediately, upon notification via email to DPH and Drug Control, if it is in accordance with guidance from, or in consultation with, USP or CriticalPoint, or obtained through consultation with a microbiologist, infection control professional or industrial hygienist each knowledgeable in USP 797 garbing procedures.

4. If a hospital or health-system pharmacy, in consultation with the Director of Pharmacy and Designated Pharmacist, intends to deviate from USP 797 garbing requirements where there is no guidance issued by USP or CriticalPoint, before implementation, the deviation shall be assessed by: (1) an individual or individuals with credentialed expertise in the content area where the deviation will be implemented and shall be knowledgeable in USP 797 (e.g., expertise in sterile products, environmental controls, microbiology, infection control, industrial hygiene); and (2) the hospital or health system's infection control committee. The assessments shall address quality and safety of implementing the deviation, and mitigation strategies to minimize contamination.

5. After an assessment of the deviation(s), the processes to be implemented are documented, and documentation is maintained indicating the duration of time the pharmacy is operating under the deviation or deviations.

6. The hospital or health system pharmacy has developed a policy that details the conditions under which the deviation may be implemented. Training of compounding personnel shall be documented and compounding personnel shall demonstrate competency for such deviation.

7. Master formulas are evaluated to determine if changes are necessary to the criteria for establishing beyond-use dating.

Products compounded in accordance with this Policy and Waiver shall be dispensed pursuant to a patient-specific prescription or patient-specific medication order in the hospital setting, or may be transferred or distributed within the state of Connecticut to another affiliated hospital or to another Connecticut licensed hospital, with e-mail notice of the transfer or distribution to Drug Control pursuant to the process on www.ct.gov/dcp/dcd.