2016 CMS Update to Pharmacy Services

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Standards Interpretation

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AAHHS Surveyors: You may follow the recording with this slide set or follow just the recording slides, but if you follow only the recording slides, please note the changes described on Slide 3.
Objectives

The purpose of this program is to provide an overview of:

1. The eleven (11) HFAP standards affected by the CMS S&C 16-01 Pharmacy Services, published 10/30/2015.

2. The new CMS requirements for Compounded Sterile Preparations (CSP).

3. Required hospital practices to determine the date a drug / biological is unusable in accordance with the ‘BUD’ concept.
### HFAP Revised / New Standards...

#### Differences for AAHHS:

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- Column 2 = Review Guidelines
- Column 3 = Review Procedures
Compounded Sterile IV Preparations

May Result in Harmful / Fatal Errors –

• In 2012: Reported 64 deaths related to contaminated compounded solutions.

• In 2006: A 2-year old died due to a Chemotherapy Error
Need to Customize Medications

1. Needed dose is not available
   • Children, the elderly, or patients with liver and kidney problems, often require medication dosage adjustments to strengths that aren't available.

2. A commercial medication may contain ingredients a patient needs to avoid due to side effects, irritation or allergies, such as opiates, sugar, alcohol, preservatives, dyes or gluten.

2. Drug shortages due to back orders or shortages.
   a) Injectable sodium bicarbonate
   b) Calcium gluconate
Standard 25.00.00

Condition of Participation: Pharmaceutical Services
Standard 25.00.00
Condition of Participation

Column 2: Review Guidelines

1. A hospital provides pharmaceutical services that meet the needs of its patients.

2. The services includes either:
   - A pharmacy that is directed by a pharmacist, or,
   - A drug storage area that is competently supervised.
Standard 25.00.01

Standard: Pharmacy Services

New Standard:
• Hospitals must meet the needs of the patients
• The scope and complexity of pharmaceutical services available in the hospital must be consistent with the volume and types of patients the hospital serves.
• Not every hospital is expected to offer the same level of pharmaceutical services.
  • Psychiatric services
  • Oncology services

HFAP 25.00.01 was not adopted by AAHHS.

• Surveyor report tool will provide a mechanism for noting Condition or Standard level deficiency recommendation.
Standard 25.00.01 – Cont’d

Column 3 Review Procedures:
• Similar to Standard 25.00.00 which requires the hospital to meet the needs of the patients as a Condition of Participation.
• Standard 25.00.01 is scored when multiple CFR (Code of Federal Regulations) deficiencies are noted; however, the manner and degree of non-compliance does not rise to the Condition level.
• Non-compliance with HFAP-standards is not included with this decision.

HFAP 25.00.01 was not adopted by AAHHS.
• Surveyor report tool will provide a mechanism for noting Condition or Standard level deficiency recommendation at 25.00.00.
Standard 25.00.04 25.00.2

Pharmacy Management & Administration
Standard 25.00.04 25.00.02
Pharmacy Management – What’s New?

**Column 2 Review Guidelines:**
The Pharmacy ensures safe and appropriate procurement, storage, preparation, dispensing, use, tracking and control, and disposal of medications and medication-related devices throughout the hospital, for both:

- Inpatient and Outpatient services
Standard 25.00.04 25.00.02  
Pharmacy Management – Cont’d

Acknowledges the challenges of small hospitals.

If a hospital has a Drug Storage area –

- It uses ONLY drugs that are pre-packaged and need no further preparation beyond that required at the point of care.
Standard 25.00.04 25.00.02
Pharmacy Management – Cont’d

1. The Medical Staff is responsible for developing policies and procedures that minimize drug errors.
   a) May delegate to Pharmacy – but Medical Staff approve
   b) Are designed to minimize drug errors
   c) Reflect accepted professional pharmacy principles
   d) Identify the source(s) used
   e) Are CONSISTENT with Manufacturer’s Instructions
Standard 25.00.04 25.00.02
Pharmacy Management – Cont’d

The Pharmacy has a process to:

1. Train & monitor its staff compliance with policies

2. Proactively identify and review Adverse Drug Events

3. Be aware of external alerts

4. Standardize infusion pumps / delivery systems

5. Ensure current medication information is available

6. Provide Pharmacy expertise on-call when pharmacy does not operate 24/7
Standard 25.00.04 25.00.02
Pharmacy Management – Cont’d

