STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
25.01.01 Medication Control & Distribution. *In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice consistent with Federal and State law.* §482.25(b)	Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations that apply to pharmaceutical care and the control and distribution of drugs and biologicals. The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970. **Other sources of additional guidelines could include, but are not limited to: American Society of Health-System Pharmacists, American College of Clinical Pharmacy, American Pharmacists Association, United States Pharmacopeia, etc.** **Note re: US Pharmacopeia/National Formulary (USP/NF)** **According to the Federal Food, Drug and Cosmetic Act (FCDA), the official compendia of the United States for excipients, drug substances, and drug products is the USP/NF. It is published every year in November by the United States Pharmacopeial Convention (http://www.usp.org/) and includes two supplements published in February and June.**	**DOCUMENT REVIEW & OBSERVATION** 1. **Are questions regarding medication orders resolved with the prescriber and a written notation of these discussions documented in the patient's medical record or pharmacy copy of the prescriber's order?** 2. Does the hospital retrieve and remove medications available **for** patient use when the hospital has been informed of a drug recall? 3. **Are medication orders routinely reviewed by the pharmacy before the first dose? What evidence can the hospital present that such reviews take place?** 4. **Does the hospital pharmacy have a system for monitoring the effects of medication therapies for cases specified per hospital policy?**	☐ 1 = Compliant ☐ 2 = Not Compliant **This standard is not met as evidenced by:**

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The USP is a not-for-profit, non-governmental organization that since 1820 has established quality standards for, among other things, drug substances, drug products and compounded preparations. Congress established a role for USP standards in the adulteration provision of the 1906 Food and Drug Act. That role was expanded in the modern Food, Drug and Cosmetic Act (FDCA) beginning in 1938, with a role for USP compendial standards for naming and identity; strength, quality, and purity; and packaging and labeling, in both the adulteration and misbranding provisions of FDCA. (See, for example, §501(b) of the FDCA regarding compendial standards for strength, quality and purity, §502(g) for compendial standards for packaging and labeling). Under the FDCA, a drug with a name recognized in the USP/NF must comply with compendial identity standards, or be deemed adulterated, or misbranded, or both. To avoid being deemed adulterated, such drugs must also comply with compendial standards for strength, quality, and purity, unless labeled to show all respects in which the drug differs.

The hospital must have a process in place for medication orders to be received in the pharmacy and dispensed in a safe and timely manner.

Safe dispensing of medications must be in accordance with accepted standards of practice and includes, but is not limited to, the following:

1. **Implementing systems such as dose limits, pre-**

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printed orders, special labeling, or double checks to minimize adverse drug events, especially for high alert medications;

2. **Reviewing all medication orders (except in emergency situations) for appropriateness by a pharmacist before the first dose is dispensed. A process is established for resolving questions with the prescribing practitioner and the discussion and outcome are documented in the patient's medical record or pharmacy copy of the prescriber's order;**

   This review should include:
   - **Therapeutic appropriateness of a patient's medication regimen;**
   - **Therapeutic duplication in the patient's medication regimen;**
   - **Appropriateness of the drug, dose, frequency, and route of administration;**
   - **Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;**
   - **Real or potential allergies or sensitivities; and**
   - **Other contraindications.**

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RECALLED OR DISCONTINUED MEDICATIONS
Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.

- **Policies and procedures that address the use of medications brought into the hospital by patients or their families when self-administration of medications is permitted by hospital policy; and**

- **Having a system in place to reconcile medications that are not administered (e.g., left in the patient's medication drawer) when the pharmacy inventories patient medications or restocks patient medications. For example, did the patient refuse the medication, was there a clinical or treatment reason the medication was not used, or was the medication not used due to an error?**

MONITORING THE EFFECTS OF MEDICATIONS
The pharmaceutical service may be responsible for monitoring the effects of medication(s) specified per hospital policy to assure medication therapy is appropriate and minimizes the occurrence of adverse events. Typically this occurs with anticoagulant therapy and antibiotics prescribed for the pharmacy to establish or adjust the dosage (i.e.; "pharmacy to dose" order). In such cases, the pharmacy's monitoring process includes:

- **Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or**

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	evaluate toxicity and adverse effects; • **Physical signs and clinical symptoms relevant to the patient's medication therapy;** • **Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.** **(See also the Nursing CoP discussion regarding monitoring of patients at §482.23(c)(4)).**		