

AHC Media January 28, 2016

## New Pharmacy & Medication Standards: the CMS CoPs



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### Speaker



- Sue Dill Calloway RN, Esq.  
CPHRM CCMSCP
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Education
- 5447 Fawnbrook Lane
- Dublin, Ohio 43017
- 614 791-1468 (Call with questions, No emails)
- [sdill1@columbus.rr.com](mailto:sdill1@columbus.rr.com)

### Objectives

- Explain the CMS requirements regarding compounding of medication and beyond use date.
- Describe the CMS policy for high risk drugs.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

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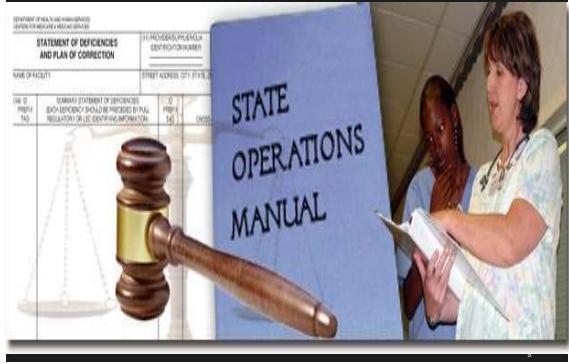
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## Introduction to the CMS Hospital Pharmacy CoPs



## You Don't Want One of These From CMS



## Additional Objectives

- Recall that all hospitals that receive Medicare reimbursement must follow the CMS medication guidelines even if the hospital is accredited by the Joint Commission, DNR, CIHQ, or AOA
  - Discuss that if a nurse implements a standing order it must be entered as an order in the chart
  - Describe the requirements for high risk drugs such as double checks or dose limits
  - Discuss that CMS has a long list of required medication policies
  - Recall that CMS made changes to the 30 minute rule for the timing of medications and now has 3 timeframes

## TJC Revised Requirements

- Joint Commission has made many changes in the past and these are to bring their standards into closer compliance with the CMS CoP
  - TJC has had a chapter on Medication Management standards since 2004
    - Has 8 sections and 20 elements of performance and very detailed
  - TJC also has FAQs on medication management
    - Some standards are the same but others are different and all hospitals should consider adopting since important in reducing medication errors

TJC Medication Management Chapter

## **Chapter Outline:**

- I. Planning
    - A. Medication Planning (MM.01.01.01, MM.01.01.03) (*MM.01.01.05 is not applicable to hospitals*)
    - B. Look-alike/Sound-alike Medications (MM.01.02.01)
  - II. Selection and Procurement (MM.02.01.01)
  - III. Storage (MM.03.01.01, MM.03.01.03, MM.03.01.05)
  - IV. Ordering and Transcribing (MM.04.01.01)
  - V. Preparing and Dispensing (MM.05.01.01, MM.05.01.07, MM.05.01.09, MM.05.01.11, MM.05.01.13, MM.05.01.15, MM.05.01.17, MM.05.01.19) (*MM.05.01.15 is not applicable to hospitals*)
  - VI. Administration (MM.06.01.01, MM.06.01.03, MM.06.01.05)
  - VII. Monitoring (MM.07.01.01, MM.07.01.03)
  - VIII. Evaluation (MM.08.01.01)

## The Conditions of Participation (CoPs)

- Regulations first published in 1986
    - Manual updated more frequently now
  - First regulations are published in the **Federal Register** then CMS publishes the **Interpretive Guidelines** and some have **survey procedures** <sup>2</sup>

- Hospitals should check this website once a month for changes

<sup>1</sup>[www.gpoaccess.gov/fr/index.html](http://www.gpoaccess.gov/fr/index.html) <sup>2</sup>[www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp](http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp)

## Location of CMS Hospital CoP Manuals

**Medicare State Operations Manual**

**Appendix**

Email questions to [hospitalscg@cms.hhs.gov](mailto:hospitalscg@cms.hhs.gov)

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the red button in the 'Download' column to see any available file in PDF.
- To return to this page after opening a PDF file on your desktop, use the browser "back" button. This is because closing the file usually will also close most browsers

CMS Hospital CoP Manuals new address contains all manuals  
[www.cms.hhs.gov/manuals/downloads/som107\\_Appendixtoc.pdf](http://www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf)

App. No.	Description	PDF File
A	Hospitals	 2,185 KB
AA	Psychiatric Hospitals	 606 KB

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## CoP Manual Also Called SOM

**State Operations Manual**

**Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals**

[Table of Contents \(Rev. I-49, 10-09-15\)](#)

[www.cms.hhs.gov/manuals/downloads/som107\\_Appendixtoc.pdf](http://www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf)

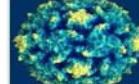
**Transmittals for Appendix A**

**Survey Protocol**

**Introduction**

Task 1 - Off-Site Survey Preparation  
 Task 2 - Entrance Activities  
 Task 3 - Information Gathering/Investigation  
 Task 4 - Preliminary Decision Making and Analysis of Findings  
 Task 5 - Exit Conference  
 Task 6 - Post-Survey Activities

**Psychiatric Hospital Survey Module**  
**Psychiatric Unit Survey Module**  
**Rehabilitation Hospital Survey Module**  
**Inpatient Rehabilitation Unit Survey Module**



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## The Revised Final CoPs

- Every hospital should have a copy of the hospital CoP manual and consider placing it on hospital intranet<sup>1</sup>
- Slides have tag number so you can go back and review each section
- Check CMS website once a month for changes<sup>3</sup>

<sup>1</sup>[www.cms.hhs.gov/transmittals/downloads/R37SOMA.pdf](http://www.cms.hhs.gov/transmittals/downloads/R37SOMA.pdf)

<sup>2</sup>[http://www.cms.hhs.gov/manuals/downloads/som107\\_Appendixtoc.pdf](http://www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf)

<sup>3</sup><http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage>

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# OIG Report January 22, 2015

## ISMP Guidelines

## ASHP Resources

## Surveyor Training on Compounding

- The OIG issued a report regarding a recommendation that called on CMS to ensure hospital surveyors are trained on nationally recognized compounding practices
- Recommend it change the CoPs interpretive guidelines to address hospital contracts with stand-alone compounding pharmacies
- OIG said the lack of surveyor training preventing the oversight entities from effective evaluating the hospital's use of CSP or compounded sterile preparations

OIG Report on Oversight of Hospital Pharmacies

OFFICE OF  
INSPECTOR GENERAL

<http://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf>

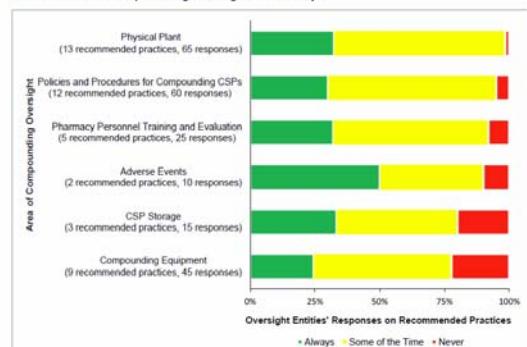
**MEDICARE'S OVERSIGHT OF  
COMPOUNDED  
PHARMACEUTICALS USED IN  
HOSPITALS**

## The OIG Report Jan 2015

- May find the surveyor may review the contracts of the standalone compounding pharmacy
- This includes surveyors from TJC, DNV, AOA HCAP, and CIHQ
- Surveyors will likely be more aware of standards with additional training and more likely to discover if hospital is not doing safe compounding practices
  - Discussed the 64 deaths from the fungal meningitis case from NECC
  - Made 55 recommendations on overseeing CSPs in hospitals

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**Figure 1: Extent to Which the Five Oversight Entities Incorporate Recommended Practices for Each Area of Compounding Oversight into Surveys**



Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

**Table A1: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to the Hospital Physical Plant and Environmental Quality**

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors request a copy of the hospital's pharmacy cleaning logs?	1	4	0
Do surveyors request a copy of the hospital's pharmacy environmental sampling logs?	0	5	0
If the hospital prepares CSPs onsite, do surveyors assess whether the area of preparation is appropriate for all CSP risk levels compounded at the hospital?	2	3	0
If the hospital prepares hazardous CSPs onsite, do surveyors assess the appropriateness of the physical area where hazardous CSPs are compounded?	3	2	0
If the hospital prepares CSPs onsite, do surveyors assess the environmental quality and control in the area of preparation?	3	2	0
If always or some of the time, do surveyors assess the adequacy of the environmental quality and control for each risk level of CSP prepared at the hospital?	2	3	0
If the hospital prepares CSPs onsite, do surveyors review the hospital's written procedures outlining the following:			
Cleaning and disinfecting of the compounding areas?	1	4	0
Personnel hand hygiene and garbing in compounding areas?	3	2	0
Employee aseptic technique in compounding areas?	2	3	0
Environmental sampling in compounding areas?	0	5	0
Facility and engineering control testing and certification in compounding areas?	0	4	1
If the hospital prepares CSPs onsite, do surveyors assess the adequacy of personal protective equipment for compounding CSPs, including applicable	2	3	0

## ISMP Guidelines on Sterile Compounding

- ISMP published guidelines in 2013 for the safe preparation of CSP or compounded sterile preparations
- Goal to provide procedures and safe practices for reducing errors in CSP preparation
- Address drug storage, compounding, labeling, and staff management
- Also ASHP issued guidelines on contracting for sterile compounding services
  - Suggested contract language

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## ASHP Guidelines on Outsourcing

[www.ashp.org/DocLibrary/BestPractices/MgmtGdlOutsourcingSterileComp.aspx](http://www.ashp.org/DocLibrary/BestPractices/MgmtGdlOutsourcingSterileComp.aspx)

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### ASHP Guidelines on Outsourcing Sterile Compounding Services

#### Purpose

The purpose of these guidelines is to provide an overview of key issues to consider when contracting with compounding pharmacies or outsourcing facilities to obtain sterile compounding services. These guidelines are intended for health care organizations considering outsourcing the preparation of compounded sterile compounding pharmacies or outsourcing facilities, reviewing the outsourcing process and outsourcing arrangements, and recommendations for evaluating a contractor's performance. The guidelines also include information on how to evaluate other sources of which relate to the subject of other ASHP guidelines. Other guidelines refer to pertinent ASHP guidelines for additional information, such as those on contract provisions, agreements, and decisions.<sup>1-3</sup> The purpose of these guidelines is to provide an overview of key issues to consider when contracting with compounding pharmacies or outsourcing facilities to obtain sterile compounding services. These guidelines are intended for health care organizations considering outsourcing the preparation of compounded sterile compounding pharmacies or outsourcing facilities, reviewing the outsourcing process and outsourcing arrangements, and recommendations for evaluating a contractor's performance. The guidelines also include information on how to evaluate other sources of which relate to the subject of other ASHP guidelines. Other guidelines refer to pertinent ASHP guidelines for additional information, such as those on contract provisions, agreements, and decisions.<sup>1-3</sup> The purpose of these guidelines is to provide an overview of key issues to consider when contracting with compounding pharmacies or outsourcing facilities to obtain sterile compounding services. These guidelines are intended for health care organizations considering outsourcing the preparation of compounded sterile compounding pharmacies or outsourcing facilities, reviewing the outsourcing process and outsourcing arrangements, and recommendations for evaluating a contractor's performance. The guidelines also include information on how to evaluate other sources of which relate to the subject of other ASHP guidelines. Other guidelines refer to pertinent ASHP guidelines for additional information, such as those on contract provisions, agreements, and decisions.<sup>1-3</sup> This document addresses representative outsourcing options and contract agreements and is not intended to cover all situations. Health care organizations considering outsourcing should use their professional judgment about appropriate to their own needs and circumstances.

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*Compounding Pharmacies:* Section 503A clarified the FD&C Act for activities described as traditional patient-specific compounding (sometimes now called "303A compounding"). Hospitals and other health care organizations fall into this category, as do other pharmacies that fill prescriptions or manufacture medications for individual patients in a pharmaceutical relationship. All 503A compounding pharmacies, except those in federal facilities, are regulated by state boards of pharmacy. Federal facilities are subject to inspection by Food and Drug Administration (FDA) inspection under the agency's authority to enforce section 503A of the FD&C Act. The agency's enforcement authority is specified in the FDA Compliance Policy Guide (CPG) on *Pharmacy Compounding Activities Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.<sup>4</sup> In addition to current regulatory requirements, such as prescriptions, labeling, and record keeping, there are additional compliance with applicable *United States Pharmacopeia* (USP) chapter 797 and 797.<sup>5,6</sup> Inspectors may look for implementation of additional CPG recommendations. The services provided by compounding pharmacies are subject to the same licensing requirement for individual prescriptions or medication orders and may be limited by state and federal regulations of distribution across state lines, state and federal restrictions on office-use preparations, and other limitations of section 503A.

*Outsourcing Facilities:* Section 503B outsourcing facilities

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[http://apic.org/Resource/TinyMceFileManager/Academy/ASC\\_101\\_resources/Sterilization/ASHP\\_Outsourcing\\_Sterile\\_Compounding\\_2010.pdf](http://apic.org/Resource/TinyMceFileManager/Academy/ASC_101_resources/Sterilization/ASHP_Outsourcing_Sterile_Compounding_2010.pdf)

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### ASHP Guidelines on Outsourcing Sterile Compounding Services

#### Purpose

Health care organizations considering outsourcing sterile compounding services should have a clear understanding of what they want to accomplish. Consideration should include an assessment of internal needs and resources, and a careful review of prospective compounding pharmacies. The organization should examine the potential long-term consequences of outsourcing as well as the short-term outcome expected during a contract period.

The purpose of these guidelines is to provide an overview of factors and processes for health care organizations to consider when exploring outsourcing of pharmacy sterile compounding. The ideas presented in this document could be used by health care organizations as a starting point for decision-makers, for drafting contract provisions, for comparing prospective compounding pharmacies, for preparing for contract negotiations, or for evaluating a compounding pharmacy's performance.

This document includes ideas about reasons for outsourcing and reasons for not outsourcing, services available from compounding pharmacies, the outsourcing process and outsourcing arrangements, and evaluation of a compounding pharmacy's performance. It also provides a topical list of other ASHP guidelines on topics that may also be the subject of other American Society of Health-System Pharmacy (ASHP) guidelines. Organizations should refer to pertinent ASHP guidelines for additional information on which to base their contract provisions, agreements, and deci-

• Shortage of pharmacy personnel with specific experience and capabilities.

#### Financial and Cost Control

- Reduced budgets.
- Increased operating costs.
- Increased drug costs.
- Increased emphasis on measuring performance in terms of staffing and costs.

#### Quality Assurance

• Increased expectations of and pressures from payers, accreditation organizations, and consumer groups to improve the quality of patient care, reduce the incidence of hospital infections, and demonstrate compliance with applicable standards and regulation.

#### Governmental and Regulatory

- Reductions of federal, state, and local government reimbursement for health care.
- Increased numbers of individuals dependent on federal and state governments for health care.
- Increased federal and state interest in standards for sterile compounds (i.e., *United States Pharmacopeia* [USP] chapter 797).

**ASHP Has Compounding Resource Center**

[www.ashp.org/sterilecompounding](http://www.ashp.org/sterilecompounding)

**Sterile Compounding Resource Center**

Health system pharmacists routinely compound medications in response to patient needs. This ASHP Resource Center is a compendium of tools and resources for health care professionals to ensure the quality of compounded sterile products.

**Topic Areas**

- Policies, Best Practices, and Resources
- Safety Alerts
- Compounding and Outsourcing
- Publications and Presentations
- External Resources

**News**

- FDA Issues Right Information Tools to Help Ensure Product Safety
- FDA Issues Guidance on Compounding
- Compounding Suppliers Issue Recall of Insulin Due to Purity Problem
- FDA Admits Pharmaceuticals Held by One Firm Raise Laboratories' Risk

**Featured Product**

Compounding Services Readiness Assessment Tool, 2nd Edition  
Empower your staff to implement operational readiness and compliance with the help of new guidelines and practical tools.

[View in Store](#)

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**Compounding Assessment Tool**

**ASHPFoundation**  
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- Engaging the C-suite
- Insourcing Assessment Tool
- Insulin-Use Safety
- My Medicine List™
- Antifungal-Use Assessment Tool
- Outsourcing Assessment Tool
- Pharmacy Residency Expansion Grant Program

**Insourcing Sterile Compounding Services Readiness Assessment Tool**

Sponsored by Baxter Medical Products, U.S. Nutrition

The ASHP Foundation Insourcing Sterile Compounding Services Readiness Assessment Tool provides a systematic process to determine operational readiness for hospitals, and in particular key pharmacy leaders who assume responsibility for compounding sterile preparations. The contents of this tool can also be considered by hospitals and health systems as they undertake comprehensive organizational analyses to identify the best source for compounding sterile preparations to meet the needs of patients.

Access the Insourcing Sterile Compounding Services Readiness Assessment Tool now.

Sponsored by Baxter Medical Products, U.S. Nutrition.  
Developed by the ASHP Foundation.

[www.ashpfoundation.org/InsourcingTool](http://www.ashpfoundation.org/InsourcingTool)

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**ISMP's Guidelines 2013**



Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds

[www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.pdf](http://www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.pdf)

**ISMP**  
INSTITUTE FOR SAFE MEDICATION PRACTICES

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# Important CMS Memos Related to Pharmacy and Medications

# CMS Survey and Certification Website

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[CMS Home](#) | [Healthcare](#) | [Survey & Certification](#) | [General Information](#) | [Policy & Memos by States and Regions](#)

**Survey & Certification - General Information**

- Overview
- Spotlight
- CLIA
- Contact Information
- CMS National Background Check Program
- Nursing Home Quality Assurance & Performance Improvement Initiative
- Renovate User Experience Program
- Accreditation
- > **Policy & Memos to States and Regions**

**Policy & Memos to States and Regions**

CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices

**Select From The Following Options:**

Show all items

Show only (select one or more options)  
 Show only items whose \_\_\_\_\_ is within the past \_\_\_\_\_  
 Show only items whose Fiscal Year is \_\_\_\_\_  
 Show only items containing the following word \_\_\_\_\_

[Show Items](#)

Click on Policy & Memos to States and Regions

There are 455 items in this list.

