**JUNE 2019 | USP <797> BUD Briefing Paper**

On June 1st, 2019 the United States Pharmaceopeia (USP) released their new version of General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. A copy of the new chapter can be downloaded from USP here: https://www.usp.org/compounding/general-chapter-797. The chapter is not yet enforceable as it will become official in USP on December 1st, 2019.

In the current and soon to be former Chapter <797> sterile preparations were divided into Low, Medium, and High Risk Preparations. However, in the new Chapter <797> this system has been removed in favor of Category 1 and Category 2 Compounded Sterile Preparations (CSPs).

Category 1 CSPs are defined as "CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter." Category 1 CSPs may be prepared in an unclassified Segregated Compounding Area while Category 2 cannot. Category 1 CSPs do not require sterility testing while Category 2 CSPs may require a sterility test depending on the beyond use date assigned.

A Category 2 CSP is defined as: "A CSP that is assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter." The vast majority of compounding pharmacies will be preparing Category 2 CSPs under the new system. The Beyond Use Dates (BUDs) allowed for Category 2 CSPs are dictated by the method of sterilization, whether or not a sterility test is performed, passed, and the storage temperature of the preparation. Table 11 of the new Chapter <797>[1] provides the following maximum BUDs:

**Table 11. BUDs for Category 2 CSPs**

| Preparation Characteristics | | Storage Conditions | | |
|---|---|---|---|---|
| Compounding Method | Sterility Testing Performed and Passed | Controlled Room Temperature (20°–25°) | Refrigerator (2°–8°) | Freezer (–25° to –10°) |
| Aseptically processed CSPs | No | Prepared from one or more nonsterile starting component(s): 1 day | Prepared from one or more nonsterile starting component(s): 4 days | Prepared from one or more nonsterile starting component(s): 45 days |
| | | Prepared from only sterile starting components: 4 days | Prepared from only sterile starting components: 10 days | Prepared from only sterile starting components: 45 days |
| | Yes | 30 days | 45 days | 60 days |
| Terminally sterilized CSPs | No | 14 days | 28 days | 45 days |
| | Yes | 45 days | 60 days | 90 days |

When USP released their proposed draft of <797> it included the following statement[2]: "Additionally, the Expert Committee is considering the development of new resource(s) to assist compounders in extending BUDs for Category 2 CSPs to include criteria for validated stability-indicating assays and testing for sterility, endotoxins,

[1] United States Pharmacopeia. General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. USP-NF 42-NF37. 2019.

[2] https://www.usp.org/sites/default/files/usp/document/our-work/compounding/proposed-revisions-gc-797.pdf

container-closure integrity, and particulate matter. The resource(s) are intended to guide correct interpretation and application of testing results."

Despite this statement, the newly released version of Chapter <797> does not provide any resources to assist compounders in extending BUDs for Category 2 CSPs. In plain language the maximum BUDs you can have for any Category 2 CSP under the new <797> are the ones in the chart despite any valid scientific data you may have obtained to substantiate a longer BUD. For those Category 2 CSPs that will have a sterility test performed the minimum time that it takes to perform the USP <71> sterility test is 14 days not including time to transport samples to the testing facility. The result is approximately 30 useable days for aseptically processed CSPs and 45 useable days for terminally sterilized CSPs.

These new restrictive BUDs force pharmacies to make smaller batches of compounded sterile preparations much more frequently. Pharmacies will have to devote more time to compounding more small batches and will have a higher utilization of consumable items in the process. When pharmacies make a batch the testing requirements and thus cost are approximately the same independent of the size of the batch. All of this leads to much higher costs for patients which will become a patient access issue as these medications are pushed out of being affordable for more and more Americans.