1. High-Alert Medications include:
   a) Controlled medications
   b) Medications with a narrow therapeutic range
   c) Psychotherapeutic medications
   d) Look-alike/sound-alike medications
   e) Those new to the market or new to the hospital
Standard 25.00.04 25.00.02
Pharmacy Management – Cont’d

2. Processes to minimize errors include:
   a) Dosing limits
   b) Administration guidelines
   c) Packaging
   d) Labeling
   e) Storage
Standard 25.00.04 25.00.02
Pharmacy Management – Cont’d

Standardize Prescribing and Communication Practices

1. Avoid dangerous abbreviations

2. Ensure medication orders contain all elements

3. Use ‘approved’ pre-printed order sheets, when possible

4. Prohibit “resume previous orders”

5. Identify when weight-based dosing for pediatric is indicated
Standard 25.00.04 25.00.02
Pharmacy Management – Cont’d

1. The hospital’s pharmacy services must be integrated into its hospital-wide QAPI program.

2. Flag new ‘types’ of mistakes.

3. As a result of an analysis of errors and adverse events, refine policies and procedures.

4. Report error data related to:
   • New medications
   • New infusion devices
   • New technology, e.g., bar code
Standard 25.00.04 25.00.02

Survey Tips:

1. Has Medical Staff approved all policies? Every 3 years?

2. What is the evidence?
   • Policies incorporated accepted professional principles?
   • Staff have been trained on applicable pharmaceutical policies?
   • Pharmacy monitors the staff adherence to policies?

3. Is Pharmacy responsible for INPATIENT and OUTPATIENT medications?
Standard 25.00.05 25.00.03

Management
Standard 25.00.05 25.00.03
Management – What’s New?

Column 2 Review Guidelines:

- Pharmacy services are under direction of a pharmacist, who may be
  - full-time,
  - part-time, or
  - consulting

- Even if hospital has a Drug Storage Area instead of a pharmacy.

- The written criteria for qualifications of the pharmacy director, consistent with State scope of practice, are approved by the medical staff.
25.00.05 25.00.03/ 25.00.04 25.00.02

(§482.25)

JOB DESCRIPTION – To Include:

1. Criteria & qualifications for Pharmacy Director

2. Based on complexity of services

3. Required training and experience

4. Credentialing and Privileging is NOT required

5. Job description includes:
   a) Supervision of pharmacy department
   b) Coordination of all pharmacy activities including Inpatient, Outpatient, & Remote locations
   c) Development and leadership for policies
Standard 25.00.05 25.00.03 – Cont’d

• The extent of pharmaceutical services provided determines whether a part-time director is sufficient.

Depending on the volume & complexity of services,

• Full-time on-site management at the hospital’s pharmacy, may not be required

• May be accomplished through regularly scheduled visits.
Standard 25.00.05 25.00.03 – Cont’d

If the hospital DOES NOT have a Full-Time pharmacist,

- It must **provide evidence** of how a part-time or consulting pharmacist is able to perform all functions:
  - Developing,
  - Supervising and
  - Coordinating all pharmacy services activities.
Small hospitals that DO NOT have a pharmacy:

1. May utilize a drug storage area for dispensing pre-packaged drugs.

2. Day-to-day operations of pharmaceutical services must be under the supervision of an individual who,
   - If not a pharmacist, has documented competency to oversee compliance with all the pharmaceutical services regulatory requirements (e.g., security, access to locked areas, etc.).

3. The hospital establishes in writing the qualifications of the drug storage area supervisor.
Standard 25.00.05 25.00.03

Surveyor Tips:

1. Is Pharmacy Director: Full Time, Part Time, or Consultant?

2. Based on complexity of pharmaceutical services provided,
   - Does this meet the needs of the facility?

3. Review Pharmacist’s File - Does Director:
   - Meet the written job qualifications?
   - Have evidence of required training?

4. Ask the pharmacy director: How are policies and procedures developed, approved, implemented?
Standard 25.00.05 25.00.03

Surveyor Tips:
5. How are staff trained?

6. How are staff monitored?

7. Do problems in pharmacy services suggest lack of supervision?

8. Is there evidence the drug storage area is under competent supervision?
Standard 25.01.01

Medication Control & Distribution
Standard 25.01.01 – Medication Control & Distribution – What’s New?

A. Hospital must have a process for medication orders to be received in pharmacy and dispensed in a safe and timely manner.