Policy & Memos to States and Regions				
CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.				
Show entries:	10	▼		
Filter On:	<input type="text"/>			
Title	Memo #	Posting Date	Escal Year	
Advanced Copy - Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)	15-43-ASC	2015-06-26	2015	
Use of Portable Reverse Osmosis (RO) Units and Block Carbon	15-44-ESRD	2015-06-26	2015	
Clarification of Critical Access Hospital (CAH) Rural Status, Location and Distance Requirements	15-45-CAH	2015-06-26	2015	
Surveyor Guidance for Approval of Home Dialysis Modalities	15-41-ESRD	2015-06-12	2015	
Information Only - Review and Status of Nursing Home Survey: Summary of Traditional and Quality Indicator Survey (QIS) Findings and Issues	15-40-NH	2015-05-22	2015	
Revised Hospital Radiologic and Nuclear Medicine Services Interpretive Guidelines - State Operations Manual (SOM)/Appendix A	15-36-Hospitals	2015-05-15	2015	
Release of the Individualized Quality Control Plan (IQCPL) Workbook	15-39-CLIA	2015-05-15	2015	
Proposed Rule: SNF Medicare FY 2016 Payments, Quality Reporting, Value-Based Purchasing and Staffing Requirements - Informational Only	15-37-NH	2015-05-01	2015	
New Instructions for Providers Filing an Appeal with the Departmental Appeals Board (DAB)	15-36-ALL	2015-04-24	2015	

## Advanced Memo on Pharmacy Changes

- CMS issues 45 page advance memo on changes to the hospital pharmacy CoPs and final Nov 20, 2015
  - Amends ten tag numbers in pharmacy and retain 8 more
  - Tag numbers 489, 490-492, 500-502, 505, 507, and 510
  - Also had a change to nursing tag 405
- Changes were made to bring pharmacy interpretive guidelines into alignment with acceptable standards of practice
- Discusses hospitals should follow recommended best practices and mentions organizations like USP, ISMP, and ASHP

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## Advanced Memo on Pharmacy Changes

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
2500 Security Boulevard, Mail Stop C2-21-16  
Baltimore, Maryland 21204-1850



Center for Clinical Standards and Quality/Survey & Certification Group

**DATE:** October 30, 2015      **Ref:** S&C: 16-01-Hospital  
**TO:** State Survey Agency Directors  
**FROM:** Director  
 Survey and Certification Group  
**SUBJECT:** Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications

### Memorandum Summary

**Hospital Appendix A Updated:** The Centers for Medicare & Medicaid Services (CMS) has updated the State Operations Manual (SOM) to respect both the hospital survey process and the interpretive guidelines for the pharmaceutical services Condition of Participation (CoP). The update includes the following features:

- **Pharmaceutical Services:** Revisions were made to portions of the pharmaceutical services CoP to bring them into alignment with current accepted standards of practice. To improve clarity, the revised guidance addresses: accepted professional pharmacy principles, including United States Pharmacopeia (USP) standards; compounding of medications, particularly compounded sterile preparations (CSPs); determining beyond-use dates (BUDs); safe and appropriate storage and use of medications; and,

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## Important CMS Memos Related to Pharmacy and Medications



**CMS Survey and Certification Website**

The screenshot shows the CMS Survey and Certification website. The main navigation bar includes links for Medicare, Medicaid, Medicare-Medicaid Coordination, Insurance Oversight, Innovation Center, Regulations, Guidance & Standards, Research, Statistics & Data & Systems, and Outreach & Education. The current page is 'Policy & Memos to States and Regions'. The page title is 'Policy & Memos to States and Regions'. It features a search bar and a link to 'www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage'. There are several filter options: 'Show all items' (selected), 'Show only (select one or more options)', and three dropdown menus for filtering by date range, fiscal year, and keyword. A large button labeled 'Click on Policy & Memos to States and Regions' is present. At the bottom, it says 'There are 455 items in this list'.

**Policy & Memos to States and Regions**

This screenshot shows a detailed view of the 'Policy & Memos to States and Regions' page. It displays a table of 10 memos, each with a title, memo number, posting date, and fiscal year. The columns are 'Title', 'Memo #', 'Posting Date', and 'Fiscal Year'. The memos listed are:

Title	Memo #	Posting Date	Fiscal Year
Advanced Copy - Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)	15-43-ASC	2015-06-26	2015
Use of Portable Revenue Oscillators (IRO) Units and Block Cation	15-44-ESRD	2015-06-26	2015
Clarification of Critical Access Hospital (CAH) Rural Status, Location and Distance Requirements	15-45-CAH	2015-06-26	2015
Surveyor Guidance for Approval of Home Dialysis Modalities	15-41-ESRD	2015-06-12	2015
Information Only - Review and Status of Nursing Home Survey: Summary of Traditional and Quality Indicator Survey (QIS) Findings and Issues	15-40-NHI	2015-05-22	2015
Revised Hospital Radiologic and Nuclear Medicine Services Interpretive Guidelines—State Operations Manual (SOM) Appendix A	15-38-Hospitals	2015-05-15	2015
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Proposed Rule: RNF Medicare FY 2016 Payments, Quality Reporting, Value-Based Purchasing and Staffing Requirements – Informational Only	15-37-NHI	2015-05-01	2015
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- Discusses hospitals should follow recommended best practices and mentions organizations like USP, ISMP, and ASHP

**Advanced Memo on Pharmacy Changes**

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-21-16  
Baltimore, Maryland 21244-1850

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

**Center for Clinical Standards and Quality/Survey & Certification Group**

**DATE:** October 30, 2015 **Ref:** S&C: 16-01-Hospital

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

**SUBJECT:** Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications

**Memorandum Summary**

**Hospital Appendix A Updated:** The Centers for Medicare & Medicaid Services (CMS) has updated the State Operations Manual (SOM) Appendix A with respect to both the hospital survey process and the interpretive guidelines for the pharmaceutical services Condition of Participation (CoP). The update includes the following features:

- Pharmaceutical Services:** Revisions were made to portions of the pharmaceutical services CoP to reflect the significant changes in accepted professional practice.
- To this end, the revised guidance addresses: accepted professional pharmacy principles, including United States Pharmacopeia (USP) standards; compounding of medications; particularly compounded sterile preparations (CSPs); determining beyond-use dates (BUDs); safe and appropriate storage and use of medications; and,

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## Pharmacy CoP Changes

- Address compounding of medication especially compounded sterile preparations (CSP)
- It also includes determining beyond-use dates (BUDs)
  - Hospital must implement policies on how to determine a BUD if it is not available from the manufacturer
- CMS also made changes regarding safe and appropriate storage and use of medications
- There are many sections that address required policies and procedures

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## CMS Adds Section on Compounding

The screenshot shows a news article from Pharmacy Practice News. The headline reads "CMS Adds Section on Compounding". The article discusses the addition of a new section on compounding to the State Operations Manual (SOM) Appendix A. It highlights changes in accepted professional practice, including USP standards for compounded sterile preparations (CSPs), determining beyond-use dates (BUDs), and safe storage and use of medications. The article is dated December 2015, Volume 40, Issue 12.

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## Free Article Compliance Mentor

Compliance Mentor  
 January 2016  
 Sue Dill Calloway  
[Sdill1@columbus.rr.com](mailto:Sdill1@columbus.rr.com)  
[www.ahcmedia.com](http://www.ahcmedia.com)

### CMS and the Revised Pharmacy Standards What Every Hospital Should Know

DEPARTMENT OF HEALTH & HUMAN SERVICES  
 Centers for Medicare & Medicaid Services  
 7500 Security Boulevard, Rm. 22-216  
 Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Survey & Certification Group

DATE: October 30, 2015 Ref: S&C: 16-01-Hospital  
 TO: State Survey Agency Directors  
 FROM: Director, Survey and Certification Group  
 SUBJECT: Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications

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## CMS Memo on Safe Injection Practices

- June 15, 2012 CMS issues a 7 page memo on safe injection practices
- Discusses the safe use of single dose medication to prevent healthcare associated infections (HAI)
- Notes new exception which is important especially in medications shortages
- General rule is that single dose vial (SDV) can only be used on one patient
- Will allow SDV to be used on multiple patients if prepared by pharmacist under laminar hood following USP 797 guidelines

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## Single Dose Medication Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES  
 Centers for Medicare & Medicaid Services  
 7500 Security Boulevard, Rm. 22-216  
 Baltimore, Maryland 21244-1850



Office of Clinical Standards and Quality/Survey & Certification Group

DATE: June 15, 2012 Ref: S&C: 12-25-ALL  
 TO: State Survey Agency Directors  
 FROM: Director, Survey and Certification Group  
 SUBJECT: Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections

### Memorandum Summary

- Under certain conditions, it is permissible to repackage single-dose vials or single-use medications into smaller doses for use with one patient. The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by USP, are intended to ensure the safety and quality of compounded products under 955-01 and 502 of the Federal Food, Drug and Cosmetic Act (FDCA). These USP compounding standards include USP General Chapter 797, "Pharmaceutical Compounding - Sterile Preparations." A facility may only repackage SDVs into smaller doses, each intended for use with one patient. Among other things, the facility must:
  - The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions with respect to the preparation of sterile pharmaceutical products. The repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
  - All repackaged doses prepared under these conditions must be aseptically compounded and labeled with the date and time of preparation, and the name and address of the facility on risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process.

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### CMS Memo on Safe Injection Practices

- All entries into a SDV for purposes of repackaging must be completed with 6 hours of the initial puncture in pharmacy following USP guidelines
- Only exception of when SDV can be used on multiple patients
- Otherwise using a single dose vial on multiple patients is a violation of CDC standards
- CMS will cite hospital under the hospital CoP infection control standards since must provide sanitary environment
  - Also includes ASCs, hospice, LTC, home health, CAH, dialysis, etc.

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### CMS Memo on Safe Injection Practices

- Bottom line is you can not use a single dose vial on multiple patients
- CMS requires hospitals to follow nationally recognized standards of care like the CDC guidelines
- SDV typically lack an antimicrobial preservative
- Once the vial is entered the contents can support the growth of microorganisms
- The vials must have a beyond use date (BUD) and storage conditions on the label

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### CMS Memo on Safe Injection Practices

- Make sure pharmacist has a copy of this memo
- If medication is repackaged under an arrangement with an off site vendor or compounding facility ask for evidence they have adhered to 797 standards
- ASHP Foundation has a tool for assessing contractors who provide sterile products
- Go to [www.ashpfoundation.org/MainMenuCategories/Practice Tools/SterileProductsTool.aspx](http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx)
- Click on starting using sterile products outsourcing tool now

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FOSTERING SAFE AND EFFECTIVE MEDICATION USE

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Pharmacy Practice Model Initiative

Outsourcing Sterile Products Preparation: Contractor Assessment Tool

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Preparation of sterile parenteral products is a critical component of health-system pharmacy practice. For departments that choose to outsource the preparation of parenteral medications, this web-based tool can be used to evaluate proposals during the selection of an external organization that would provide parenteral product preparation services.

The assessment tool helps you evaluate each of these areas:

- Regulatory compliance
- Quality and patient safety measures
- Medication administration safety features
- Service excellence

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[www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx](http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx)

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## Safe Injection Practices

**EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION**

**Safe Injection Practices Patient Safety Brief**  
Emergency Medicine Patient Safety Foundation

By: Sue Dill Calloway RN MSN JD CPHRM  
Ruth Carrico PhD RN FSHEA CIC

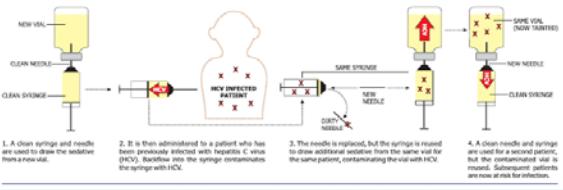
July 2012



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**Unsafe Injection Practices and Disease Transmission**

Reuse of syringes combined with the use of single-dose vials for multiple patients undergoing anesthesia can transmit infectious diseases. The syringe does not have to be used on multiple patients for this to occur.



1. A clean needle and syringe are used to draw the sedative from a new vial.

2. It is then administered to a patient who has been previously infected with hepatitis C virus (HCV). In this step, the syringe contaminates the syringe with HCV.

3. The needle is replaced, but the syringe is reused to draw additional sedative from the same vial for the same patient, contaminating the vial with HCV.

4. A clean needle and syringe are used for a second patient, drawing sedative from a new vial. Subsequent patients are now at risk for infection.

Source: [www.southernnevadahealthdistrict.org](http://www.southernnevadahealthdistrict.org)

CDC

## Not All Vials Are Created Equal

### SINGLE-DOSE OR MULTI-DOSE?

#### NOT ALL VIALS ARE CREATED EQUAL.

Dozens of recent outbreaks have been associated with the reuse of single-dose vials or the reuse of multiple-dose vials. As a result of these incidents, patients have suffered significant harm, including sepsis, blindness, and death. Only CancerCare.org encourages healthcare providers to recognize the differences between single-dose and multiple-dose vials and to use safe and appropriate uses for each container type. This information can literally save a life.



CANCERCARE.ORG

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### DO YOU PROVIDE TREATMENT FOR PATIENTS WITH CANCER?

#### PROTECT YOUR PATIENTS, YOURSELF, AND YOUR BUSINESS

Since 2002, at least nine serious infectious disease outbreaks have occurred in cancer clinics. These outbreaks involved unsafe injection practices, including the reuse of syringes. As a result, hundreds of patients became infected and thousands more required notification and testing for bloodborne pathogens.

#### REMEMBER! WHEN PREPARING MEDICATIONS AND INJECTIONS...

##### NEVER reuse these items:



##### ALWAYS follow aseptic technique\* when:



\*Aseptic technique is used by health care workers to prevent the contamination of clean areas, equipment, and sterile medications. This will help prevent the spread of infection. Please refer to CDC's Best Practices Control and Prevention Plan for Supplemental Oncology Settings for more information.

LEARN MORE ABOUT WAYS YOU CAN KEEP YOUR PATIENTS



## Watch Award Winning Video



**Safe Injection Practices - How to Do It Right**

[www.youtube.com/watch?v=v=6D0stMoz80k&feature=youtu.b](http://www.youtube.com/watch?v=v=6D0stMoz80k&feature=youtu.b)

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## CMS Memo May 30, 2014

- CMS publishes 4 page memo on infection control breaches and when they warrant referral to the public health authorities
- This includes a finding by the state agency (SA), like the Department of Health, or an accreditation organization
  - TJC, DNV Healthcare, CIHQ, or AOA HFAP
- CMS has a list and any breaches should be referred
- Referral is to the state authority such as the state epidemiologist or State HAI Prevention Coordinator

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## Infection Control Breaches

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-21-16  
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 14-36-AB

**DATE:** May 30, 2014  
**TO:** State Survey Agency Directors  
**FROM:** Director  
**SUBJECT:** Infection Control Breaches Which Warrant Referral to Public Health Authorities

### Memorandum Summary

- **Infection Control Breaches Warranting Referral to Public Health Authorities:** If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they should refer them to appropriate State authorities for public health assessment and management.
- **Identification of Public Health Contact:** SAs should consult with their State's Healthcare Associated Infections (HAI) Prevention Coordinator or State Epidemiologist on the preferred referral process. Since AOs operate in multiple States, they do not have to confer with State public health officials to seek referrals, but are expected to refer identified breaches to the appropriate State public health contact identified at <http://www.cdc.gov/HAI/state-based-index.html>

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## CMS Memo Infection Control Breaches

- Using the same needle for more than one individual
- Using the same (pre-filled/manufactured/insulin or any other) syringe, pen or injection device for more than one individual
- Re-using a needle or syringe which has already been used to administer medication to an individual to subsequently enter a medication container (e.g., vial, bag), and then using contents from that medication container for another individual
- Using the same lancing/fingerstick device for more than one individual, even if the lancet is changed

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## Fingerstick Devices



- Anyone performing fingerstick procedures should ensure that a device is not used on more than one patient
  - Use auto-disabling single-use disposable fingerstick devices
  - Pen like devices should not be used on multiple patients due to difficulty with cleaning and disinfection (one patient use)

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## CMS Memo on Insulin Pens

- CMS issues memo on insulin pens
  - Insulin pens are intended to be used on one patient only
  - CMS notes that some healthcare providers are not aware of this
  - Insulin pens were used on more than one patient which is like sharing needles
  - Every patient must have their own insulin pen
  - Insulin pens must be marked with the patient's name

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## Insulin Pens

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-21-16  
Baltimore, Maryland 21244-1850

**CMS**

Office of Clinical Standards and Quality/Survey & Certification Groups

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Ref: E&G: 13-30 ALL

**DATE:** May 18, 2012

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

**SUBJECT:** Use of Insulin Pens in Health Care Facilities

### **Memorandum Summary**

**Insulin Pen devices:** The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in hospitalization. CMS has issued a memorandum indicating that reports of such unsafe healthcare personnel do not adhere to safe practices and may be cause for removal of the rights to use unsafe practices post to patients. Insulin pens are meant for use by a single patient only. Each unsafe/patient must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be ended, consistent with the applicable provider/supplier specific survey guidelines, in the same manner as re-use of needles or syringes.

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**CDC Reminder on Insulin Pens**

**Injection Safety** [www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html](http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html)

**Injection Safety**

CDC's Role  
CDC Statement  
Information for Providers  
Information for Patients  
Preventing Unsafe Injection Practices  
Infection Prevention during Blood Glucose Monitoring and Insulin Administration  
FAQs regarding Assisted Blood Glucose Monitoring and Insulin Administration  
CDC Clinical Reminder: Fingerstick Devices  
► Clinical Reminders: Insulin Pens  
Recent Publications  
Recent Meetings  
The One & Only Campaign  
Related Links

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- Recommendations
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**Contact Us:**

**Summary**

The Centers for Disease Control and Prevention (CDC) has become increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV). This notice serves as a reminder that insulin pens must **never** be used on more than one person.

