Guidance Document

Compounding Record and Master Formulation Record for Sterile Compounds

USP Chapter <797> requires that a compounding record be created and maintained for sterile products. USP Chapter <797> does not define the specific elements to be included in the compounding record. North Carolina Board of Pharmacy rules have always required a compounding record and did so well before implementation and enforcement of USP standards for compounding. The Board of Pharmacy currently requires and will continue to require the following elements for compounding records.

(Pharmacist should note that proposed revisions of USP Chapter <797> do specifically list the following required elements for both the Compounding Record and the Master Formulation Record. Pharmacists are advised to follow communications from USP concerning potential updated revisions to USP Chapter <797> anticipated to come into effect on December 1, 2019.)

Compounding Record

- Official name, strength, and dosage form of the compounded sterile preparations (CSP).
- Master Formulation Record reference for the CSP, when used.
- Name and quantity of all component.
- Sources, lot number, expiration date of each component.
- Total quantity compounded or number of units compounded.
- Date of preparation of the CSP.
- Assigned internal identifications number (e.g., prescription number or batch number).
- Signature or initials of all the individual pharmacists and technicians involved in each step of the compounding process.
- Documentation of calculations made to determine and verify quantities and/or concentrations of each component (where required to prepare a compound).
- Documentation of quality control procedures in accordance with standard operating procedures (e.g., filter integrity, pH, visual inspection, testing procedures and testing results). Documentation of sterilization method (if applicable).
- Description of final product as a part or separate piece of the quality control procedures.
- Documentation of any deviations from the master formulation record.
- Assigned Beyond Use Date (BUD), including referenced compatibility, stability and sterility data if BUD is extended past the BUD's set forth in USP <797>
- Duplicate container label.

The Board of Pharmacy also requires that the following element be included in the Master Formulation Record. Master Formulation Records are required for drugs compounded in batches or any compound that is made more than once.

Master Formulation Record

- Official Name, strength, and dosage form of the CSP.
- Physical description of the final preparation.
- Description of all ingredients and their quantities.
- Complete instructions for preparing the CSP including: equipment, supplies, and description of compound steps including sterilization method, if applicable.
- Assigned BUDs that are compliant with USP <797>standards. If extending BUD beyond USP <797> standards, then references establishing compatibility and stability must be included.
- Storage requirements
- Quality control procedures (e.g., pH, sterilization method, and visual inspection).

Hospital Pharmacy Records for Patient-Specific Individual Single Doses including TPNs

Board staff have been asked about Board expectations concerning Master Formulation Records and Compounding Records created by hospitals that make several different patient-specific individual doses of sterile compounded medications, including TPNs. Board staff have consulted with USP experts, and this document provides guidance for hospital pharmacies arising from these consultations.

In the case of patient-specific individual single doses, the Medication Order may serve as the Master Formulation Records if it contains all the required elements and is readily retrievable. The pharmacy can then generate a medication label that will be considered the compounding record as long as the following information is documented on that record: Beyond Use Date, description of final product, components of the compound, the lot numbers and expiration dates of each component. Documenting lot numbers and expiration dates of the components must be done for <u>all</u> components in all compounded products. This is required in order to facilitate recalls of compounded sterile products containing recalled components. <u>The pharmacy must also have written policies and procedures in place detailing how these patient-specific individual single dose compounds are made and documented.</u>

Any sterile compounded drug product that is produced in batches and made at the hospital must have a specific Master Formulation Record and a specific Compounding Record that documents lot numbers and expiration dates for those batches.