B. Hospital has safe dispensing of medications in accordance with accepted standards of practice.
Standard 25.01.01 – Cont’d

C. Hospital implements systems to minimize adverse drug events, especially for high alert medications, such as:
   1. Dose limits
   2. Pre-printed orders
   3. Special labeling
   4. Double checks
Standard 25.01.01 – Cont’d

D. Hospital has a process to review all medication orders for appropriateness before first dose (except in emergency).

To review:
1. Therapeutic appropriateness of the medication regimen
2. Therapeutic duplication of the medication regimen
3. Appropriateness of drug, dose, frequency, and route
4. Real / potential interactions
5. Contraindications
Standard 25.01.01 – Cont’d

E. Hospital has a process to resolve questions with the prescriber.

F. The above discussion and outcome is documented in:
   1. Patient’s medical record – or –
   2. Pharmacy copy of the order
Standard 25.01.01 – Cont’d

G. Hospital has a process for Recalled or Discontinued Medications

H. Hospital has a process for Monitoring the Effects of Medications, such as:

1. Anti-coagulation Therapy

2. Antibiotic Therapy
Standard 25.01.01

Surveyor Tips:

1. What is the process for reviewing orders before first dose?

2. How are questions regarding medication orders resolved?

3. What is the process for recalling medications?

4. What is the process for monitoring antibiotic therapy? Anti-coagulation therapy?
Standard 25.01.02

Supervision of Pharmacy Activities
Standard 25.01.02 – Supervision of Pharmacy – What’s New?

“Compounded Preparations”

Column 2 Review Guidelines:

Hospitals use many medications that need to be reconstituted, mixed or which otherwise may be considered “COMPOUNDED” preparations.

Some may be compounded:

1. In the hospital pharmacy and/or
2. Hospital may obtain some or all from EXTERNAL sources.
Standard 25.01.02 – Cont’d

**RISK:** If standards for safe compounding are NOT MET, the compounded medications may:

1. Contain LESS or MORE than the intended dose
2. May be chemically or microbiologically contaminated
3. May result in devastating or lethal consequences
Standard 25.01.02 – Cont’d

The EXTERNAL sources could include:

1. Manufacturers

2. Registered Outsourcing Facilities – “503B Pharmacies”

3. Compounding pharmacies – “503A Pharmacies”
Registered Outsourcing Facilities “503B” Pharmacies

1. A facility at one geographic location or address that is engaged in the compounding of sterile drugs;

2. Has elected to register as an outsourcing facility; and

3. Complies with all of the requirements of section 503B of the FDCA.
Standard 25.01.02 – Cont’d

Facilities that are registered per Section 503B:

1. Must comply with FDA’s “Current Good Manufacturing Practice (CGMP) requirements… that make sure a product is safe for use, and has the ingredients and strength it claims to have.

2. Will be inspected by FDA according to a risk-based schedule

3. Must meet other conditions, such as reporting of adverse events
Hospital Compounding Practices
USE OF COMPOUNDING PHARMACIES

• Compounding pharmacies, not registered as an outsourcing facility with the FDA, are referred to as “503A Pharmacies”

• Generally, these are subject to oversight only by their State pharmacy board. (Not the FDA!)
Standard 25.01.02 – Cont’d

If a hospital obtains compounded medications from a “503A pharmacy”

Hospital must:
• Demonstrate how it assures the compounded medications received under this arrangement have been:
  - Prepared in accordance with accepted professional principles for compounded drugs,
  - As well as State or Federal Regulations
Use of Compounding Pharmacies

Hospital Contract with Vendor to include provisions:

1. Hospital has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements.
   - **Expectation**: Hospital documents it has obtained & reviewed the data reports.

2. Vendor is required to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products.
Standard 25.01.02 – Cont’d

MEDICATIONS COMPOUNDED BY HOSPITAL PHARMACY

• Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, an emergency or immediate patient administration of a compounded sterile preparation)

• All compounding of medications used or dispensed by the hospital must be performed consistent with standards of practice equivalent to or more stringent than those in the
Standard 25.01.02 – Cont’d

• Compounding-related chapters in the USP <797> which is recognized as authoritative guidance regarding minimum standards of practice applicable to both sterile and non-sterile compounding.

• The USP <797> outlines minimal standards to be followed by all health care personnel in any setting when preparing, storing and transporting “compounded sterile preparations” (CSPs).
Standard 25.01.02 – Cont’d

The definition of compounding as used in the USP is found in USP Chapter <795> (USP <795>):

- The preparation, mixing, assembling, altering, packaging and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice.
Compounding includes the following:

1. Preparation of drug dosage forms for humans & animals

2. Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns

3. Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients

4. Preparation of drugs or devices for the purposes of, or as incident to, research (clinical or academic), teaching or chemical analysis

5. Preparation of drugs and devices for prescriber’s office use
Standard 25.01.02 – Cont’d

Compounded medications whether sterile or non-sterile may be subject to contamination.