**Background**

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times, for a single person, using a new needle for each injection. Insulin must **never** be used for more than one person.

**On this Page**

- Summary
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Print page

Available for download: [Clinical Reminder: Insulin Pens](#) [PDF - 1.82 KB]

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**CDC Has Flier for Hospitals on Insulin Pens**

**CDC CLINICAL REMINDER**

**Insulin Pens Must Never Be Used for More than One Person**

**Summary**

The Centers for Disease Control and Prevention (CDC) has become increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV). This notice serves as a reminder that insulin pens must **never** be used on more than one person.

**Background**

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times, for a single person, using a new needle for each injection. Insulin must **never** be used for more than one person.

Reinoculation of blood into the insulin cartridge can occur after injection [1] creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed.

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration (FDA) issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single patient only and are not to be shared between patients [2]. In spite of this alert, there have been continuing reports of patients placed at risk through inappropriate reuse sharing of insulin pens, including an incident in 2011 that required notification of more than 2,000 potentially exposed patients [3]. These reports indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients.

**Recommendations**

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**FDA Issues An Alert in 2009**

**FDA U.S. Food and Drug Administration**

**Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens**

**FDA ALERT [03/19/2009]:** The FDA is issuing this alert to remind healthcare providers and patients that insulin pens and insulin cartridges\* (see description below) are never to be shared among patients. Sharing of insulin pens may result in transmission of hepatitis viruses, HIV, or other blood-borne pathogens.

The FDA has received information that insulin pens may have been shared among numerous patients (two thousand or more) in one hospital in the United States from 2007-2009 (<http://www.fda.gov/cder/amefd/amv.mif>), and in a smaller number of patients in other countries. In these cases, although the needles in the insulin pens were reportedly changed for each patient, there is still a risk of blood contamination of the pen reservoir or cartridge. Patients who were treated with insulin pens at the hospitals in question are being contacted by the hospitals, and are being offered testing for hepatitis and HIV. Some of the potentially exposed patients have reportedly tested positive for hepatitis C; however it is not known if the hepatitis infection occurred through insulin pen sharing, or if those who tested positive had previously undiagnosed hepatitis C.

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## Insulin Pen Posters and Brochures Available

The screenshot shows a web page with a header "ONE NEEDLE, ONE SYRINGE, ONE TIME. ONE & ONLY Campaign". Below the header, there's a navigation bar with links: About the Campaign, Safe Injection Practices, Healthcare Provider Information, Patient Information, Campaign Resources, News, and Contact Us. The main content area features a poster titled "Insulin Pen Safety – One Insulin Pen, One Person". The poster has a blue header "BE AWARE DON'T SHARE" and a sub-header "ONE INSULIN PEN, ONLY ONE PERSON". It includes a photograph of two insulin pens. Below the image, text reads: "The Safe Injection Practices Coalition creates an insulin pen poster and brochure for healthcare providers as a reminder that insulin pens and other injectable medications are meant for one person and should never be shared. PDFs of these educational materials are linked below." There are links for "Clinician Materials for Safe Use of Insulin Pens – For Clinicians and Patients" and "CDC Materials to order free copies of these materials from the Centers for Disease Control and Prevention (CDC)". At the bottom, there's a link to "U.S. Patient Safety Alert: Multi-Device Pen Injuries" (Department of Veterans Affairs, January 2013).

The poster features a large, bold title "BE AWARE DON'T SHARE" in blue and orange. Below the title are two insulin pens, one blue and one clear, lying next to each other. To the right of the pens, text reads: "Insulin pens that contain more than one dose of insulin are only meant for one person. They should never be used for more than one person, even when the needle is changed." Below this, a box contains the text "ONE INSULIN PEN, ONLY ONE PERSON". At the bottom left, it says "The One & Only Campaign is a public health campaign aimed at raising awareness among the general public and healthcare providers about safe injection practices." At the bottom right, it says "For more information, please visit: [www.ONEandONLYcampaign.org](http://www.ONEandONLYcampaign.org)".

## Brochure

The brochure has a dark header "DON'T DO IT" and a sub-header "Sharing Insulin Pens and Other Injection Equipment Jeopardizes Patients". Below this, a section titled "A SIMPLE RULE" states: "Injection equipment (e.g., insulin pens, needles, syringes) should never be used for more than one person." To the right, there's another section titled "About the Safe Injection Practices Coalition" with a photo of a healthcare provider and a patient. A box at the bottom right says "What Every Healthcare Professional Needs To Know". At the very bottom, it says "For more information, please visit: [www.ONEandONLYcampaign.org](http://www.ONEandONLYcampaign.org)".

**Recommendations for Safe Insulin Pen Use**

Protect yourself from infections! A basic expectation anyone locally can be informed, like you, about how to use insulin pens safely so that one person places unacceptable risks and should be considered a "one-time" user.

- **Insulin pens and other injection equipment** containing multiple doses of medication are meant for one single person only, and should never be used by another person, even when the needle is changed.
- **Insulin pens and other injection equipment** should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only by the correct individual.
- **Hospitals and other facilities** should review their policies and update their staff regarding the safe use of insulin pens and similar devices.
- If a user is identified, **qualified personnel** should be promptly notified and offered appropriate follow-up including blood glucose monitoring testing.

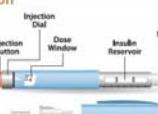
In healthcare settings, these devices are often used by healthcare personnel to administer insulin. In particular, however, it is not safe for a single person to use multiple times, using a new needle for each injection.

**ONE INSULIN PEN. ONLY ONE PERSON**

## Insulin Administration

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection.

They are intended for single-person use.



In healthcare settings, these devices are often used by healthcare personnel to administer insulin. In particular, however, it is not safe for a single person to use multiple times, using a new needle for each injection.

**The Safe Injection Practices Coalition** created an easy-to-use check list for facilities. Similar to a risk assessment, the list contains the necessary components of injection safety for facilities to quickly assess their practices.

A copy of the checklist can be found at: [www.cdc.gov/injectionsafety/Checklist](http://www.cdc.gov/injectionsafety/Checklist)

## Luer Misconnections Memo

- CMS issues memo on luer misconnections
  - This has been a patient safety issues for many years
  - Staff can connect two things together that do not belong together because the ends match
  - For example, a patient had the blood pressure cuff connected to the IV and died of an air embolism
  - Luer connections easily link many medical components, accessories and delivery devices

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## Luer Misconnections Memo



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-23-16  
Baltimore, Maryland 21244-1500

**Center for Clinical Standards and Quality /Survey & Certification Group**

DATE: March 8, 2013 Ref: S

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

**SUBJECT:** Line Misconnection Adverse Events

Математика. Бакалавриат

**Memorandum Summary**

#### **Actions to result in adverse**

- Adverse Event Complaints/Investigations:** During a complaint investigation for an adverse event, surveyors must determine whether the facility has taken actions to ensure patient safety. If the surveyor determines that the facility has not taken actions to ensure patient safety, surveyors must be alert to whether the event involved misconnection of a laser device. If so, surveyors must determine whether the facility has taken actions to ensure patient safety.
  - Facility Reporting to Food & Drug Administration (FDA):** Surveyors should encourage health care facilities to report problems with laser misconnections to the FDA, even if no adverse event occurred.

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**June 2010 Pa Patient Safety Authority**

## Tubing Misconnections: Making the Connection to Patient Safety

### ABSTRACT

Some patient care tasks have multiple tubing connections, such as the administration of multiple medications, the prevention of tubing disconnections, and the prevention of enteral feedings from becoming confluent, leading to aspiration. Handheld barcode scanners can reduce the risk of tubing misconnections by linking the patient's identification to the tubing label. One of the main risks for tubing misconnections is that the healthcare provider does not fully understand the connection and becomes complacent about the safety of the connection. This article describes how tubing misconnections have been reported between January 2008 and September 2010. The Pennsylvania Patient Safety Authority received 15 reports of tubing misconnections, all but one reported by the Pennsylvania Patient Safety Authority involving the administration of multiple medications. The remaining report involved the prevention of enteral feedings from becoming confluent. All 15 reports involved tubing misconnections that led to patient harm. The most common damage resulted in either patient or staff making a medication error or enteral feeding error due to tubing misconnections. Administrative errors, one practice and one procedure, were also reported. The most common damage listed was harm to the patient. (See Patient Safety Authority, June 2010, p. 45-46.)

### Introduction

In hospitals, on acute care, patients use basic means of tubing misconnection due to medical device and medical device connected to patient more often than the patient connected to medical device. Under these circumstances, tubing misconnections can occur due to lack of knowledge, fatigue, and/or haste for many reasons. One of the current trends in hospital safety is the reduction of the potential for harm from both intra- and interconnections (IPI). Intraconnections are those connections that are grafted onto patients in recent years, especially in the field of hemodialysis. Interconnections (IPI) are those connections placed directly by the joint manufacturers in April 2009.

for TV delivery connected to incompatible tubes.<sup>2</sup> The Aiken offices, risk reduction strategies, and administrative errors were identified as causes of the event.

There are two types of misconnections: hemostatic and self-sealing. Self-sealing tubes can be used to connect two different types of tubing, such as a central line and a peripheral line. These are frequently reported in the Pennsylvania Patient Safety Authority reports. Hemostatic tube connections, adhesive modifications or mismatch, but may also include the use of a hub or Y-site. Self-sealing tubes and hub lines are typically used for respiratory support.<sup>3</sup> Respiratory support is a common cause of tubing misconnections, especially when inserting the wrong hub site on the wrong infusion line. These are usually caused by the healthcare provider misconnecting two similar or similar to patient's respiratory tract.

A third type of tubing misconnection, whitfield liquid-to-liquid or liquid-to-powder, is when two types of medications are mixed together inappropriately. Liquid-to-liquid misconnections are often associated with mixing medications in the same container. Liquid-to-powder misconnections are often associated with mixing medications in the same container or with mixing medications in the same syringe, needles, and other medical equipment.<sup>4</sup> The Pennsylvania Patient Safety Authority received 15 reports that are just listed together under risk to patient. The following section will describe the 15 reports and some similarities in the misconnections found in these reports.

### Misconnections in Pennsylvania

Between January 2008 and September 2010, 16 reports of tubing misconnections were submitted to the Pennsylvania Patient Safety Authority. 15 individualized reports and 1 aggregate report were submitted. The aggregate report involved the prevention of enteral feedings via interconnections. The 15 individualized reports involved 13 patients, 1 healthcare provider, and 1 staff member.

The patients in 15 individualized reports exhibited 22 total adverse events. Of the 22 adverse events, 20 did not involve any harm to the patient. Some cases involved the loss of the tube or the tube became disconnected.

**ISMP Medication Safety Alert!** Volume 16, Number 10

**PREVENTING CATHETER/TUBING MISCONNECTIONS: MUCH NEEDED HELP IS ON THE WAY**

From the July 15, 2010 issue

Catheter/tubing misconnections remain a serious problem in healthcare. Just a few weeks ago we learned of another tragic case of a child who died after receiving a massive overdose of a medication. A suspension of **QUESTHAN** (cholestyramine) was accidentally given via a central venous catheter instead of the oral route.

In May 2010, another report was published about barium sulfate being administered via the superior vena cava during upper gastrointestinal study (Soghoian S, Hoffman RS, Nelson L. Unintentional IV injection of barium sulfate in a child. *J Pediatr*. 2010;156:211-213). The child had been receiving enteral nutrition and antibiotic therapy. As the procedure began, approximately 3 mL of barium sulfate was injected into the CVC, which was misidentified as the enteral feeding tube. The child died 1 day later.

Luer connector systems, common to many healthcare catheters, tubes, administration sets, extension sets, and syringe drivers, often lie at the heart of many catheter/tubing misconceptions. At the center of one of the most commonly reported problems is the fact that some manufactured enteral catheters still have ports that only accept parenteral administration sets and cannot be safely connected to administer via this type of enteral catheter port, risking the accidental administration of that drug via a parenteral line.

Please see examples of the type of reports we have received associated with catheter/tubing misconconnections, all of which we've described in previous issues:

- IV tubing connected to arterial lines or respiratory solutions connected to IV lines
- Arterial cannula connected to arterial lines or respiratory solutions connected to IV lines
- IV tubing connected to inflation balloon port of endotracheal tube or tracheostomy tube
- Sequential compression device tubing or pneumatic blood pressure cuff tubing attached to port of IV administration set
- Oxygen tubing connected to port of IV administration set
- Breast milk intravenously infused into neonates
- Bladder irrigation solutions given IV, or TPN solutions administered via foley catheter port
- IV administration set spiked into enteral nutrition container, resulting in enteral nutrition administered IV.

**FDA Luer Misconnections**

**Tubing and Luer Misconnections: Preventing Dangerous Medical Errors**

Patients in health care settings receive medications and other therapies through a variety of tubes and catheters. These delivery systems often use parts called small-bore connectors to link various components. Small-bore refers to the small size of the opening of the connector. Luer connectors are a commonly used type of small-bore connector and throughout this website that term Luer will be used to refer to all types of small-bore connectors.

Despite these connectors are compatible between different delivery systems, patient injuries and deaths have occurred when medicines, liquid feeding formulas, or air were accidentally delivered through the wrong tubing. These errors are sometimes called tubing misconnections, wrong route errors, catheter misconnections or Luer misconnections. It is vitally important that all health care clinicians understand the risks of these errors and take steps to prevent them from occurring.

This includes not only acute care settings, but, long-term care, rehabilitation facilities, home health care, physician offices, and any non-clinical settings in which a small-bore connector may be used on a patient.

The following section describes how misconnection errors occur, provides real-life examples of misconnections, and offers tips and additional resources for preventing them. Guidance for manufacturers of enteral feeding systems is also provided.

[www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)



**New Standards Prevent Tubing Misconnections**

- New and unique international standards being developed in 2016 for connectors for gas and liquid delivery systems
- To make it impossible to connect unrelated systems
- Includes new connectors for enteral, respiratory, limb cuff inflation neuraxial, and intravascular systems
- Phase in period for product development, market release and implementation guided by the FDA and national organizations and state legislatures
  - FAQ on small bore connector initiative

**Managing Risk During the Transition**

**Sentinel Alert**

A complimentary publication of The Joint Commission  
Issue 53, August 20, 2014

Published for Joint Commission accredited organizations and interested health care professionals, Sentinel Alert identifies specific types of sentinel and adverse events and high risk conditions, their common underlying causes, and recommendations to reduce risk and prevent future occurrences.

Accredited organizations should receive information in a *Sentinel Alert* when designing or redesigning processes or programs for implementing relevant recommendations in the alert or reasonable alternatives.

Managing risk during transition to new ISO tubing connector standards

Tubing misconnections continue to cause serious patient injury and death, since tubes with different apertures can easily be connected using adapters, tubing or catheters. This is why new ISO (International Organization for Standardization) tubing connector standards are being developed for manufacturers. Through an international process, these new connector standards have been developed and approved to assure reliable designs and processes. The phased implementation of redesigned tubing connectors that are the result of these new ISO connector standards is underway. The Joint Commission and its partners encourage hospitals to be vigilant and begin planning for the upcoming period of transition, which will introduce changes and new risks into the health care environment. Under the new ISO connector standards, the new connectors will be designed so that they cannot be connected to another delivery system that serves a completely different function, such as connecting a ventilator circuit to a epidural infusion set to a tracheostomy tube, or an intravenous (IV) tube to an epidural site.

The first new ISO connector standard (ANSI/AAMI/ISO 80399-1) has been adopted and others are expected to be introduced and adopted through 2014 and 2015. Health care organizations should begin preparing for changes in

## Nursing CoPs affecting Pharmacy and Medication



### Timing of Medications

- Nursing tag number 405, in nursing section, use to say all medications had to be given within 30 minutes of scheduled time
- Now **three** time frames to give medications
  - 30 minutes- some medications are critical and must be given timely such as fast acting insulin with meal or antibiotic in surgery within 1 hour
  - Meds given twice a day or more, such as tid, bid, qid, every 6 hours) give 1 hour before or after so 2 hour window
  - More than once a day, such as once a week, month, year, give 2 hours before or after so 4 hour window

### 3 Time Frames for Administering Medication

Time Critical Medicine

1 hour before or after

2 hours before or after

## IV Medication, Safe Opioid Use, Blood

- Hospitals should take the 32 page memo issued March 14, 2014 and go through it line by line to ensure compliance
    - Became effective June 6, 2014 when the manual was revised to implement these changes and CAH April 2015
  - Must implement P&P
  - Must train staff such as in orientation and CNE
  - Must have P&P approved by Medical Staff
    - Such as MEC
  - Many requirements for safe opioid use

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## Safe Use of Opioids



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C-22-10  
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&P

**TO:** State Survey Agency Directors

Moderator

- Medication Administration:** We are updating our guidance for the hospital medication administration requirements to:

  - Make clear that the medication administration requirements under the nursing services condition of participation (CoP) are related to only some components of the overall hospital medication process, but that hospitals are expected, through this and the related requirements for the medication management CoPs, to take a comprehensive approach to medication improvement CoPs, to take a comprehensive approach to the medication process.
  - Update our guidance for IV medications and blood transfusions in general; and
  - Reflect the need for patient risk assessment and appropriate monitoring during and after initiation of IV infusions for patients who are at higher-risk for adverse events from opioid medications, in order to prevent adverse events.

