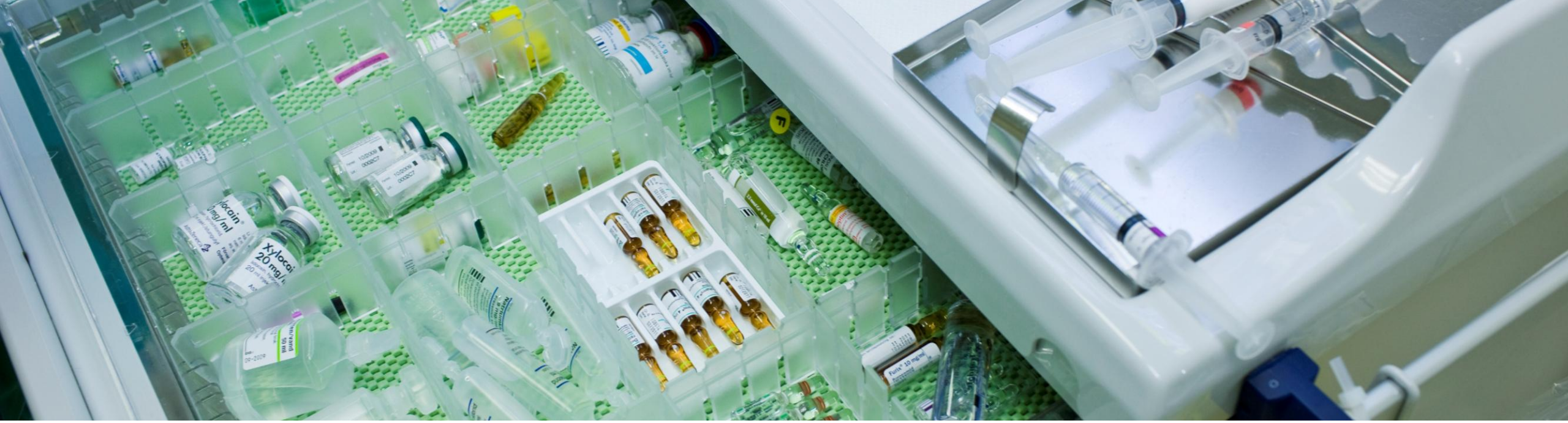

Advance Preparation of Sterile Medications and Supplies

August 2026

Presented by Regulatory & Accreditation Education

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Above all else,
we are committed to the care and improvement of human life.

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Frequently Asked Questions

FAQs Link

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Can clean or sterile supplies be prepared in advance in procedural spaces? What about setting up trauma or similar rooms in advance of emergency scenarios?

August 2026

In general, sterile supplies, fluids, and medications for surgical and procedural cases should be prepared as closely as possible to the time of use or administration with limited exception. This FAQ does not promote or allow batch staging for multiple cases or pre-spiking for convenience, batching syringes for later cases outside pharmacy or other approved sterile compounding controls, multi-patient use of single-dose vials or IV bags, or using compromised sterile supplies.

Batch preparation of supplies in advance of procedural cases would generally only be considered acceptable as a means of preparing for urgent or emergent scenarios and not solely as a means of convenience. Medications, such as IV fluids or medications drawn into syringes, follow more strict regulations.

As long as local policy or guidance and manufacturer's instructions for use (IFUs) do not expressly prohibit advance preparation of emergent room set-ups, it would generally be considered acceptable for certain types of procedure rooms (trauma operating rooms [ORs], cardiovascular ORs [CVORs], labor and delivery ORs) to have limited advance preparation of supplies to save time when receiving a patient in an emergent situation. Emergent rooms prepared in advance still must have controls in place to ensure supplies are protected and free from contamination until use. Generally, items that are open >24 hours, unlabeled, compromised, or have questionable sterility must be disposed of and replaced.

Acceptable Advance Emergency Setup

→ An anesthesia emergency setup is **acceptable only** in designated procedural rooms or areas where emergent procedures may occur.

→ Requires local **approval**, defined **guidance**, and team **education** before advance supply preparation is used in limited approved circumstances.

→ **Adhere to** pharmacy guidance, beyond-use dating requirements, medication hang times, and applicable policy at all times.