Contaminated compounded sterile preparations (CSPs) are especially hazardous.

- Body cavities
- Central nervous system
- Eyes, joints, the vascular system
- Baths for live organs and tissues

For this reason, the USP requires…
Standard 25.01.02 – Cont’d

…All compounded dosage forms that must be sterile when they are administered to patients are considered by USP <797> to be CSPs, including:

1. Aqueous bronchial and nasal inhalations
2. Baths and soaks for live organs and tissues
3. Injections [and infusions]
4. Irrigations for wounds and body cavities
5. Ophthalmic drops and ointments
6. Tissue implants
Standard 25.01.02 – Cont’d

USP <797> standards
Compounded Sterile Preparations (CSP)

1. Sets standards for the physical layout & structure of locations where compounding takes place, based on level of risk of microbial contamination of the CSP.

- The standards differ based on the level of risk of microbial contamination of the CSP

2. The risk level has implications for whether a CSP must be terminally sterilized before being dispensed and for how long a CSP may be stored.
Standard 25.01.02 – Cont’d

USP <797> specifies standards for:

1. Responsibilities of compounding personnel
2. Methods for sterilization
3. Specifications for environmental quality and control
4. Staff training and competency testing
5. Monitoring and testing the environment
USP <797> describes the physical layout & environmental controls to minimize airborne contamination of CSPs.

The RISK level of the CSPs, depends on which environmental quality control and facility design standards the hospital is able to meet.

Three (3) risk levels:

1. Low-risk
2. Medium-risk
3. High-risk
LOW – Risk Level:

1. Nonhazardous CSPs

2. Pursuant to physician order for a specific patient

3. Administer in less than 12 hours of preparation or per manufacturer’s instructions

4. Designated room:
   a) Unidirectional airflow
   b) May not have openings to high traffic or the outdoors
Standard 25.01.02 – Cont’d

PACKAGING AND LABELING OF MEDICATIONS

1. For individual drug containers:
   a) Floor stock drug containers to be labeled with name and strength of the drug, lot and control number equivalent, and expiration date.
   b) Appropriate accessory and cautionary statements are included as well as the expiration date and/or a beyond-use date (BUD).

2. 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.
Standard 25.01.02 – Cont’d

AVAILABILITY OF MEDICATIONS

Medications must be available for administration to patients when needed, including when the pharmacy is not open.

Methods:
• Automated dispensing units outside the pharmacy,
• Night cabinets,
• Contracted services via telepharmacy contracting,
• On-call pharmacists
• Automated Dispensing Cabinets (ADC)
Standard 25.01.02

Survey Tips:

1. Can the pharmacy director provide evidence that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures?

2. If the hospital obtains compounded products from external compounding sources, are the external source(s) registered with the FDA as outsourcing facilities?
   • Can hospital demonstrate that it systematically evaluates and monitors whether the compounding pharmacy adheres to accepted standards of safe compounding?
   • What is evidence that practices are consistent with <795> and <797>?
Standard 25.01.02

Survey Tips:
4. Can the pharmacy director explain the risk level(s) of the CSPs being produced in-house? E.g., Risk Level Low, Medium, High

5. Ask the pharmacy director provide evidence that sterile compounding practices are consistent with USP <797>:
   a) Verification of compounding accuracy
   b) Environmental quality testing
   c) Personnel training
   d) Packaging protects integrity and sterility of compounded medications
Standard 25.01.03

Security of Medications
Standard 25.01.03

Security of Medications

- All drugs and biologicals must be kept in a secure area, and locked when appropriate.

§482.25(b)(2)(i)

A frequently cited standard
Standard 25.01.03 – Cont’d

Column 3 Review Procedures:
Observe whether medications in various areas of the hospital are stored in a secure area, and locked when appropriate.

- Are medication storage areas periodically inspected by pharmacy staff to make sure medications are properly stored?
Drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals.

Examples:

a) Medications in a private office must be secured from patients and visitors

b) Pre-filled syringes may not be stored overnight atop of the anesthesia cart
Standard 25.01.07

Inventory Management System
Beyond Use Date – “BUD”
Standard 25.01.07
Inventory Management – What’s New?