**Immediate Post-operative Care:** Clarification is also being made to the guidance for the

1

## Assessment & Monitoring of Patients

- Staff are expected to include patient reports of his experience with medication's effect
  - Patient should be instructed to notify nurse if there is difficulty breathing or a reaction to the medication
  - Hospital needs P&P to address the manner and frequency of monitoring
  - P&P should include information to be communicated at shift change
  - Should include patient's risk factors
  - **Document** after medication administered

## Safe Opioids and Blood

- Need to closely monitor patients on opioids to prevent ADE including respiratory distress or arrest
- Four times CMS lists what places patients at high risk
- Want to be sure staff are knowledgeable about intervention protocols when patients experience adverse medication-related events
- Need to make sure staff are aware of signs of blood transfusion reaction and AE get reported into QAPI
- Need to be aware of blood P&P

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## Compounding 2016

- Must only involve simple transfer of not more than 3 commercially manufactured, sterile, nonhazardous products from the manufacturer's original container
- And not more than two entries into any one container including a vial or an IV bag
- Administration must be within **one hour** following the preparation
- Must follow aseptic technique during all phases of preparation

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## Compounding 2016

- Must label it unless you prepare it and immediately administer it to the patient
- CSP label must include: patient identification, name and amount of ingredients, name or initial of person who prepared it, and exact **one hour BUD**
- Drug is outdated after its expiration date or BUD
  - BUD is December 2017 but multi-dose vial expires in 28 days when opened unless sooner by manufacturer
- Need P&P to give clear directions to staff on how to determine BUD date if not available from manufacturer

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*procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the USP/NF (USP).<sup>3</sup>*

*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 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 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.*

## Self Administered Medication 409

- **Standard:** The hospital may allow a patient, or his or her caregiver/support person where appropriate to self administer medication
  - This is nursing standard and similar to tag 502 in pharmacy
- This includes both hospital-issued medications and the patient's own medications brought into the hospital
  - Must be defined and specified in the hospital's policies and procedures
- PCA is considered as a self administered medication

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## CMS Nursing Tag Numbers 412 & 413

### A-0412

*§482.23(c)(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.*

- (i) *If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:*
  - (A) *Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.*
    - (B) *Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).*
    - (C) *Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s).*
    - (D) *Address the security of the medication(s) for each patient.*
    - (E) *Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.*

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## ISMP IV Push Medication Guidelines



### ISMP IV Push Medications Guidelines

- ISMP has published a 26 page document called "ISMP Safe Practice Guidelines for Adult IV Push Medications"
- The document is organized into factors that increase the risk of IV push medications in adults,
  - Current practices with IV injectable medications
  - Developing consensus guidelines for adult IV push medication and
  - Safe practice guidelines
- About 90% of all hospitalized patients have some form of infusion therapy

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## IV Push Medicine Guidelines

**ISMP**

**ISMP  
Safe Practice  
Guidelines for  
Adult IV Push  
Medications**

A compilation of safe practices from the ISMP Adult IV Push Medication Safety Summit

Remember: CMS says you have to follow standards of care and specifically mentions the ISMP so surveyor can site you if you do not follow this.

Prepared by the Institute for Safe Medication Practices (ISMP)

**ISMP**  
INSTITUTE FOR SAFE MEDICATION PRACTICES

## IV Push Medications Guidelines

- Provide IV push medications in a ready to administer form
- Use only commercially available or pharmacy prepared prefilled syringes of IV solutions to flush and lock vascular access devices
- If available in a single dose vial then need to buy in single dose vial
- Aseptic technique should be used when preparing and administering IV medication
  - This includes hand hygiene before and after administration

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## IV Push Medications Guidelines

- The diaphragm on the vial should be disinfected even if newly opened
  - The top should be cleaned using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab for at least ten seconds to it dr
- Medication from a glass vial should be with a filter needle unless the specific drug precludes this
- Medication should only be diluted when recommended by the manufacturer or in accordance with evidence based practice or approved hospital policies

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## IV Push Medications Guidelines

- If IV push medication needs to be diluted or reconstituted these should be performed in a clean, uncluttered, and separate location
- Medication should not be withdrawn from a commercially available, cartridge type syringe into another syringe for administration
- It is also important that medication not be drawn up into the commercially prepared and prefilled 0.9% saline flushes
  - These are to flush an IV line and are not approved to use to dilute medication

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**CMS Infection Control Worksheet**

Safe Injection Practices and Antimicrobial Stewardship



[Redacted]

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**CMS Hospital Worksheets History**

- 3 final worksheets which addresses discharge planning, infection control, and QAPI (performance improvement)
- Final ones issued November 26, 2014
- Infection control has safe injection practices section and also antimicrobial stewardship program
- CMS also issued separate memo on safe injection practices
- Infection control worksheet is 49 pages

[Redacted]

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**Final 3 Worksheets**

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
2700 Security Boulevard, Mail Stop C2-21-16  
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

**DATE:** November 26, 2014      **REF:** S&C: 15-12-Hospital

**TO:** State Survey Agency Directors

**FROM:** Director, Survey and Certification Group

**SUBJECT:** Public Release of Three Hospital Surveyor Worksheets

**Memorandum Summary**

- **Three Hospital Surveyor Worksheets Finalized:** The Centers for Medicare & Medicaid Services (CMS) has finalized surveyor worksheets for assessing compliance with three Medicare hospital Conditions of Participation (CoPs): Quality Assessment and Improvement (QAI), Infection Control, and Discharge Planning. The worksheets are used by State and Federal surveyors on all survey activity in hospitals when assessing compliance with any of these three CoPs.
- **Final Worksheets Made Public:** Via this memorandum we are making the worksheets publicly available. The hospital industry is encouraged, but not required, to use the worksheets as part of their self-assessment tools to promote quality and patient safety.

[Redacted]

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## CMS Hospital Worksheets

- Hospitals should be familiar with the three worksheets and IC has section on safe injection practices and preventing MDRO and antibiotic use
  - Will use whenever a validation survey or certification survey is done at a hospital by CMS
  - CMS says worksheets are used by State and federal surveyors on all survey activity in assessing compliance with any of the three CoPs
  - Hospitals are encouraged by CMS to use the worksheet as part of their self assessment tools which can help promote quality and patient safety

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### Section 1.C. Systems to Prevent Transmission of MDROs and Pr Stewardship

Elements to be assessed		
1.C.1. The hospital has policies and procedures for managing the risk of development and transmission of multidrug-resistant organisms (MDROs) within the hospital (applicable to all persons in the hospital).	<input type="radio"/> Yes	
	<input type="radio"/> No	
1.C.2. Systems are in place to designate patients known to be colonized or infected with a targeted MDRO and to notify receiving units and personnel prior to movement of such patients within the hospital.	<input type="radio"/> Yes	
	<input type="radio"/> No	
1.C.3. Systems are in place to designate patients known to be colonized or infected with a targeted MDRO and to notify receiving healthcare facilities and personnel prior to transfer of such patient between facilities.	<input type="radio"/> Yes	
	<input type="radio"/> No	
<b>If no to any part of 1.C.1 through 1.C.3, cite at 42 CFR 482.42(a) (Reg. A-0749).</b>		
1.C.4. The hospital can provide a list of target MDROs.	<input type="radio"/> Yes	
	<input type="radio"/> No	
Note: Hospitals should provide a list of MDROs that are targeted for infection control because they are epidemiologically important (e.g., MRSA, VRE). Please refer to CDC's Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (http://www.cdc.gov/hicpac/pdf/isolation/isolation2007.pdf).		
1.C.5. The hospital can demonstrate the criteria used to determine epidemiologically important MDROs on their list.	<input type="radio"/> Yes	
	<input type="radio"/> No	
1.C.6. The hospital can provide justification for any epidemiologically important organisms not on their list and otherwise not targeted in their hospital.	<input type="radio"/> Yes	
	<input type="radio"/> No	

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## Safe Injection Practices and Sharps Safety

Elements to be assessed		
Element to be assessed	Unacceptable	Unacceptable
2.B.1. Injectors are given using aseptic technique in an area that has been cleaned and is free of contamination (e.g., visible blood, or body fluids).	<input type="radio"/> Yes	<input type="radio"/> Yes
	<input type="radio"/> No	<input type="radio"/> No
	<input type="radio"/> Unable to observe	<input type="radio"/> Unable to observe
2.B.2. Needles are used for only one patient.	<input type="radio"/> Yes	<input type="radio"/> Yes
	<input type="radio"/> No	<input type="radio"/> No
	<input type="radio"/> Unable to observe	<input type="radio"/> Unable to observe
2.B.3. Syringes are used for only one patient (this includes manufactured prefilled syringes).	<input type="radio"/> Yes	<input type="radio"/> Yes
	<input type="radio"/> No	<input type="radio"/> No
	<input type="radio"/> Unable to observe	<input type="radio"/> Unable to observe
2.B.4. Insulin pens are used for only one patient.	<input type="radio"/> Yes	<input type="radio"/> Yes
	<input type="radio"/> No	<input type="radio"/> No
	<input type="radio"/> Unable to observe	<input type="radio"/> Unable to observe
2.B.5. The rubber septum on all medication vials, whether unopened or previously accessed, is disinfected with alcohol.	<input type="radio"/> Yes	<input type="radio"/> Yes
	<input type="radio"/> No	<input type="radio"/> No
	<input type="radio"/> Unable to observe	<input type="radio"/> Unable to observe

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## The Federal Law on Compounding



### Federal Law on Compounding

- Drug Quality and Security Act (DQSA) has sections related to compounding
- Outsourcing facilities who compound drugs register and must comply with section 503B of the FDCA and other requirements such as the FDA's current good manufacturing practice (CGMP)
  - Will be inspected by the FDA according to risk based schedule
  - Must meet certain other conditions including reporting adverse drug events to the FDA

### Federal Law on Compounding

- The FDA sent letters encouraging hospitals and other purchasers of sterile products to require their compounding vendors to register with the agency as an outsourcing facility
- Section 503B of the Drug Quality and Security Act allows outsourcing facilities to register with the FDA and be subject to risk based inspections
- Has a list of those registered as an outsourcing facility

**Registered Outsourcing Facilities**

**FDA U.S. Food and Drug Administration**  
Protecting and advancing your health.

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**Drugs**

Home > Drugs > Guidance, Compliance & Regulatory Information > Compounding

[Compounding](#)  
Regulatory Policy Information  
Compounding, Recalls, and Other Actions  
Outsourcing Facilities

[www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378845.htm](#)

## Registered Outsourcing Facilities

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Facilities Required as Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA)

Updated as of 12/11/15

Information Code: [Human Outsourcing Facility Registration](#)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the date last updated for the latest weekly update of the table.

Facility Name	Initial Date of Registration (as of 12/11/15)	Date of Most Recent Change in Facility Information	Last Date Required to Comply (as of 12/11/15)	Was a Form FD503B Submitted?	Other Action(s) by FDA, Material and/or Status	Links to Inspections, Recalls, Draft Guidelines
Avalere Pharma Inc., Houston, TX	10/20/2014	10/19/2015	5/17/2014	Yes	Open	Fee
Anacorapharm, Inc., Las Vegas, NV	9/23/2014	11/18/2015	10/20/2015	Yes	Warning Letter - 12/03/2015	Fee
Astra Specialty Pharmacy, Phoenix,	2/24/2014	11/20/2015	3/3/2016	Yes	Open <sup>1</sup>	Fee

# FDA's Compounding Website

**FDA U.S. Food and Drug Administration Protecting and Promoting Your Health**

[Home](#) | [Food](#) | [Drugs](#) | [Medical Devices](#) | [Radiation-Emitting Products](#) | [Vaccines, Blood & Biologics](#) | [Animal & Veterinary](#) | [Cosmetics](#) | [Tobacco Products](#)

[Drugs](#) | [www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm)

Home > Drugs > Guidance, Compliance & Regulatory Information > Compounding

## Compounding

### Compounding Quality Act

#### Title I of the Drug Quality and Security Act of 2013

On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA) legislation that contains important provisions relating to the oversight of compounding of human drugs.

Title I of this new law, the Compounding Quality Act, removes certain provisos from section 503A of the Federal Food, Drug, and Cosmetic Act (FFDCA) that had been in effect since the Prescription Drug Marketing Act was passed in 2002. Section 503A describes the conditions under which certain compounded human drug products are entitled to exemptions from these sections of the FDDCA requiring:

- Compliance with current good manufacturing practices (CGMP) (section 501(k)(2)(B));
- Labeling with adequate directions for use (section 502(f)(1)); and
- Testing of excipients.

#### Spotlight

- FDA announces meeting of the Pharmaceutical Quality Advisory Committee
- Inter-governmental Working Meeting on Pharmacy Compounding, March 20-21, 2014
- Regulated Outsourcing Facilities
- Compounding and FDA: Questions and Answers
- FDA Video - FDA and Pharmacy Compounding

#### Specific Issues

- Hydrocodone/Paracetamol Capsules (HPP)

	<b>U.S. Food and Drug Administration</b> Protecting and Promoting Your Health	SEARCH   HELP   HOME PAGE   EXIT
<a href="#">Home</a>   <a href="#">Food</a>   <a href="#">Drugs</a>   <a href="#">Medical Devices</a>   <a href="#">Radiation-Emitting Products</a>   <a href="#">Vaccines, Blood &amp; Biologics</a>   <a href="#">Animal &amp; Veterinary</a>   <a href="#">Cosmetics</a>   <a href="#">Tobacco</a>		
<p><b>Drugs</b></p> <ul style="list-style-type: none"> <li>● Home</li> <li>● Drugs</li> <li>● Guidance, Compliance &amp; Regulatory Information</li> <li>● Compounding</li> </ul> <p><b>Guidance, Compliance &amp; Regulatory Information</b></p> <ul style="list-style-type: none"> <li>● Compounding</li> <li>Regulatory Policy Information</li> <li>Compounding: Inspections, Recalls, and other Actions</li> <li>Outsourcing Facilities</li> </ul> <p><b>Letter to Stakeholders</b></p> <p>On January 8, 2014, FDA sent letters from Commissioner Hamburg regarding the pharmacy compounding provisions of the Compounding Quality Act to hospital and other health care facility purchasers and to state officials, including governors, state boards of pharmacy and health departments. The purpose of the letters is to inform these stakeholders about the recent passage of new federal legislation affecting the oversight of compounded human drugs, and to encourage them to take steps to encourage compounders that produce sterile drugs to register with FDA as outsourcing facilities.</p> <ul style="list-style-type: none"> <li>● Dear Colleague (PDF - 1.32MB)</li> <li>● Dear Hospital / Purchaser (PDF - 1.09MB)</li> </ul> <p>As required by the new law, FDA has posted a list of facilities that have registered as "outsourcing facilities" under the new law. In addition to posting the list, FDA has provided information about the status of the facilities and what it does and does not mean to be a registered outsourcing facility.</p>		

## CMS Data On Hospital Pharmacy Deficiencies



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### Access to Hospital Complaint Data

- CMS issued Survey and Certification memo \regarding access to hospital complaint data
- Includes deficiency in the pharmacy standards
  - Includes acute care and CAH hospitals
  - Does not include the plan of correction but can request
  - Questions to bettercare@cms.hhs.com
- This is the CMS 2567 deficiency data and lists the tag numbers
  - Updated quarterly
  - Available under downloads on the hospital website at [www.cms.gov](http://www.cms.gov)

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### Access to Hospital Complaint Data

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Rockville Pike, Bethesda, MD 20892-3610  
Baltimore, Maryland 21244-3605

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-21- ALL

DATE: March 22, 2013

TO: State Survey Agency Directors

FROM: Director, Survey and Certification Group

SUBJECT: Access to Statements of Deficiencies (CMS-2567) on the Web for Skilled Nursing Facilities, Nursing Facilities, Hospitals, & Critical Access Hospitals

**Memorandum Summary**

- **Survey Findings Posted on <http://www.cms.gov>:** In July 2012, the Centers for Medicare & Medicaid Services (CMS) began posting redacted Statements of Deficiencies (SOEs) on the Web for Skilled Nursing Facilities, Nursing Facilities, and Hospitals on *Affiliated Home Compare*. In March 2013, CMS began posting CMS-2567s for short-term acute care hospitals on the Web for the first time. These files are the results of survey and certification investigations. This memorandum describes the contents and location of these files.
- **Other Information:** The posted CMS-2567s are not the final survey and certification findings provided by private parties (*Propublica* and the Association for Health Care Journalists), published in the news media, or otherwise made available to the public. These files are independent of CMS. CMS does not endorse or sponsor any particular private party application.
- **Plan of Correction (POC):** The posted CMS data do not contain any POC information. State Survey Agencies (SSAs) and CMS Regional Offices (RO) may see an incomplete POC in the posted CMS-2567s.
- **Question & Answer:** We plan to issue an update to this memorandum that will include an FAQ of frequently asked questions in order to provide answers to other queries that may arise.

**Background – Nursing Home Survey Findings**

In July 2012, CMS began posting nursing home statements of deficiencies, derived from the Form 102

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**Updated Deficiency Data Reports**

**CMS.gov**  
Centers for Medicare & Medicaid Services

**Hospital**  
Survey & Certification & Compliance

This page provides basic information about being certified as a Medicare and/or Medicaid hospital provider and includes links to applicable laws, regulations, and compliance information.

A hospital is an institution primarily engaged in providing, by or under the supervision of physicians, inpatient diagnostic and treatment services and related professional services, including laboratory and X-ray services, for patients as a unit for compliance with the Medicare requirements.

Psychiatric hospitals are subject to additional regulations beyond basic hospital conditions of participation. These regulations are contained in the Hospital Conditions of Participation for Psychiatric Hospitals.

Under the Medicare provider-based rules it is possible for "non-hospital" to have multiple distinct campuses and undergo separate survey and certification processes. Psychiatric hospitals that are part of a hospital system that participates in Medicare as a District Part Psychiatric hospital are not required to participate in their entity's survey and certification process.

