STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
25.01.07 <u>Inventory Management System.</u> *Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.* §482.25(b)(3)	The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patent use. **This would include drugs that are the subject of a manufacturer's recall.** **A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer's approved labeling.** **A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.** **The BUD is to be based on information provided by the manufacturer, whenever such information is available. The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information**	**OBSERVATION AND INTERVIEW** 1. Spot-check the labels of individual drug containers to verify that they conform to **Federal and** State laws, and/or contain the following minimal information: • Each patient's individual drug container bears his/her full name, the prescriber's name, and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date **and/or, if applicable, a BUD**. • Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date. 2. If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, and expiration date **and/or, if applicable, a BUD**. 3. Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications. **4. Review the pharmacy policies and procedures for determining BUDs (for medications compounded in-house as well as from external sources).**	☐ 1 = Compliant ☐ 2 = Not Compliant **This standard is not met as evidenced by:**

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE

is not available from the manufacturer. The policies and procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the United States Pharmacopeia-National Formulary (USP).[4]

According to Chapters <795> and <797> of the USP, the BUD must be safe for patients, and determined conservatively.

- **The section in USP <797> entitled "Determining Beyond-Use Dates," which addresses sterile compounding, notes that "the truly valid evidence for predicting beyond-use dating can be obtained only through product-specific experimental studies."**

- **It provides an example of testing considered more appropriate for certain types of compounded sterile preparations (CSPs) such as "CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity…."**

- **It also provides examples of important issues that a pharmacist must be able to critically interpret and evaluate when consulting literature sources in the process of determining a BUD; and distinguishes between reviewing literature specific to a particular drug, composition, concentration of ingredients, fill volume, container, storage conditions and duration of use, etc., versus merely reviewing**

- **Can the hospital demonstrate that the policies and procedures are consistent with or more stringent than the applicable USP standards?**

- **Can it demonstrate that the pharmacy personnel assigned to determining BUDs when a manufacturer's instructions are not available have the expertise and technical support needed to properly conduct the assessments needed to make such determinations in a manner consistent with standards and hospital policies?**

5. **Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy.**

   - **Interview pharmacy personnel assigned to carry out this function within the hospital and/or to assess how this is done by external source(s) of CSPs.**

   - **Is there evidence that the BUDs are determined consistent with the hospital's policies and procedures?**

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE

available publications or tables.

- **The former is the preferred approach, while the latter results in a "theoretical BUD," which has an inherent likelihood of inaccuracy or error.**

For individual drug containers:

- **Each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date.**

- **Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD.**

- **It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-punctured), the USP standard is that the BUD is 28 days, unless otherwise specified by the manufacturer.**

- **In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.**

If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE

[4] All references to "USP" herein are from: United States Pharmacopeial Convention. USP on Compounding: A Guide for the Compounding Practitioner. Current with USP 37-NF32 through First Supplement. Rockville, MD: United States Pharmacopeial Convention, 2014.