Column 2 Review Guidelines:

• 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.

• 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.
Standard 25.01.07 – Cont’d

The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur:

1. During or after the original container is opened,

2. While preparing the medication for dispensing and administration, and/or

3. 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 maintains and implements policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer.
Standard 25.01.09

Automatic Stop
Medication Orders
Standard 25.01.09 – What’s New?

Column 2 Review Guidelines:
• Hospitals with an electronic health record (EHR) system may have time and dose parameters automatically built into computerized provider order entry (CPOE) screens.

Surveyor Tip:
• Ask staff to describe the automatic stop policy. How is it enforced?
Standard 25.01.12

Informational Resources
Standard 25.01.12 – What’s New?

Column 2 Review Guidelines:

- The pharmacy must be a resource for medication-related information to the hospital’s health-care practitioners and other health care personnel to optimize therapeutic outcomes and minimize adverse drug events.
Standard 25.01.12 – Cont’d

- Information must be available concerning drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration.

- Pharmacy may assist other health care professionals with medication-related functions, such as identification of:
  
  1. Medication-therapy interactions and excessive doses.
  2. Pharmacotherapeutic goals & monitoring
Standard 16.01.01

Preparation and Administration of Drugs and Biologicals
Standard 16.01.01 – What’s New?

Column 2 Review Guidelines:

• Compounded sterile preparations (CSPs) may be a source of healthcare-associated infection if proper precautions are not followed.

• Hospitals must ensure staff adherence to accepted standards of practice required to prevent healthcare-associated infections related to medication preparation and/or administration.

• Nurses commonly prepare “immediate-use CSPs” for immediate or emergency patient
Standard 16.01.01 – Cont’d

USP <797> Guidelines
Also Apply to Nurses Preparing an Immediate-use CSP

1. Must only involve “simple transfer of not more than three commercially manufactured…sterile nonhazardous products from the manufacturer’s original containers and not more than two entries into any one container or package (e.g. bag, vial) of sterile infusion solution or administration container/device;”
Standard 16.01.01 – Cont’d

2. Administration begins **not later than one hour** following the start of the preparation of the CSP (if not, the CSP must be appropriately discarded);

3. Meticulous aseptic technique must be followed during all phases of preparation. If the CSP is not administered to the patient as soon as it is ready, “the finished CSP is under continuous supervision to minimize the potential for contact with non-sterile surfaces…,” contamination and/or confusion with other CSPs;
4. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer…,” the CSP must be labeled with at least:

- Patient identification information;
- The names and amounts of all ingredients;
- The name or initials of the person who prepared it; and
- The exact one hour “beyond use date” (see below).
Compounding in Surgery Services

Examples of Compounding in Surgery

1. Topical Creams:
   - Addition of medication, e.g., pain medications or anti-inflammatories

2. Irrigation Solutions:
   a) Flush abdomen of ruptured appendix / flush a joint
   b) Add to Saline Solution:
      - Polymyxin B
      - Gramacidin
Beyond Use Date (BUD)

- A drug or biological is outdated after its “beyond-use date” (BUD), which may be reached before the expiration date, but never later.

- The BUD is the date and time after which the medication must not be used, stored or transported.

- The BUD is to be based on information provided by the manufacturer, whenever such information is available.

- See Standard 25.01.07 for additional BUD requirements
Avoid Compounding Errors
Lack of Knowledge

- Many sterile compounding tasks are by pharmacy techs with minimal oversight by a qualified pharmacist.
- New pharmacists learn non-evidence based “tricks of the trade” handed down from others.
- Pressure related to turnaround time affects training.
- Teaching may be hurried and without time to teach the rationale for certain steps to ensure sterility and safety.
- Variations / deviations from safe practice become “normalized”.
- Violations are “overlooked” and / or “tolerated”.
Standardize Process:
Laminar Hood Compounding

Laminar Hood

Layout Equipment & Sequence

1. Don gloves and gown in proper order

2. Area is free of clutter

3. Medications are assembled in consistent order
Multi-dose Vial

Protective Cap is only a Dust Cover; the membrane is NOT STERILE

Assess Processes

1. Cleanse Membrane

2. Contents good 28 days after opened.

3. Determine the number of needle entries
Standardize:
Limit the Number of Entries into Vial
Best Practice Resources

1) 2013 Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: “Guidelines for SAFE Preparation of Sterile Compounds”


References


Resources

- [http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm)

- [http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm)

- [http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm)

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