Components are not considered parts of the hospital and are not to be included in the evaluation of the hospital's compliance:

- Components independently certified as other kinds of providers or hospitals, i.e., a distinct part of the hospital that is not a hospital, such as a dialysis center, a medical office, a clinic, a residential, custodial, and non-service units not meeting certain definitions in the Social Security Act, and psychiatric facilities located in spaces owned by the hospital but not functioning as hospital outpatient services or departments.

Accredited Hospitals: A hospital accredited by a CMS-approved accreditation program may substitute accreditation for survey and certification under the Hospital Conditions of Participation (Cover the all services, areas and locations covered by the hospital's provider-based rule).

Although the survey generally occurs during dayshift working hours (Monday through Friday), surveys may conduct

Deficiency reports available at [www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Hospitals.html](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Hospitals.html)

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<b>Pharmacy Deficiencies Total 440</b>		
<b>Section</b>	<b>Tag Number</b>	<b>Nov 10, 2015</b>
Pharmacy Services	Tag 490	64
Pharmacy Administration	Tag 491	56
Delivery of Drugs	Tag 500	72
Pharmacy Drug Records	Tag 494	21
Formulary/Access to Drug Info Reporting Losses	Tag 511/510	6
	Tag 509	2
Pharmacist Responsibility	Tag 492	24
Pharmacy Personnel	Tag 493	5
Pharmacist Supervision Locked Controlled Drugs	Tag 501	19
	Tag 503	4
Access to Locked Area Reporting Adverse Events	Tag 504	4
	Tag 508	29
After Hours Access to Drugs Secure Storage	Tag 506	4
	Tag 502	36
Unusable Drug Stop Orders	Tag 505	58
	Tag 507	1

## Hospital Pharmacy CoPs



## CMS Hospital CoPs

- Hospital Conditions of Participation are called the CoPs for short
- It is Appendix A and is 510 pages long
- Is called the state operations manual or SOM
- Has section numbers called tag numbers and go from Tag A-0001 to A-1164
- Pharmacy section at tag **489-511**
- [www.cms.hhs.gov/manuals/downloads/som107\\_Appendixestoc.pdf](http://www.cms.hhs.gov/manuals/downloads/som107_Appendixestoc.pdf)

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## Pharmacy Section Starts a Tag 489

**A-0489**  
(Rev.)

**§482.25 Condition of Participation: Pharmaceutical Services.**

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.

*Interpretive Guidelines §482.25*

*A hospital must provide pharmaceutical services that meet the needs of its patients. The services must include either a pharmacy that is directed by a pharmacist, or, when appropriate, a drug storage area that is competently supervised. The hospital's medical staff is responsible for developing pharmaceutical policies and procedures that minimize the potential for medication errors, but may delegate this function to the pharmaceutical service.*

*The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether there is substantial noncompliance with the Condition, warranting a Condition-level citation.*

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## Pharmaceutical Services 489

- **Standard:** Hospital must have a pharmacy to meet the patient's needs and need to promote safe medication use process
- Must be directed by registered pharmacist or drug storage area under competent supervision
- MS is responsible for developing P&P to minimize drug error
- Function may be delegated to the pharmacy service

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## Pharmacy Service 489 490

- CMS added a new section related to whether it will be considered a standard or condition level deficiency
- This allows the surveyor to cite to the regulatory language found in the condition stem statement at either level in their computer system
  - Either standard level or condition level deficiency (which is worst)
- CMS also added a new tag number 489 and took much of the content from 490 and put it in 489

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A-0490  
(Rev.)**Standard-level Tag for****§482.25 Condition of Participation: Pharmaceutical Services.***The hospital must have pharmaceutical services that meet the needs of the patients....***Interpretive Guidelines §482.25****What is included in pharmaceutical services?**

Pharmaceutical services encompass the functions of procuring, storing, compounding, repackaging, and dispensing all medications, biologicals, chemicals and medication-related devices within the hospital. They also include providing medication-related information to care professionals within the hospital, as well as direct provision of medication-related care.

**Meeting patient needs**

Hospitals must provide pharmaceutical services that meet the needs of their 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. Except in unusual circumstances, the pharmaceutical service is expected to make available in a timely manner the volume and types of medications typically needed. These would be those medications typically prescribed by the hospital's practitioners for hospital patients receiving inpatient services, surgical services, diagnostic services involving medications as a component of testing, and outpatient drug therapies administered while the patient is in the hospital.

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## Meet Needs of the Patients 490

- **Standard:** The hospital must have pharmacy services that meet the needs of the patients
  - Pharmaceutical services include procuring, storing, compounding, repackaging, and dispensing
- Includes providing medication related information to staff
- Scope and complexity of services is consistent with volume and types of patients served

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## Meet Needs of the Patients 490

- Acute care hospital with busy chemo outpatient department would offer more than a behavioral health hospital
- Has survey procedure
- Surveyor to ask nursing staff if medications are available when needed and timely
- If reports of frequent delay then surveyor is to talk further with the pharmacy director
- Surveyor will ask how hospital has determined that the services meet the needs of patients

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## P&P and Drug Storage 491

- **Standard:** The MS is responsible for developing P&P that minimize drug errors
- This function can be delegated to the pharmacy
- Many required P&Ps required
- **Standard:** The pharmacy or drug storage area must be administered in accordance with accepted professional principles
- This is TJC 03.01.01 and problematic CMS standard

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## Pharmacy Management 0491

- Must ensure safe and appropriate procurement, storage, preparation, dispensing, use, tracking, control, and disposal of medications
  - Includes medication devices
- Must be administered in accordance with accepted professional principles
- This includes compliance with state laws (pharmacy laws), and federal regulations (USP 797, upcoming USP 800 hazardous drugs), standards by nationally recognized organizations (ASHP, FDA, NIH, USP, ISMP, etc.)

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## USP 800 Hazardous Drugs

**BRIEFING**

(**800**) **Hazardous Drugs—Handling in Healthcare Settings.** Because there is no existing USP chapter for this topic, the Compounding Expert Committee and the Compounding with Hazardous Drugs Expert Panel propose this new general chapter to guide the handling of hazardous drugs in healthcare settings. This new general chapter has been developed to harmonize the requirements for the handling, storage, distribution, compounding, dispensing, and administration of hazardous drugs to protect the patient, healthcare personnel, and environment. Facility requirements that differ from general chapter (**707**) *Pharmaceutical Compounding—Sterile Preparations* and the chapter will be harmonized. These differences include the following:

1. Elimination of the current allowance in (**707**) for facilities that prepare a low volume of hazardous drugs that permits placement of a BSC or CACI in a non-negative pressure room. All hazardous drug compounding shall be done in a separate room dedicated for hazardous drug compounding.
2. Allowance for a Containment Segregated Compounding Area (C-SCA), a separate, negative pressure room with at least 12 air changes per hour (ACPH) for use with compounding hazardous drugs. Low- and medium-risk hazardous drug C-SCAs may be used in a BSC or CACI if the proposed procedure beyond-use date of the CSP does not exceed 12 hours. A CACI that meets the requirements in (**707**) may be used for hazardous drug compounding if it is placed in a C-SCA.

The proposed chapter is posted online at [www.usp.org/usp-nf/notices/compounding-notice](http://www.usp.org/usp-nf/notices/compounding-notice) with line numbers. To ensure that your comments are received and addressed, please provide the line numbers corresponding to your comments when submitting comments to [Comments@usp.org](mailto:Comments@usp.org).

[www.usp.org/sites/default/files/usp\\_pdf/EN/m7808.pdf](http://www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf)

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## NIOSH Hazardous Drugs

- Updated in 2014 and proposed additions in 2016 as published in the Federal Register
- NIOSH reviewed 70 new drugs that received FDA approval in 2014 updates
- NIOSH reviewed 180 drug that received new special warnings (usually black box warnings)
- Found 26 of these that were added to the list
- Removed 15 drugs that are no longer available in the ED

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## List of Hazardous Drugs in Healthcare

The screenshot shows the NIOSH website with the specific page for the List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014. The page includes a table of contents, a search bar, and various links related to the document and NIOSH resources.

**CDC Home** **CDC** Centers for Disease Control and Prevention  
CDC 24/7: Saving Lives. Protecting People.  
A-Z Index for All CDC Topics

The National Institute for Occupational Safety and Health (NIOSH)

**NIOSH Publications & Products** **NIOSH-Issued Publications**

**NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014**

**Publication Type:** Lists (NIOSH) Publication Number 2014-4-158 (Revised, 2012-158) September 2014

The National Institute for Occupational Safety and Health (NIOSH) Alert: Preventive Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings was published in September 2014. This alert provides recommendations for the safe handling of hazardous drugs for their respective institutions, as well as a list of the pharmaceuticals and manufacturers of these drugs. This current update (2014) adds 27 drugs and includes a review of the 2004 list and the 2012 list. The 2014 update also includes revised NIOSH criteria for hazardous drugs. In addition, a new format has been developed for the list of hazardous drugs, as described below. The revised list of hazardous drugs is also described in the alert. The alert is available in the Federal Register: <http://www.federalregister.gov/documents/2014/09/03/e73310/NIOSH-List-of-Antineoplastic-and-Other-Hazardous-Drugs-in-Healthcare-Settings-2014>

**NIOSH Publications & Products - NIOSH-Issued Publications**

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**Contact Us:** National Institute for Occupational Safety and Health (NIOSH)  
Centers for Disease Control and Prevention (CDC)  
800-CDC-INFO  
TTY (888) 232-4348  
Hours: 8 a.m. – 4 p.m. ET Monday-Friday  
Docket: Docket (CDC-INFO)

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NIOSH List of Hazardous Drugs			
NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014			
Drug	AHFS Classification	Links	
Diltuxetam (Diltuxetam)	10:00 Antineoplastic Agents	<a href="#">DailyMed</a>	
Pomalidomide (Pomalyst)	10:00 Antineoplastic Agents	<a href="#">DailyMed</a>	
Panobinostat (Farykrist)	10:00 Antineoplastic Agents	<a href="#">DailyMed</a>	
Ivacitinib (Niraliq)	10:00 Antineoplastic Agents	<a href="#">Not available</a>	
Trotuzinase/Tropizumab (Lonsurf)	10:00 Antineoplastic Agents	<a href="#">DailyMed</a>	

# Hazardous Update List 2016

**Lerry A. Richardson,**  
Chief, Information Collection Review Office,  
Office of Management and Budget  
**and Associate Director for Science, Office of the**  
**Directorate for Science, Safety and Prevention,**  
National Institute for Occupational Safety and Health  
Centers for Disease Control and Prevention  
1400 Recanati Street, Room 207-15, 44405 and  
Bldng. Code 444-14-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[CDC-2015-0034; NIOSH 233-A]**

**NIOSH List of Potentially Hazardous and Other Drugs in Nonoccupational Settings; Proposed Additions to the NIOSH Hazardous Drugs in Nonoccupational Settings; Proposed Additions to the NIOSH Hazardous Drugs in Nonoccupational Settings; Request for Comment**

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

**ACTION:** Notice of draft document available for public comment.

**COMMENT DUE DATE:** December 1, 2015 for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC). This announcement specifies the availability of the following document: "NIOSH List of Potentially Hazardous and Other Drugs in Nonoccupational Settings; Proposed Additions to the NIOSH Hazardous Drugs in Nonoccupational Settings; Proposed Additions to the NIOSH Hazardous Drugs in Nonoccupational Settings; Request for Comment".

Instructions for submitting comments can be found at [www.regulations.gov](http://www.regulations.gov); please include the docket number and the title and force of law.

**Table of Contents**

**INTRODUCTION**  
**— ADDRESSEES**  
**— ADDITIONAL INFORMATION**  
**CONTACT**  
**EXPLANATORY INFORMATION**  
**DATES:** Electronic or written comments must be received by July 27, 2015.  
**ADDRESSEES:** The following comments identified by CDC-2015-0034a and Docket Number NIOSH 233-A may be either of the two following methods:  
1. Electronic comments may be submitted via the Internet at [www.regulations.gov](http://www.regulations.gov). Follow the instructions for "Comment Submission".  
2. Mail: National Institute for Occupational Safety and Health (NIOSH) Division of Safety and Health, 4500 Cincinatti Avenue, Cincinnati, OH 45226. All comments received in response to this notice must include the docket number and title and force of law (CDC-2015-0034; NIOSH 233-A). All comments received in response to this notice must be posted without change to prevent disclosure of any personal information provided. All electronic comments must be submitted in Microsoft Word. Please save files as Microsoft Word documents and use the docket number NIOSH 233-A. All information received in response to this notice will be made available for public examination and review at the NIOSH Applied Research and Technology, Robert A. Taft Laboratories, 10960 Rock Creek Center Drive, Bethesda, MD 20892, Cincinnati, OH 45226, (513) 533-8132 (ext. 100), and [www.cdc.gov/niosh/hazardsupdate@cdc.gov](http://www.cdc.gov/niosh/hazardsupdate@cdc.gov).

**IMPLEMENTATION INFORMATION:** The NIOSH List of Potentially Hazardous and Other Drugs in Nonoccupational Settings ("NIOSH List of Potentially Hazardous and Other Drugs in Nonoccupational Settings") was published in September 2009 ([www.cdc.gov/niosh/hazardsupdate@cdc.gov](http://www.cdc.gov/niosh/hazardsupdate@cdc.gov)). This Alert contained information on approximately 100 drugs that were deemed to be hazardous and nonoccupational. The list of hazardous drugs was updated in November 2012 and again in January 2014. The list of new approved drugs and drugs with new warnings up to December 2014 ([www.cdc.gov/niosh/hazardsupdate@cdc.gov](http://www.cdc.gov/niosh/hazardsupdate@cdc.gov)). Between January 2012 and December 2014, 200 new drugs received FDA approval and 270 drugs received adverse effects in patients. From this list of new drugs, NIOSH and NIOSH members were asked to comment on this alert and the potential hazard to nonoccupational stakeholders. Three additional drugs had safe handling recommendations developed by NIOSH and NIOSH members following their review of the manufacturer's information. Therefore, three drugs will be listed as hazardous drugs in the NIOSH List of Potentially Hazardous and Other Drugs in Nonoccupational Settings.

**RECOMMENDATION:** A panel consisting of four experts and one consumer will review the comments and determine if any changes are needed to the NIOSH List of Potentially Hazardous and Other Drugs in Nonoccupational Settings.

[www.cdc.gov/niosh/docket/review/docket233a/pdfs/233a\\_2015-12857.pdf](http://www.cdc.gov/niosh/docket/review/docket233a/pdfs/233a_2015-12857.pdf)

**ISMP Institute for Safe Medication Practices**

The Institute for Safe Medication Practices (ISMP) is a nonprofit organization dedicated to improving patient safety and medication management processes in healthcare settings. ISMP's mission is to prevent medication errors and adverse drug events through education, research, and advocacy.

**Institute for Safe Medication Practices**  
A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices

[Home](#) | [Request ISMP®](#) | [Newsletters](#) | [Webinars](#) | [Request Events](#) | [Educational](#) | [Store](#) | [Consulting](#) | [FAQ](#) | [Tools](#) | [About ISMP](#) | [Contact Us](#)

[Facebook](#) | [Twitter](#) | [LinkedIn](#)

[www.ismp.org](http://www.ismp.org)

This website is for use by healthcare professionals. Consumers can access our consumer website here.

**Medication Safety Intensive**  
March 31 and April 1, 2016  
Orlando, FL  
May 12-13, 2016  
Boston, MA  
December 2-3, 2016  
Las Vegas, NV

[CLICK HERE FOR DETAILS](#)

**Education & Awareness**

- [Webinars](#)
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- [Educational Programs](#)
- [Let ISMP Be Your PISO](#)
- [Professional Development](#)
- [Self-Assessments](#)
- [ISMP Guidelines](#)
- [QuickerWatch](#)

**Medication Safety Tools & Resources**

**Featured Tools**

- [Toolkits for healthcare connectors...the "Stay Connected" program!](#)
- [The Root Cause Analysis Workbook for Community/Ambulatory Pharmacy](#)
- [National Patient Safety Foundation Guidelines on Root Cause Analysis](#)
- [Special Alert Alerts](#)
- [2014-15 Targeted Medication Safety Best Practices for Hospitals](#)
- [ISMP Guidelines](#)

**QuickerWatch**

Annual Report | Issue

[Get Started](#) | [Help Desk](#) | [Feedback](#)

**ISMP Suite Medication Safety for Adult IV/Patch Monitoring**

**2016-17**

Targeted Medication Safety Best Practices for Hospitals

[Join the mailing list](#) and get news, announcements, and event notifications

[JOIN NOW!](#)

American Society of Healthsystem Pharmacist

USP Website

P&P and Drug Storage 491

- May use unit dose, floor stock, individual prescriptions or a combination
- Hospitals with drug storage areas only must use pre-packaged drugs that require no further preparation
- MS is responsible for P&Ps but can delegate it to pharmacy
- Hospital must review P&P periodically and revise
  - Remember to date policy to show last review and include sources such as CMS CoP or TJC standard or cite the source

## P&P and Drug Storage 491

- Must train staff on P&Ps
- Must monitor to make sure P&Ps are being followed
- P&Ps for Minimizing Drug Errors
  - Need to take steps to prevent, identify, and minimize drug errors
  - This includes ensuring that the pharmacy process conforms to accepted standards of pharmacy practice

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## P&Ps for Minimizing Drug Errors

- Must proactively identify and review ADEs
- Must be aware of external alerts to real or potential pharmacy related problems
- Many organization issues sentinel event alerts or alerts
  - Such as Joint Commission, ISMP, FDA, IHI, AHRQ, Med Watch, NCCMER, MEDMARX
  - If medication management committee can assign each to one of the members to report at monthly meeting
- Has a list of policies that are expected to be addressed

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## National Coordinating Council



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# Pharmacy Alerts NAN



The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The coalition for State Medicaid Practices (SSMP) and the American Society of Health-System Pharmacists (ASHP) provide the alerts and recommendations. NAN is a collaborative effort by these organizations to ensure patient safety drives. The NCC MERP, SSMP and the ASHP encourage the sharing and reporting of medication errors, so that lessons learned can be used to increase the safety of the medication use system.