→ Prepare sterile supplies, fluids, and medications **as close as possible** to use or administration.

Advance Emergency Medication Setup

Not Permitted

- Approved advance setup does **not include** convenience-based preparation, routine staging, or preparation for multiple future cases.
- No **convenience-based** batch staging, pre-spiking, syringe batching, or multi-patient use of single-dose vials or IV bags.

Discard medications that are:

- Compromised, with questionable sterility
- Unlabeled
- Prepared in syringes and not administered within **4 hours**
- Not used within **24-hours**

Emergent room setups must maintain sterility and protect supplies from contamination until use.

Regulatory Findings

Prioritize top immediate action items for your facility

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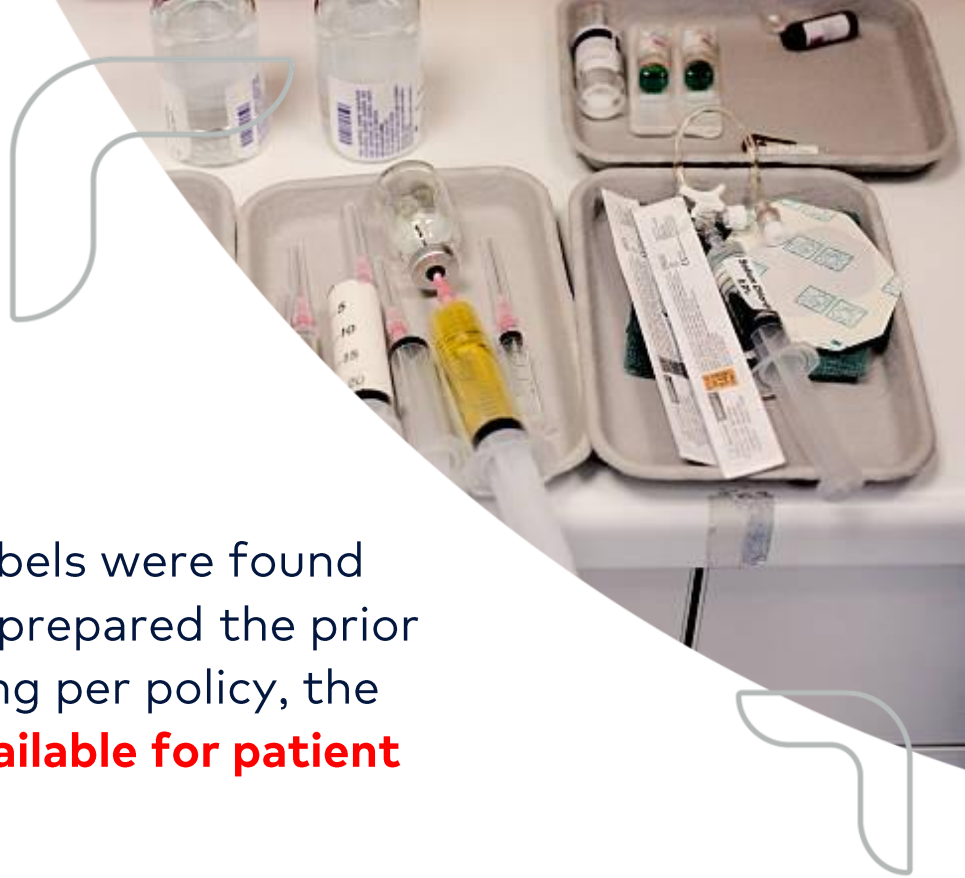
MM.13.01.01, EP 4

Standard prior to 1/1/26: MM.03.01.01, EP 8

The hospital removes all expired, damaged, contaminated, or unusable medications and stores them separately from medications available for patient use.



Top Box on SAFER Matrix

- Four 100 mL normal saline IV bags with medication-added labels were found for use on the OR anesthesia cart. The medication had been prepared the prior day for immediate use but was **not used**. Instead of discarding per policy, the expired medication was left on top of the anesthesia cart **available for patient use the next day**.