**June 30, 2015** Mixed toward full one of metoclopramide. Eliminate message if says that measure liquids in fluid measure. Use cups that measure mL.

**March 23, 2015** Dislodges and Vacuums potential for bone spurs

**February 18, 2014** Potential inaccuracy of electronically transmitted medications history information used for medical record creation

**June 10, 2013** Important Change with Hepatitis Labels

**April 17, 2013** Confusion regarding the generic name of the HER2 targeted drug Kadcyla® (T-DMO/Trastuzumab emtansine).

**January 25, 2013** Severe burns and permanent scarring after glacial acetic acid (40% H2O2) mistake applied topically

**Apri 29, 2012** Proper disposal of medications, patches is crucial to prevent accidental

Many TJC SEAs are Medication Related	
<p>Search terms can be used by keyword, content or program.</p> <p><b>Keywords:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Medication Errors</li> <li><input type="checkbox"/> Pain Management</li> <li><input type="checkbox"/> Patient Safety</li> <li><input type="checkbox"/> Patient centered communication</li> <li><input type="checkbox"/> Restraints</li> </ul> <p><b>Web Site Content</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Blog</li> <li><input type="checkbox"/> Content Page</li> <li><input type="checkbox"/> News</li> <li><input type="checkbox"/> Standards FAQ</li> <li><input checked="" type="checkbox"/> Topics Library</li> <li><input type="checkbox"/> Videos</li> </ul> <p><b>Accreditation/Certification Programs</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Ambulatory Health Care</li> <li><input type="checkbox"/> Behavioral Health</li> <li><input type="checkbox"/> Children's Health</li> <li><input type="checkbox"/> Disease/Pain Management</li> <li><input type="checkbox"/> Disease/Specialty Care</li> </ul>	<p><b>Sentinel Event Alert/Topics Library Updates</b></p> <p><a href="#">Most Recent</a></p> <p><b>Sentinel Event Alert 55: Preventing falls and fall-related injuries in health care facilities</b></p> <p>Falls are a leading cause of patient safety concerns. Elderly and frail patients who fall are not the only ones at risk and are vulnerable to falling in health care facilities.</p> <p><b>Related Items:</b> Falls, Sentinel Event Alert</p> <p><a href="#">Read More</a></p> <p>08/26/2018</p> <p><b>Sentinel Event Alert 54: Safe use of health information technology</b></p> <p>Health information technology (health IT) is rapidly evolving and its use is growing, presenting new challenges to health care organizations. The Joint Commission has issued Sentinel Event Alert 54 to help you stay safe. We hope you will use this information helpful and pass it on.</p> <p><b>Related Items:</b> Sentinel Event Alert, Safe Health IT</p> <p><a href="#">Read More</a></p> <p>03/10/2018</p> <p><b>Sentinel Event Alert 53: Managing risk during transition to new (SO) tubing connection standards</b></p> <p>Transitioning to new standards for single-use, non-sterile tubing can affect patient safety and death, since tubes with different functions can easily be connected using our connectors, or connections can be "ligated" (connected) using adhesives, labels, or ties.</p> <p><b>Related Items:</b> Ambulatory Health Care, Critical Access Hospital, Home Care, Hospital, Nursing Care Center, Sentinel Event, Sentinel Event Alert, Infographic</p> <p><a href="#">Read More</a></p> <p>08/20/2018</p> <p><b>Topics Library</b></p> <p><b>Sentinel Event Alert Issue 53: Preventing infections from the misuse of vials</b></p> <p>Thousands of patients have been adversely affected by the misuse of single-dose/single-use and multiple-dose oral medications.</p> <p><b>Related Items:</b> Sentinel Event, Sentinel Event Alert, Infection Prevention and Control, Sentinel Event Infection</p> <p><a href="#">Read More</a></p> <p>05/18/2014</p>

# FDA Website Has Many Resources

U.S. Department of Health and Human Services

**FDA** U.S. Food and Drug Administration Protecting and Promoting Your Health

Home Press Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

**Drugs**

Home > Drugs

[www.fda.gov/Drugs/default.htm](http://www.fda.gov/Drugs/default.htm)



Drug reverses muscle paralysis induced by surgical drugs  
Injektions-tropfen zu beobachten anzuwenden in adults

Navigation links: Home, Press, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Tobacco Products.

**Spotlight**

- Find information about a drug
- Search Drugs@FDA
- Orange Book Search
- Medication Guide Directory
- Drug Shortages

**Recalls & Alerts**

- Drug Recalls
- Infestations - The FDA Safety Information and Adverse Event Reporting System
- Recalls, Market Withdrawals & Safety Alerts

**Approvals & Clearance**

- The Week's Drug Approvals

## Required Policies and Procedures 491

- High alert medications
  - Include LASA meds (look alike-sound alike)
  - Includes meds with narrow therapeutic range (Warfarin), psychotherapeutic medications
  - Ways to minimize include dosing limits, packaging, guidelines, labeling and storage (TJC MM.01.01.03)
  - ISMP (Institute for Safe Medication Practice) and USP have list of high alert medications

## ISMP High Alert Medications

**So What's In Your Policy?**

**WISCONSIN PATIENT SAFETY INSTITUTE**

**MODEL HIGH ALERT MEDICATIONS POLICY & PROCEDURES**

**PURPOSE**

- To provide guidance to acute care organizations for the safe handling and administration of medications designated as High Alert Medications.
- To increase awareness of High Alert Medications and the potential patient safety risks.

**DEFINITION**

High Alert Medications are drugs that bear a higher risk of causing significant patient harm when they are used in error.

**POLICY**

- The following medications are appropriate for inclusion in a High Alert Medications policy:
  - Liquid medications
  - Fentanyl
  - Heparin (>100 units, Russek exception)
  - Inhalation medications except NFM, and gloridex
  - Large volume epinephrine vials
  - Neuromuscular blocking agents (succinylcholine, rocuronium, mivacurium, atracurium, cisatracurium, vecuronium, etomidate, rocuronium, suxamethonium)
  - Pain Control by Analgesia (PCA) infusions of any medication
  - Total Parenteral Nutrition (TPN) and Total Nutrient Admixture (TNA) solutions
  - Desflurane
  - Moderate sedation agents (e.g., midazolam)
- The following medications may also be appropriate for inclusion in a High Alert Medication policy in addition to the medications listed above:
  - Glycogenase IIb/IIIa inhibitors (eptifibatide, abciximab, tirofiban)
  - Antiplatelet agents
  - Anticoagulants
  - Anticonvulsants

**PROCEDURES**

Safety procedures during the ordering, preparation, dispensing, and administration of High Alert Medications include:

**Prescribing**

- All medical orders for High Alert Medications should be discontinued.
- All High Alert prescribing for High Alert Medications should be standardized using preprinted orders.

**Preparation and dispensing**

- All High Alert medications should be clearly labeled and separated from regular stock. If High Alert medications are stored in regular stock, locked storage areas should be used with a distinct color and a prominent warning label clearly etched on the exterior box.

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**High Alert How to Guide IHI**

**PROTECTING 5 Million lives FROM HARM**

**Getting Started Kit: Prevent Harm from High-Alert Medications**

**How-to Guide**

A national initiative led by IHI, the 5 Million Lives Campaign aims to dramatically improve the quality of American health care by protecting patients from the hidden mistakes of health between December 2009 and December 2010. The How-to

[www.ihi.org/NR/rdonlyres/882475CD-56C7-4D9B-B359-801F3CC3A8D5/0/HighAlertMedicationsHowToGuide.doc](http://www.ihi.org/NR/rdonlyres/882475CD-56C7-4D9B-B359-801F3CC3A8D5/0/HighAlertMedicationsHowToGuide.doc)

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**Required Policies and Procedures 491**

- Must follow standards of practice for all compounding, packaging, dispensing, and drug disposal
  - ASHP has sterile compounding resource center
- P&P to ensure investigational meds are safely controlled and administered
  - Written process to approve, review, supervise, and monitor investigational drugs
  - Pharmacy must control storage, dispensing, and labeling

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**ASHP Sterile Compounding Resources**

**Outsourcing Vendor Assessment Tool**

**Safety Concerns of Investigational Meds**

Required Policies and Procedures 491

- Standardize equipment and medication related devices
  - CMS says can't have more than 1 or 2 types of infusion pumps
  - Availability of up to date medication information
  - Pharmacist on call if not open 24 hours
  - "Resume previous orders" is prohibited
  - Patient specific information that should be readily available (TJC tells you exactly what this is, like age, sex, allergies, current medications, etc.)

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Standardize Rx & Communication Practices 491

- Avoid dangerous abbreviations (TJC IM.02.02.01)
  - All elements of order; dose, strength, route, units, rate, frequency
  - Alert system for sound alike/look alike (LASA) and also TJC standard MM.04.01.01 and NPSG.03.03.01
    - 8<sup>th</sup> Annual MedMaRX report issued in 2008 shows problems with 3,170 drug pair names which is doubled number since 2004
    - USP has website to check LASA drugs
  - Use of facility approved pre-printed order sheets whenever possible

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# USP Confused Name List



 Institute for Safe Medication Practices

## ISMP's List of Confused Drug Names

This list of confused drug names, which includes look-alike and sound-alike name pairs, consists *only* of those name pairs that have been involved in medication errors published in the ISMP Medication Safety Alert®. The errors involving these medications were reported to ISMP through the USP-ISMP Medication Errors Reporting Program (MERP).

Drug Name	Confused Drug Name	ISMP Medication Safety Alert® Acute Care Edition
ABELCET™	amphotericin B™	Vol. 8, Issue 13, 6/26/03
ACCPURIL	ACIPHEX	Vol. 5, Issue 9, 5/9/00
acetazolamide™	acetohexamide™	Vol. 5, Issue 12, 6/14/00
acetohexamide™	acetazolamide™	Vol. 5, Issue 12, 6/14/00
ACIPHEX	ABREPT	Vol. 5, Issue 24, 11/29/00
ACIPHEX	ACCUPIRIL	Vol. 5, Issue 9, 5/9/00
ACTHRASE	TINase	Vol. 8, Issue 11, 5/29/03
ACTIONEL	ACTOS	Vol. 9, Issue 13, 7/1/04
ACTOS	ACTIONEL	Vol. 9, Issue 13, 7/1/04
ADERALL	INDERAL	Vol. 1, Issue 4, 2/28/95
aniracetam	ATRIVAN	Vol. 9, Issue 13, 7/1/04

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## Required Policies and Procedures 491

- Be integrated into the hospital wide QAPI and flag new types of mistakes and continue to improve P&Ps as well as analyze errors and ADEs
    - RSC (systematic analysis) and FMEA are two tools
  - Voluntary, non-punitive reporting system to monitor and report adverse drug events
    - System analysis theory recognizes most errors are a system problem and not due to bad practitioner
    - Many hospitals balance with Just Culture
    - TJC has the same standard
- 143

## Required Policies and Procedures 491

- Monitor drug alerts and recalls
  - Need to incorporate external alerts and recommendations from national associations and governmental agencies
    - Need to use to revise policies
    - CMS says hospital should consider ISMP, NCCMERP, FDA, and MedWatch Program
  - The FDA has a list of drug recalls and can sign up to receive alerts
  - ASHP has resources on drug shortages and guidelines
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**ASHP Website on Shortages**

**FDA has a List of Drug Recalls**

**FDA Drug Recalls Website**

**Sign Up to Get Recall Alerts from FDA**

The screenshot shows the FDA's "Recalls, Market Withdrawals, & Safety Alerts" page. At the top, there's a search bar and a link to "Sign up to receive Recalls, Market Withdrawals and Safety Alerts". Below that are filters for "Keyword(s)" and "Recall Type" (set to "All"). A table lists a single recall entry:

Date	Brand Name	Product Description	Reason/ Problem	Company	Details / Photo
12/13/2013	Sotybius	Ibuprofen (ibuprofen) 800 mg/5 mL Concentrated solution	Found to contain visible particles	Alexion Pharmaceuticals, Inc.	<a href="#">Details / Photo</a>

Page number 148 is at the bottom right.

**FDA MedWatch Program**

The screenshot shows the FDA's "MedWatch: The FDA Safety Information and Adverse Event Reporting Program" homepage. It features a sidebar with links for "Recalls, Market Withdrawals, and Safety Alerts", "Safety Information", "Reporting Serious Problems to FDA", and "Resources for You". The main content area has a search bar, social media links, and three buttons: "Report a Problem", "Safety Information", and "Stay Informed". A "What's New" section includes a link to a "Smart Lipid Recall - Underlined Drug Ingredients". Page number 149 is at the bottom right.

**Required Policies and Procedures 491**

- Identification of weight based dosing for pediatric populations
  - May also require weights for elderly patients in renal failure on antibiotics
  - Generally want to weigh babies in grams
  - Generally should weigh children in kg and not pounds or both
  - Weight based charts may help prevent medication errors in high risk medications

Page number 150 is at the bottom right.

## Use Kg and Not Pounds for Children

**Acetaminophen Dosing Chart**

Acetaminophen (Drops) Dose every 4 to 6 hours <i>Maximum dose 15 mL in 24 hours</i>		Intravenous Concentrated Drops 90 mg/mL each Dropperful overdosage avoided.	Children's Suspension Liquid 100 mg/mL Dropperful overdosage avoided.	Children's Soft Chewable Tablets 100 mg each	Junior Strength Chewable 100 mg each	Adult Regular Strength Tablets 325 mg
Weight	Age	Teaspoon (tsp)	Tablet	Tablet	Tablet	Tablet
12-17 lbs	0-11 mos	3 = 0.8 mL				
12-17 lbs	1-2 yrs	3 = 0.8 mL	1/2 tsp			
24-35 lbs	2-3 yrs	3 = 0.8 + 0.8 mL	1/2 tsp	2	1	
48-59 lbs	6-8 yrs	1 1/2 tsp	4	2		
60-71 lbs	9-10 yrs	2 1/2 tsp	5	2 1/2	1	
96 lbs +	12 yrs +	4 tsp	8	4	2	

**Ibuprofen Dosing Chart**

Ibuprofen (Drops - Adults) Dose every 6 to 8 hours <i>Maximum dose 15 mL in 24 hours</i>		Intravenous Concentrated Drops 90 mg/mL each Dropperful overdosage avoided.	Children's Suspension Liquid 100 mg/mL Dropperful overdosage avoided.	Children's Chewable Tablets 100 mg each	Junior Strength 100 mg each	Adult Regular Strength Tablets 200 mg
Weight	Age	Teaspoon (tsp)	Tablet	Tablet	Tablet	Tablet
Under 6 mos					Consult Your Child's Provider	
12-17 lbs	6-11 mos	1 = 1.25 mL				
12-17 lbs	1-2 yrs	1 = 1.875 mL				
24-35 lbs	2-3 yrs	1 tsp	2			
48-59 lbs	6-8 yrs	1 1/2 tsp	4	2		
60-71 lbs	9-10 yrs	2 1/2 tsp	5	2 1/2		
96 lbs +	12 yrs +	3 1/2 tsp	6	3		
96 lbs +	12 yrs +	4 tsp	8	4	2	

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## Acetaminophen& Ibuprofen Dosing Charts

### Fever Medication: Dosage Charts

#### Acetaminophen Dosing Chart

Dosage may be repeated every four hours, but should not be given more than five times in twenty-four hours. (Nore-Mildine is abbreviated as mL; 1 mL equals 1 teaspoon [tsp]. Don't use household measure, which can vary in size.) Be sure to read the label to make sure you are using the right product.

Age*	Weight*	Intravenous Children's Elast Chewable Tablets 10 mg/1 mL 180 mg/7 mL	Infant Drops - Children's Elast Chewable Tablets 10 mg/1 mL 180 mg/7 mL
0-11 mos	0-11 lbs	0 mL	0 mL
0-11 mos	0.75 kg	0 mL	-
6-11 mos	0.75-1.75 kg	0.5 mL	1/2 tsp
6-11 mos	1.75-2.75 kg	1 mL	1 tsp
6-11 mos	2.75-3.75 kg	1.5 mL	1 1/2 tsp
6-11 mos	3.75-4.75 kg	2 mL	2 tsp
6-11 mos	4.75-5.75 kg	2.5 mL	2 1/2 tsp
6-11 mos	5.75-6.75 kg	3 mL	3 tsp
6-11 mos	6.75-7.75 kg	3.5 mL	3 1/2 tsp
6-11 mos	7.75-8.75 kg	4 mL	4 tsp
6-11 mos	8.75-9.75 kg	4.5 mL	4 1/2 tsp
6-11 mos	9.75-10.75 kg	5 mL	5 tsp
6-11 mos	10.75-11.75 kg	5.5 mL	5 1/2 tsp
6-11 mos	11.75-12.75 kg	6 mL	6 tsp
6-11 mos	12.75-13.75 kg	6.5 mL	6 1/2 tsp
6-11 mos	13.75-14.75 kg	7 mL	7 tsp
6-11 mos	14.75-15.75 kg	7.5 mL	7 1/2 tsp
6-11 mos	15.75-16.75 kg	8 mL	8 tsp
6-11 mos	16.75-17.75 kg	8.5 mL	8 1/2 tsp
6-11 mos	17.75-18.75 kg	9 mL	9 tsp
6-11 mos	18.75-19.75 kg	9.5 mL	9 1/2 tsp
6-11 mos	19.75-20.75 kg	10 mL	10 tsp
6-11 mos	20.75-21.75 kg	10.5 mL	10 1/2 tsp
6-11 mos	21.75-22.75 kg	11 mL	11 tsp
6-11 mos	22.75-23.75 kg	11.5 mL	11 1/2 tsp
6-11 mos	23.75-24.75 kg	12 mL	12 tsp
6-11 mos	24.75-25.75 kg	12.5 mL	12 1/2 tsp
6-11 mos	25.75-26.75 kg	13 mL	13 tsp
6-11 mos	26.75-27.75 kg	13.5 mL	13 1/2 tsp
6-11 mos	27.75-28.75 kg	14 mL	14 tsp
6-11 mos	28.75-29.75 kg	14.5 mL	14 1/2 tsp
6-11 mos	29.75-30.75 kg	15 mL	15 tsp
6-11 mos	30.75-31.75 kg	15.5 mL	15 1/2 tsp
6-11 mos	31.75-32.75 kg	16 mL	16 tsp
6-11 mos	32.75-33.75 kg	16.5 mL	16 1/2 tsp
6-11 mos	33.75-34.75 kg	17 mL	17 tsp
6-11 mos	34.75-35.75 kg	17.5 mL	17 1/2 tsp
6-11 mos	35.75-36.75 kg	18 mL	18 tsp
6-11 mos	36.75-37.75 kg	18.5 mL	18 1/2 tsp
6-11 mos	37.75-38.75 kg	19 mL	19 tsp
6-11 mos	38.75-39.75 kg	19.5 mL	19 1/2 tsp
6-11 mos	39.75-40.75 kg	20 mL	20 tsp
6-11 mos	40.75-41.75 kg	20.5 mL	20 1/2 tsp
6-11 mos	41.75-42.75 kg	21 mL	21 tsp
6-11 mos	42.75-43.75 kg	21.5 mL	21 1/2 tsp
6-11 mos	43.75-44.75 kg	22 mL	22 tsp
6-11 mos	44.75-45.75 kg	22.5 mL	22 1/2 tsp
6-11 mos	45.75-46.75 kg	23 mL	23 tsp
6-11 mos	46.75-47.75 kg	23.5 mL	23 1/2 tsp
6-11 mos	47.75-48.75 kg	24 mL	24 tsp
6-11 mos	48.75-49.75 kg	24.5 mL	24 1/2 tsp
6-11 mos	49.75-50.75 kg	25 mL	25 tsp
6-11 mos	50.75-51.75 kg	25.5 mL	25 1/2 tsp
6-11 mos	51.75-52.75 kg	26 mL	26 tsp
6-11 mos	52.75-53.75 kg	26.5 mL	26 1/2 tsp
6-11 mos	53.75-54.75 kg	27 mL	27 tsp
6-11 mos	54.75-55.75 kg	27.5 mL	27 1/2 tsp
6-11 mos	55.75-56.75 kg	28 mL	28 tsp
6-11 mos	56.75-57.75 kg	28.5 mL	28 1/2 tsp
6-11 mos	57.75-58.75 kg	29 mL	29 tsp
6-11 mos	58.75-59.75 kg	29.5 mL	29 1/2 tsp
6-11 mos	59.75-60.75 kg	30 mL	30 tsp
6-11 mos	60.75-61.75 kg	30.5 mL	30 1/2 tsp
6-11 mos	61.75-62.75 kg	31 mL	31 tsp
6-11 mos	62.75-63.75 kg	31.5 mL	31 1/2 tsp
6-11 mos	63.75-64.75 kg	32 mL	32 tsp
6-11 mos	64.75-65.75 kg	32.5 mL	32 1/2 tsp
6-11 mos	65.75-66.75 kg	33 mL	33 tsp
6-11 mos	66.75-67.75 kg	33.5 mL	33 1/2 tsp
6-11 mos	67.75-68.75 kg	34 mL	34 tsp
6-11 mos	68.75-69.75 kg	34.5 mL	34 1/2 tsp
6-11 mos	69.75-70.75 kg	35 mL	35 tsp
6-11 mos	70.75-71.75 kg	35.5 mL	35 1/2 tsp
6-11 mos	71.75-72.75 kg	36 mL	36 tsp
6-11 mos	72.75-73.75 kg	36.5 mL	36 1/2 tsp
6-11 mos	73.75-74.75 kg	37 mL	37 tsp
6-11 mos	74.75-75.75 kg	37.5 mL	37 1/2 tsp
6-11 mos	75.75-76.75 kg	38 mL	38 tsp
6-11 mos	76.75-77.75 kg	38.5 mL	38 1/2 tsp
6-11 mos	77.75-78.75 kg	39 mL	39 tsp
6-11 mos	78.75-79.75 kg	39.5 mL	39 1/2 tsp
6-11 mos	79.75-80.75 kg	40 mL	40 tsp
6-11 mos	80.75-81.75 kg	40.5 mL	40 1/2 tsp
6-11 mos	81.75-82.75 kg	41 mL	41 tsp
6-11 mos	82.75-83.75 kg	41.5 mL	41 1/2 tsp
6-11 mos	83.75-84.75 kg	42 mL	42 tsp
6-11 mos	84.75-85.75 kg	42.5 mL	42 1/2 tsp
6-11 mos	85.75-86.75 kg	43 mL	43 tsp
6-11 mos	86.75-87.75 kg	43.5 mL	43 1/2 tsp
6-11 mos	87.75-88.75 kg	44 mL	44 tsp
6-11 mos	88.75-89.75 kg	44.5 mL	44 1/2 tsp
6-11 mos	89.75-90.75 kg	45 mL	45 tsp
6-11 mos	90.75-91.75 kg	45.5 mL	45 1/2 tsp
6-11 mos	91.75-92.75 kg	46 mL	46 tsp
6-11 mos	92.75-93.75 kg	46.5 mL	46 1/2 tsp
6-11 mos	93.75-94.75 kg	47 mL	47 tsp
6-11 mos	94.75-95.75 kg	47.5 mL	47 1/2 tsp
6-11 mos	95.75-96.75 kg	48 mL	48 tsp
6-11 mos	96.75-97.75 kg	48.5 mL	48 1/2 tsp
6-11 mos	97.75-98.75 kg	49 mL	49 tsp
6-11 mos	98.75-99.75 kg	49.5 mL	49 1/2 tsp
6-11 mos	99.75-100.75 kg	50 mL	50 tsp
6-11 mos	100.75-101.75 kg	50.5 mL	50 1/2 tsp
6-11 mos	101.75-102.75 kg	51 mL	51 tsp
6-11 mos	102.75-103.75 kg	51.5 mL	51 1/2 tsp
6-11 mos	103.75-104.75 kg	52 mL	52 tsp
6-11 mos	104.75-105.75 kg	52.5 mL	52 1/2 tsp
6-11 mos	105.75-106.75 kg	53 mL	53 tsp
6-11 mos	106.75-107.75 kg	53.5 mL	53 1/2 tsp
6-11 mos	107.75-108.75 kg	54 mL	54 tsp
6-11 mos	108.75-109.75 kg	54.5 mL	54 1/2 tsp
6-11 mos	109.75-110.75 kg	55 mL	55 tsp
6-11 mos	110.75-111.75 kg	55.5 mL	55 1/2 tsp
6-11 mos	111.75-112.75 kg	56 mL	56 tsp
6-11 mos	112.75-113.75 kg	56.5 mL	56 1/2 tsp
6-11 mos	113.75-114.75 kg	57 mL	57 tsp
6-11 mos	114.75-115.75 kg	57.5 mL	57 1/2 tsp
6-11 mos	115.75-116.75 kg	58 mL	58 tsp
6-11 mos	116.75-117.75 kg	58.5 mL	58 1/2 tsp
6-11 mos	117.75-118.75 kg	59 mL	59 tsp
6-11 mos	118.75-119.75 kg	59.5 mL	59 1/2 tsp
6-11 mos	119.75-120.75 kg	60 mL	60 tsp
6-11 mos	120.75-121.75 kg	60.5 mL	60 1/2 tsp
6-11 mos	121.75-122.75 kg	61 mL	61 tsp
6-11 mos	122.75-123.75 kg	61.5 mL	61 1/2 tsp
6-11 mos	123.75-124.75 kg	62 mL	62 tsp
6-11 mos	124.75-125.75 kg	62.5 mL	62 1/2 tsp
6-11 mos	125.75-126.75 kg	63 mL	63 tsp
6-11 mos	126.75-127.75 kg	63.5 mL	63 1/2 tsp
6-11 mos	127.75-128.75 kg	64 mL	64 tsp
6-11 mos	128.75-129.75 kg	64.5 mL	64 1/2 tsp
6-11 mos	129.75-130.75 kg	65 mL	65 tsp
6-11 mos	130.75-131.75 kg	65.5 mL	65 1/2 tsp
6-11 mos	131.75-132.75 kg	66 mL	66 tsp
6-11 mos	132.75-133.75 kg	66.5 mL	66 1/2 tsp
6-11 mos	133.75-134.75 kg	67 mL	67 tsp
6-11 mos	134.75-135.75 kg	67.5 mL	67 1/2 tsp
6-11 mos	135.75-136.75 kg	68 mL	68 tsp
6-11 mos	136.75-137.75 kg	68.5 mL	68 1/2 tsp
6-11 mos	137.75-138.75 kg	69 mL	69 tsp
6-11 mos	138.75-139.75 kg	69.5 mL	69 1/2 tsp
6-11 mos	139.75-140.75 kg	70 mL	70 tsp
6-11 mos	140.75-141.75 kg	70.5 mL	70 1/2 tsp
6-11 mos	141.75-142.75 kg	71 mL	71 tsp
6-11 mos	142.75-143.75 kg	71.5 mL	71 1/2 tsp
6-11 mos	143.75-144.75 kg	72 mL	72 tsp
6-11 mos	144.75-145.75 kg	72.5 mL	72 1/2 tsp
6-11 mos	145.75-146.75 kg	73 mL	73 tsp
6-11 mos	146.75-147.75 kg	73.5 mL	73 1/2 tsp
6-11 mos	147.75-148.75 kg	74 mL	74 tsp
6-11 mos	148.75-149.75 kg	74.5 mL	74 1/2 tsp
6-11 mos	149.75-150.75 kg	75 mL	75 tsp
6-11 mos	150.75-151.75 kg	75.5 mL	75 1/2 tsp
6-11 mos	151.75-152.75 kg	76 mL	76 tsp
6-11 mos	152.75-153.75 kg	76.5 mL	76 1/2 tsp
6-11 mos	153.75-154.75 kg	77 mL	77 tsp
6-11 mos	154.75-155.75 kg	77.5 mL	77 1/2 tsp
6-11 mos	155.75-156.75 kg	78 mL	78 tsp
6-11 mos	156.75-157.75 kg	78.5 mL	78 1/2 tsp
6-11 mos	157.75-158.75 kg	79 mL	79 tsp
6-11 mos	158.75-159.75 kg	79.5 mL	79 1/2 tsp
6-11 mos	159.75-160.75 kg	80 mL	80 tsp
6-11 mos	160.75-161.75 kg	80.5 mL	80 1/2 tsp
6-11 mos	161.75-162.75 kg	81 mL	81 tsp
6-11 mos	162.75-163.75 kg	81.5 mL	81 1/2 tsp
6-11 mos	163.75-164.75 kg	82 mL	82 tsp
6-1			

## CDC Dosing Charts HIV Meds

Pediatric Dosing Guide 22" x 10" 11/27/04 11/27/04 11:10 AM Page 1 www.cdc.gov/globalaids/docs/program-areas/pmtct/peds-dosing-guide.pdf									
Weight (kg)	Abacavir (Ziagen®, ABC)		Didanosine (Videx®, DDI)		Lamivudine (Epzicom®, 3TC)		Stavudine (Zerit®, ZDV)		Zidovudine (Retrovir®, ZDV, AZT)
	8 mg/kg/day TWICE daily	90-120 mg 250 mg TWICE daily	120 mg 250 mg TWICE daily	180-240 mg 250 mg ONCE daily	4 mg/kg/day TWICE daily	1 mg/kg/day TWICE daily	180-240 mg 250 mg TWICE daily		
20 mg/ml solution	200 mg tablets	10 mg/ml suspension	25, 50, 100 mg chewable tablets	125, 250, 400 mg EC capsules	10 mg/ml solution	150 mg tablets	3 mg/ml solution	15, 20, 30 mg capsules	10 mg/ml syrup
5 - 5.9	2 ml		4 ml 25 mg tabs		3 ml		6 ml		6 ml
6 - 6.9	3 ml		5 ml 25 mg tabs		3 ml		7 ml		
7 - 7.9	4 ml		6 ml 25 mg tabs		4 ml		8 ml		8 ml (an 0.5 x 20 mg)
8 - 8.9	4 ml		6 ml 25 mg tabs		4 ml		9 ml		10 mg (an 0.5 x 20 mg)
			--				10 ml		9 ml 1 cap

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## Pharmacist 492

- **Standard:** Must have pharmacy directed by a registered pharmacist or a drug storage under competent supervision
  - If has drug storage area instead of pharmacy still need to be under the direction of the pharmacist
- **Standard:** Must have pharmacist to develop, supervise, and coordinate activities of pharmacy
- Can be part time, full time or consulting
- Must have documented training or expertise in hospital pharmacy practice and management

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## Pharmacy Director 492

- Need to have written criteria for qualifications of the pharmacy director in accordance with scope of service
  - Most hospitals have a job description
  - Include responsible for supervision and coordination of all pharmacy services
  - Include active leadership of committees responsible for medication P&Ps
- Some small hospitals may not have a pharmacy but use a drug storage area for dispensing pre-packaged drugs

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## Pharmacist 492

- Must still make sure this area is under the supervision of a pharmacist or qualified person to ensure compliance with pharmacy requirements
  - Qualifications must be in writing, ensure security, access to locked areas and same is true if remote locations or satellites
- Has survey procedures and will ensure pharmacist has been appointed to be the director
- Will look at HR file to make sure qualified
- Will ask director how P&P developed, approved, and implemented

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## Enough Staff 493

- **Standard:** Must have adequate number of pharmacy staff to ensure quality pharmaceutical services
  - This include emergency services
- Need enough staff to meet the needs of the patient
- Must have sufficient staff in types, numbers, and training 24 hours 7 days a week
- Must have enough staff based on the scope and complexity of the hospital's pharmaceutical services
- Must participate in QAPI program

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## Pharmacy Delivery of Service 494

- **Standard:** Keep accurate records of receipt and disposition of all scheduled drugs
- Records must be current and accurate
- Must trace movement of scheduled drugs throughout the service
- Pharmacist must make sure records are reconciled
- Need policy to minimize drug diversion

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## So What's In Your Policy?

**POLICY AND PROCEDURE MANUAL**

Page 1 of 6

**Medication Security and Storage Policy**

**Purpose:**  
This policy promotes patient safety by ensuring compliance with State and Federal laws as well as Joint Commission and Aspen regulations while limiting the opportunity for unauthorized use or loss of medication.

**Definitions:**  
A listing of definitions of key terms is provided in Appendix A of this policy.

This policy separates medication security and storage into eight distinct pieces:

- 1) Receipt
- 2) Storage – pharmacy
- 3) Transportation
- 4) Secure – unit
- 5) Medication Removal
- 6) Waste
- 7) Inspection of Units
- 8) Disposal

**Pharmacy Receipt of Medication**  
The process of receiving medications must include the proper checks and balances to insure accuracy received as intended.

Specifically, JDH will receive prescriptions handling of medications by allowing only Pharmacists/Pharmacy technicians to receive deliveries of medications.

Controlled substances may only be handled by authorized Pharmacy personnel and must be processed in accordance with Pharmacy procedure C-009.

Additional procedures over the receipt of medications may be found in Pharmacy Manual

## Pharmacy Delivery of Service 500

- **Standard:** Drugs and biologicals must be controlled and distributed in accordance with federal and state law and standards of practice
- To prevent unauthorized use and distribution of medications
- To provide for an accounting of the receipt and distribution of drugs
  - Drugs subject to the Comprehensive Drug Abuse and Control Act of 1970
  - Law requires physical security of medications and strict record keeping for certain types of drugs such as controlled substances

## Copy of Federal Law 21 CFR 1300

e-CFR data is current as of December 17, 2015

Title 21 — Chapter II http://www.ecfr.gov/cgi-bin/text—  
idx?SID=3f3fe330fb5d263e3a8a7b105a5c3&mc=true&tpl=ecfrbrowse/TitleI  
TITLE 21—Food and Drugs  
CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

Part	Table of Contents	Headings
1300	1300.01 to 1300.05	DEFINITIONS
1301	1301.01 to 1301.93	REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES
1302	1302.01 to 1302.07	LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES
1303	1303.01 to 1303.07	QUOTAS
1304	1304.01 to 1304.05	RECORDS AND REPORTS OF REGISTRANTS
1305	1305.01 to 1305.29	ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES
1306	1306.01 to 1306.27	PRESCRIPTIONS
1307	1307.01 to 1307.05	MISCELLANEOUS
1308	1308.01 to 1308.49	SCHEDULES OF CONTROLLED SUBSTANCES
1309	1309.01 to 1309.73	REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF CONTROLLED SUBSTANCES
1310	1310.01 to 1310.54	RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

## Pharmacy Delivery of Service 500

- CMS specifically mentions ISMP, ASHP, USP, American College of Clinical Pharmacy (ACCP) and American Pharmacists Association (APA)
- CMS has blue boxes which are advisories
- Has a blue box on the USP's National Formulary
- Need a process where medication orders are received in the pharmacy and dispensed in a safe and timely manner
  - Pharmacists dispense and nurse administer medications
- Safe dispensing must be in accordance with SOP

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## USP's National Formulary Blue Box

### Note re: US Pharmacopeia/National Formulary (USP/NF)

*According to the Federal Food, Drug and Cosmetic Act (FDCA), 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.*

*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.*

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## APA American Pharmacists Association

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**ACCP Website**

**ACCP** American College of Clinical Pharmacy

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- Online Position Listings
- Ambulatory Care
- Interprofessional Recertification Recertification Course
- Clinical Care Pharmacy
- Community Pharmacy
- Pediatric Pharmacy
- Pharmacy Practice Course
- Interprofessional Preparatory Review and Recertification Course
- Pharmacotherapy Self Assessment Program (PSAP)
- Ambulatory Care Self Assessment Program (ASAP)
- Clinical Reasoning Series
- Advocate with ACCP

Announcements

[www.accp.com/index.aspx](http://www.accp.com/index.aspx)

 Johnson to Join ACCP Staff as Director of Health Policy and Interprofessional Affairs

David L. Johnson, D. FCCP, BCPP-AQ Cardiology, will join the ACCP staff on January 11, 2016, in the position of Director of Health Policy and Interprofessional Affairs. [Read the ACCP Report article.](#)

 Call for Nominations

Nominations for the 2016 "New" Award (New Clinical Practitioner, New Educator, and New Investigator), 2016 Parker Medal, and 2016 ACCP Fellows (FCCPs) are now open and must be submitted by February 15, 2016. [Read the ACCP Report article.](#)

 Registration Now Available for ACCP Updates in Therapeutics™ 2016

Registration is now open for ACCP Updates in Therapeutics™ 2016, which will feature the Ambulatory Care Pharmacy, Pediatric Pharmacy, and Pharmacotherapy preparatory review and recertification courses, each of which grants more than 20 hours of recertification credit in its respective specialty. [Read the ACCP Report article.](#)

 Washington Report: 2015 Year in Review from Washington, D.C.