- A damaged, unsecured anesthesia cart containing medications was observed in the operating room, creating the potential for unauthorized access and compromised **medication integrity**. Medications stored under these conditions were not appropriately protected and should not have remained available for patient care.

MM.13.01.01, EP 4

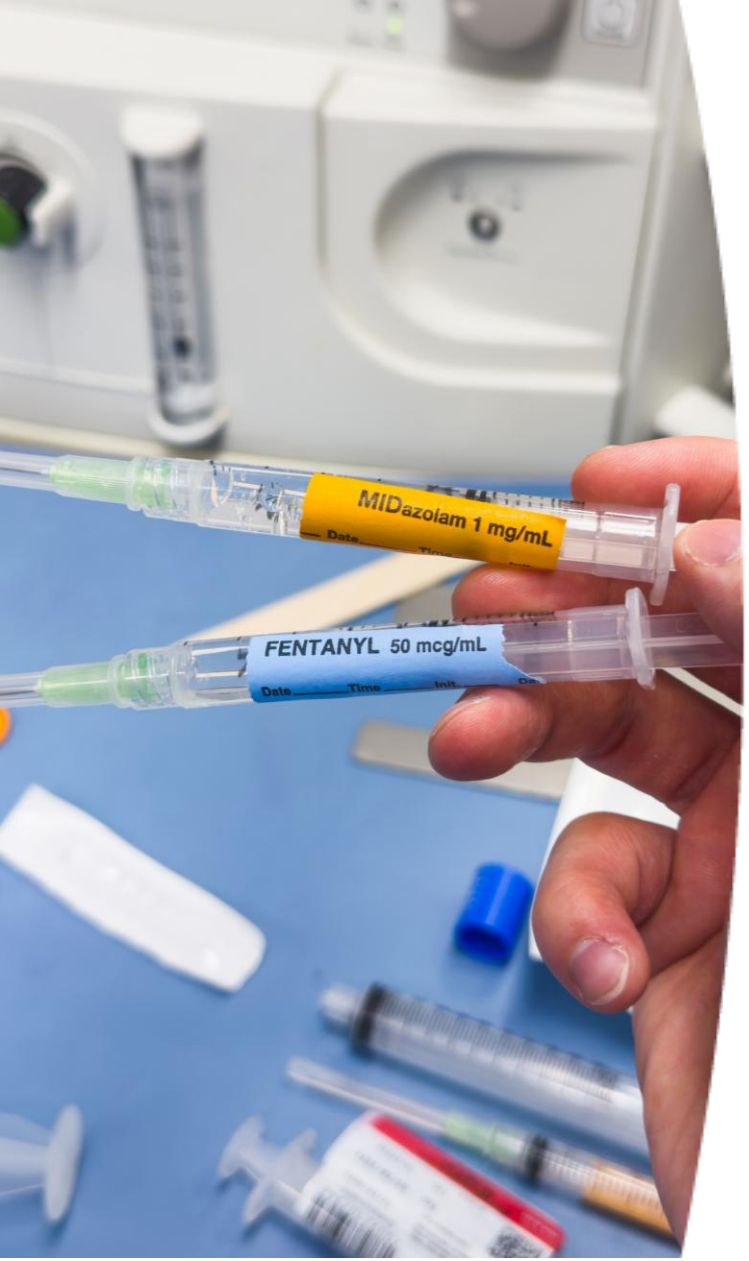
§482.25(b)(3) Condition of Participation: Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

Hospital Survey Process

Observation:

- ✓ Spot-check the labels of individual drug containers to verify that they conform to federal and state law and/or contain the following minimal information:
  - Patient's full name
  - Strength and quantity of the drug dispensed
  - Appropriate accessory and cautionary statements
  - Expiration date and/or, if applicable, a beyond use date (BUD)
- ✓ Spot-check each floor stock container to ensure labels bear the name and strength of the drug, lot and control number of equivalent, and expiration date.
- ✓ If the unit dose system is used, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, expiration date, and/or, if applicable, a BUD.
- ✓ Inspect patient-specific and floor stock medications to identify expired, mislabeled, or unusable medications.

Survey Process Guide



NPG.14.03.01, EP 3

Standard prior to 1/1/26: NPSG.03.04.01, EP 3

In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the following: medication name, strength, amount of medication, diluent name and volume, expiration date and time.

Top Box on SAFER Matrix

- During Cardiac Cath Lab tracer activity, two **unlabeled syringes** containing clear liquid were observed alongside labeled syringes.
- Surveyor witnessed a previously prepared, **unlabeled syringe** was stored on the Endoscopy anesthesia cart and subsequently **administered** to a patient.
- In a procedural room, an IV-push Fentanyl syringe prepared for moderate sedation had an **incomplete and inaccurate pre-printed label:** the medication strength was not marked, and the label displayed the wrong unit of measure, listing milligrams instead of micrograms.

NPG.14.03.01, EP 3

Hospital Survey Process

Interview:

- ✓ Discuss with staff in procedural areas what procedures are followed for medication safety specific to labeling of medications and containers.

Document Review:

- ✓ Review any policy or procedures, data collection, PI activities for hospital performance and evaluation. Data collection may also be found with hospital internal reporting systems.

Observation:

- ✓ In perioperative and other procedural settings observe actions of staff for medication preparation both on and off the sterile field.

Survey Process Guide

Regulatory Education SharePoint

RegEd SharePoint

Regulatory and Accreditation Education Quick Links

Education Repository

Just-in-Time Resources

Tracers in Action & Safety Alert Tracers

Survey Process Guide

Survey Process Guide for Hospitals

Tracers in Action & PSO Safety Alert Tracers

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Thank you

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Appendix

Regulatory Framework

Identify the regulatory standards for Advance Preparation of Sterile Medications

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Regulatory Standards

Standard prior to 1/1/26:
MM.03.01.01 = MM.13.01.01

MM.13.01.01: The hospital safely stores medications.

- **EP 1 –** The hospital maintains current and accurate records of the receipt and disposition of all scheduled drugs.
- **CoP §482.25(a)(3) -** Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.
- **EP 2 –** The hospital stores all medications and biologicals, including controlled (scheduled) medications, in a secured area and locked when necessary to prevent diversion in accordance with law and regulation.

  Note 1: Scheduled medications include those listed in Schedules II–V of the Comprehensive Drug Abuse Prevention and Control Act of 1970.
  Note 2: This element of performance is also applicable to sample medications
  Note 3: Only authorized staff have access to locked areas.
- **CoP §482.25(b)(2)(i) -** All drugs and biologicals must be kept in a secure area, and locked when appropriate.
- **CoP §482.25(b)(2)(ii) -** Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.
- **CoP §482.25(b)(2)(iii) -** Only authorized personnel may have access to locked areas.

Regulatory Standards

Standard prior to 1/1/26:
MM.03.01.01 = MM.13.01.01

- **EP 4 –** The hospital removes all expired, damaged, mislabeled, contaminated, or otherwise unusable medications and stores them separately from medications available for patient use.

  Note: This element of performance is also applicable to sample medications.

- **CoP §482.25(b)(3) -** Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

Regulatory Standards

Standard prior to 1/1/26:
NPSG.03.04.01 = NPG.14.03.01

NPG.14.03.01: The hospital labels all medications, medication containers, and other solutions on and off the sterile field in perioperative and procedural settings. Note: Medication containers include syringes, medicine cups, and basins.

- **EP 1 –** In perioperative and other procedural settings both on and off the sterile field, the hospital labels medications and solutions that are not immediately administered. This applies even if there is only one medication being used.

  Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.

- **EP 2 –** In perioperative and other procedural settings both on and off the sterile field, labeling occurs when any medication or solution is transferred from the original packaging to another container.

- **EP 3 –** In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the following:

  - Medication or solution name
  - Strength
  - Amount of medication or solution containing medication
  - Diluent name and volume
  - Expiration date and time

  Note: The date and time are not necessary for short procedures, as defined by the hospital.

Regulatory Standards

Standards prior to 1/1/26:
MM.08.01.01 = LD.12.01.01

LD.12.01.01: Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" [PI] chapter.)

- **EP 3 –** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for the following:
  - An ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained
  - The hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and all improvement actions are evaluated
  - Clear expectations for safety are established
  - Adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients
  - The determination of the number of distinct improvement projects is conducted annually
- **CoP §482.21(e)(1) -** That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.
- **CoP §482.21(e)(2) -** That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

Regulatory Standards

Standards prior to 1/1/26:
MM.08.01.01 = LD.12.01.01

- **CoP §482.21(e)(3) -** That clear expectations for safety are established.
- **CoP §482.21(e)(4) -** That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.
- **CoP §482.21(e)(5) -** That the determination of the number of distinct improvement projects is conducted annually.

Regulatory Standards

Standards prior to 1/1/26:
MM.07.01.03 = LD.13.01.09

LD.13.01.09: The hospital has policies and procedures that guide and support patient care, treatment, and services.

- **EP 5 –** The hospital develops and implements policies and procedures that minimize drug errors. The medical staff develops these policies and procedures unless delegated to the pharmaceutical service.
- **CoP §482.25 -** The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

Resources

Recognize methods of compliance and validation

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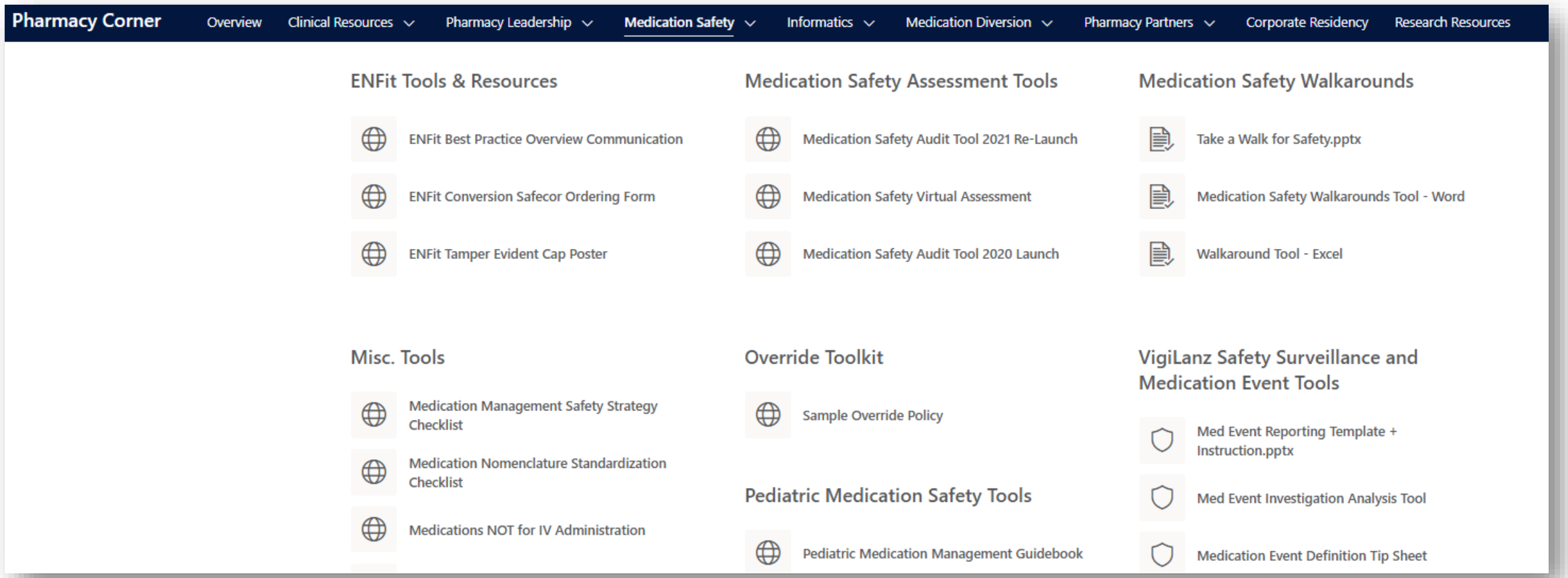
Pharmacy Corner



Pharmacy Corner

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Resources

- AORN Guidelines
- Medication Administration Policy
- Pharmacy Corner SharePoint
- Regulatory Education SharePoint
- Survey Process Guide