The Washington Report: 2015 Year in Review from Washington, D.C. highlights the advocacy efforts of ACCP members and congressional offices, and the advocacy efforts that calls on Congress to enact legislation to provide Medicare patients with greater access to prescription medication management (PMM) within the Part B benefit. [Read the ACCP Report article.](#)

 Call for Abstracts for the 2016 ACCP Virtual Poster Symposium

All investigators in the field of clinical pharmacy and therapeutics, ACCP members and non-members, are invited to submit abstracts for presentation at the ACCP Virtual Poster Symposiums (May 10–19, 2016). [Read the ACCP Report article.](#)

 ACCP Clinical Research Challenge: Local Competition Exam Available

Critically evaluating and applying primary literature is an essential skill for clinical researchers. [Read the ACCP Report article.](#)

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## Safe Dispensing of Medications 500

- Safe dispensing includes implementing systems such as dose limits, pre-printed orders, special labeling, double checks to minimize drug events
- Especially for high alert medications
- Ensure staff are aware of high alert medications and what the P&P says
- Need process to resolve questions with prescribing practitioner before medications are given
  - Need a culture of safety where staff feel comfortable
- Outcomes are documented in the chart

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## So What's In Your High Risk Med Policy?

General Hospital MEDICAL CENTER

**HIGH ALERT MEDICATIONS**

- POLICY:** To operate a safe medication administration and delivery system that will prevent the misuse medications and prevent misuse of a defined list of high-risk medications that have potential for significant harm.
- PURPOSE:** To reduce the potential for harm to patients by adopting and maintaining measures that specifically target medications with the highest risk of causing injury.
- EQUIPMENT:**
  - High Alert Medication List
  - Medication Administration Record
- WHO DOES IT:**
  - Two licensed nurses, one being an RN
- PROCEDURE:**
  - The high-alert list includes the medication groups that we determined were our highest risk medications. The list may be altered as necessary.
    - Inulin, (subcutaneous, IV)
    - Heparin (LMWH, subcutaneous, IV)
    - Potassium chloride, for injection concentrate

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### Delivery of Service 500 First Dose Rule

- **Standard:** All medication orders must be reviewed by a pharmacist before **first dose** is dispensed
- Includes review of therapeutic appropriateness of medication regime
- Therapeutic duplication
- Appropriateness of drug, dose, frequency, route and method of administration
- Real or potential med-med, med-food, med-lab test, and med-disease interactions
- Allergies or sensitivities and variation from organizational criteria for use

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### Pharmacy Delivery of Service 500

- Medications dispensed are retrieved when recalled or discontinued by manufacturer or FDA
  - Such as Vioxx or Darvocet
- Policy to address use of medications brought in
  - Policy, count drugs, patient signs release, locked in drawer
  - This will help with medication reconciliation to bring in
- Have a system in place to reconcile medications not administered
  - Such as left in drawer when pharmacy restocks or does inventory and determine if refused or not given by error

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### Medication Reconciliation 500

- Note that this is different from medication reconciliation that will be required in revised discharge planning standards
  - Requires that a list of medications be provided in writing on discharge along with doses and reason for taking
  - Would need to compare admission list to discharge list to ensure not missing any
  - Similar to TJC NPSG.03.06.01 on medication reconciliation
  - Would require information on major side effects
  - Consider how patients would obtain their post-discharge medications such as identify a pharmacy
  - Consider if patient has prescription drug coverage and check state's PDMP

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TJC Medication Reconciliation	
Joint Commission	
Reconciling Medication Information	
Hospital Accreditation Program	
<b>NPSQ.03.06.01</b>	
Maintain and communicate accurate patient medication information.	
Elements of Performance for NPSQ.03.06.01	
<p>1. Obtain information on the medications the patient is currently taking when he or she is admitted to the hospital or is seen in an outpatient setting. This information is documented in a list or other format that is useful to those who manage medications. Frequently, medications include those taken at scheduled times and those taken on an as-needed basis. Refer to the Glossary for a definition of medications.</p> <p>Note: The hospital may have a policy for obtaining medication information from the patient. A good faith effort to obtain this information from the patient and/or other sources will be considered as meeting the intent of the EP.</p>	
<p>2. Define the types of medication information to be collected in non-24-hour settings and different patient circumstances.</p> <p>Note 1: Examples of non-24-hour settings include the emergency department, primary care, outpatient radiology, ambulatory surgery, and diagnostic imaging.</p> <p>Note 2: Examples of medication information that may be collected include name, dose, route, frequency, and purpose.</p>	
<p>3. Compare the medication information the patient brought to the hospital with the medications ordered for the patient by the health care provider and any discontinuations.</p> <p>Note: Discontinuations, code outliers, duplications, contraindications, unclear information, and changes. A qualified individual, identified by the hospital, does the comparison. (See also HQR.06.01, EP 1)</p>	
<p>4. Provide the patient (or family as needed) with written information about the medications the patient should be taking when he or she is discharged from the hospital or transferred to another provider (for example, name, dose, route, frequency, purpose).</p> <p>Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only the name and purpose. For more information about communications to other providers of care when the patient is discharged or transferred, refer to Standard PC.04.02.01.</p>	
<p>5. Explain the importance of managing medication information to the patient when he or she is discharged from the hospital or at the end of an outpatient encounter.</p> <p>Note: Help the patient (and family if applicable) instructing the patient to give a list to his or her primary care physician; to update the information when medications are discontinued, doses are changed, or new medications (including over-the-counter products) are added; and to carry medication information at all times as the event of emergency situations. (For information on patient education on medications, refer to Standards MM.06.01.03, PC.02.03.01, and PC.04.01.05.)</p>	

# CMS Proposed Discharge Planning



## FEDERAL REGISTER

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Vol. 80                          Tuesday,  
No. 212                           November 3, 2015

[www.gpo.gov/fdsys/pkg/FR-2015-11-03/pdf/2015-27840.pdf](http://www.gpo.gov/fdsys/pkg/FR-2015-11-03/pdf/2015-27840.pdf)

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**Part IV**

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**Department of Health and Human Services**

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Centers for Medicare and Medicaid Services

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42 CFR Parts 482, 484, 485  
Medical and Medicaid Programs; Revisions to Requirements for  
Discharge Planning for Hospitals, Critical Access Hospitals, and Home  
Health Agencies; Proposed Rule

## Monitoring Effects of Medication 500

- Must monitor medication effects as per policy to minimize ADE
- Usually with anticoagulants and antibiotics
- May receive a pharmacy to dose order
- Monitoring effects of medication may include:
  - Clinical or lab data to evaluate dose, toxicity, or ADE
  - Physical signs and clinical symptoms
  - Assess patient's own perceptions about side effects
  - References nursing standards on monitoring of patients

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## Anticoagulant Resources UM

[About UW Medicine Anticoagulation Services](#)

[Conditions](#)

[Drugs](#)

[Most Popular](#)

[New Guidelines for Conversion \("Switching"\) From One Anticoagulant to Another](#)

[New Guidelines for Management of Superficial Venous Thrombosis](#)

[3/10/2015: New Assay for Prothrombin Factor X](#)

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Warfarin Maintenance Dosing Nomogram			
Guidelines for warfarin maintenance dosing adjustments			
For Goal INR	Dosing Adjustments	For Goal INR	
INR 2.0	<ul style="list-style-type: none"> <li>consider a booster dose of 1/2 - 2 times daily maintenance dose</li> <li>consider resumption of prior maintenance dose if factor causing decreased INR is transient [eg. missed warfarin]</li> <li>If dosage adjustment is needed, increase maintenance dose by 5%-20%</li> </ul>	INR 2.5	<ul style="list-style-type: none"> <li>consider a booster dose of 1/2 - 2 times daily maintenance dose</li> <li>consider resumption of prior maintenance dose if factor causing decreased INR is transient [eg. missed warfarin]</li> <li>If dosage adjustment is needed, increase maintenance dose by 5-15%</li> </ul>
INR 1.5-1.9	<ul style="list-style-type: none"> <li>no dosage adjustment may be necessary if the last two INRs were in range. If there is no clear explanation for the INR to be out of range, and if the judgment of the clinician is that the INR does not represent an increased risk of thromboembolism to the patient:</li> <li>consider a booster dose of 1/2 - 2 times daily maintenance dose if factor causing decreased INR is transient [eg. missed warfarin]</li> <li>If a dosage adjustment is needed, increase maintenance dose by 5%-10%</li> </ul>	INR 2.0-2.4	<ul style="list-style-type: none"> <li>no dosage adjustment may be necessary if the last two INRs were in range. If there is no clear explanation for the INR to be out of range, and if the judgment of the clinician is that the INR does not represent an increased risk of hemorrhage for the patient:</li> <li>consider continuation of prior maintenance dose if factor causing elevated INR is transient [eg. acute alcohol ingestion]</li> <li>If a dosage adjustment is needed, decrease maintenance dose by 5%-10%</li> </ul>
INR 3.1-3.4	<ul style="list-style-type: none"> <li>consider holding 1/2 to 1 dose</li> <li>consider resumption of prior maintenance dose if factor causing elevated INR is transient [eg. acute alcohol ingestion]</li> </ul>	INR 3.5-3.9	

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## Compounding of Drugs 501

- **Standard:** All compounding, packaging, and disposal of drugs and biologicals must be under the supervision of pharmacist
- Must be performed as required by state or federal law
- Must have P&P to ensure all drugs are prepared by authorized staff
- Medications that need to be reconstituted or mixed are considered compounded preparations

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## Compounding of Drugs 501

- Some are compounded by pharmacy
- Some get them from manufacturer, registered outsourcing facility or compounding pharmacy
- Must meet standards for safe compounding to prevent contamination
- Drug Quality and Security Act (DQSA) has sections related to compounding
  - Signed into law Nov 27, 2013
  - Provides for oversight of compounding of drugs

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## Compounding and Federal Law 501

- Under Section 503B a compounder can become an outsourcing facility
- Must register as one and comply with requirements, be inspected by the FDA, and provide AE information
- To be a registered outsourcing facility must comply with FDA's current good manufacturing practice (CGMP)
  - Has minimum requirements for manufacturer, processing, and packaging of drug product

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## Compounding and Federal Law 501

- As previously discussed, FDA wants hospitals to only use a registered outsourcing facility
- Pharmacies not registered as outsourcing facilities are called 503B pharmacies
  - These pharmacies are generally subject to oversight by the State Pharmacy board
- If hospital gets compounded medications from compounding pharmacy and not the manufacturer or a registered compounding pharmacy
  - Then hospital must demonstrate that compounded medicines have been prepared in accordance with SOC

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## FDA's Compounding Website

The screenshot shows the FDA's website for compounding. The main navigation bar includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco. The specific page shown is titled "Compounding Quality Act" under the "Guidance, Compliance & Regulatory Information" section. The page content discusses the Title I of the Drug Quality and Security Act of 2013, which removed certain provisions from the FDCA regarding compounded human drugs. It also mentions the FDA's role in overseeing compounded human drug products and provides links to specific issues like CGMP and labeling requirements.

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## Use a Company that is Registered

The screenshot shows the FDA's website for drugs, specifically the "Letters to Stakeholders" page related to the Compounding Quality Act. The page header includes the FDA logo and "U.S. Food and Drug Administration Protecting and Promoting Your Health". The main content discusses the January 2014 letters sent by Commissioner Hamburg to stakeholders regarding the pharmaceutical compounding provisions of the Compounding Quality Act. It provides links to Dear Colleague and Dear Hospital/Purchaser letters, as well as information about FDA's list of registered outsourcing facilities.

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## Compounding and Federal Law 501

- So if hospital gets from compounding pharmacy then need to make sure they have access to quality assurance data
  - Hospital should get and review this data
- In the contract, the hospital would want to require that the compounding pharmacy meet the requirements of Section 503A of the FDCA
  - Remember ASHP Foundation has free toolkit to assess the contractors

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## Medication Compounded by Hospital 501

- Only the pharmacy compounds or admixes all sterile medications, IVs or other drugs
- Except in emergencies
  - There is a need for emergency or immediate patient administration
- All compounding must be done in accordance with SOP equivalent to the USP National Formulary
- Compounding is defined in USP 795 and includes reconstituting or manipulating commercial products by adding one or more ingredients

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## Definition of Compounding 501

*The definition of compounding as that term is 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:*

- Preparation of drug dosage forms for both human and animal patients
- Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients
- Preparation of drugs or devices for the purposes of, or as incident to, research (clinical or academic), teaching or chemical analysis
- Preparation of drugs and devices for prescriber's office use where permitted by federal and state law."

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## Medication Compounded by Hospital 501

- Compounded medication can result in contamination and unintended variations in strength
- Microbial contamination and bacterial endotoxins can be hazardous to patients
- USP 797 outlines SOP when preparing, storing, or transporting compounded sterile preparations (CSP)
  - This includes nasal inhalations, baths and soaks, injections, wound irrigation, eye drops and tissue implants
- Standard differs based on the level of risk
  - Low, medium or high risk level

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## Risk Categories Include Factors Such As

- *The structural design, environmental controls, air quality levels (based on International Organization for Standardization (ISO) standards for particulate matter in air) and air flow patterns in and surrounding the environment to which the contents of the CSP as well as the surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSP's are exposed.*
- *The sterility of the original ingredients and/or device(s) used in compounding, the number of containers that need to be entered, how many times they need to be entered, the nature and complexity of the manipulations and length of time required to prepare the CSP.*
- *Whether compounding personnel are appropriately garbed and gloved.*
- *Whether multiple doses of sterile products are pooled to produce a CSP that will be administered on more than one occasion or to more than one patient.*

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## Medication Compounded by Hospital 501

- This includes if the CSP must be sterilized before being used
- It includes how long it can be stored before it must be used
- Mentions the immediate use CSP standards which are published in the nursing section tag 405
- Some hospitals only prepare low-risk nonhazardous CSP from a physician's order for a specific patient and must be administered within 12 hours of preparation
  - Designated room with unidirectional airflow Class 5

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### Medication Compounded by Hospital 501

- The room can not be in an area with unsealed openings or openings to high traffic locations and only used to prepare low-risk CSPs
- If hospital preparing medium or high risk CSP with a BUD greater than 12 hours then must meet additional design and monitoring standards
  - Meet additional standards in the ante and buffer rooms
- USP 797 has separate standard for compounding of hazardous medications

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### Medication Compounded by Hospital 501

- USP 797 includes many standards for safe preparation of all risk levels of CSP
  - Need to implement proper procedures
  - Methods for sterilization and for verifying sterility
  - Training and ensuring competency in preparing CSP using visual observations and bacterial sampling
  - Monitoring and testing in ante and buffer areas
  - Cleaning and disinfecting
  - Standards for personal health, attire and garbing and gloving and form QA program
  - Quality checks, patient education issues, etc.

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### Packaging and Labeling of Medications 501

- Proper packing and labeling is needed to reduce risk of error
- Each floor stock medication or unit dose must include:
  - Name, strength, lot and control number, and expiration date
  - If applicable must have a BUD
  - Multi-dose vials BUD is 28 days unless sooner by manufacturer
  - Make sure expiration date is on vial

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## Dispensing of Medications 501

- Meds should be dispensed in safe manner and to meet the needs of the patient
- Medications should be dispensed timely
  - Need system where medication orders get to the pharmacy and back to the patient promptly
- If feasible in unit dose
- In most ready to administer form
- Use the same dose packaging system
- Quantities are minimized to avoid diversion

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## FDA Resources on Drug Diversions

**Risks of Healthcare-associated Infections from Drug Diversion**

When prescription medicines are obtained or used illegally, it is called drug diversion. Addiction to prescription medicines has become an epidemic proportion and is a major driver of drug diversion. Drug diversion can occur in many settings involving healthcare providers who steal prescription medicines for their own use. This can result in several types of patient harm:

- Substandard care delivered by an impaired healthcare provider;
- Prescription of potent pain medications or therapy, or
- Harm of infection (e.g., with hepatitis C virus) if a patient injects or breathes potent respiratory drugs.

**Outbreaks**

CDC and state and local health departments have assisted in the investigation of infection outbreaks stemming from drug diversion activities that involved healthcare providers who tampered with medications. Below is a summary of recent outbreaks to illustrate the importance of prevention.

**U.S. Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013**

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## Prevention Resources:

- National Association of Drug Diversion Investigators [PDF](#)
- Minnesota Hospital Association Drug Diversion Prevention Toolkit [PDF](#)
- Drug Diversion in Hospitals: A Guide to Preventing and Investigating Diversion Issues [Word](#) [Word - 137 KB] [PDF](#)
- CDC Public Health Ethics Case Study, Unsafe Injections: Duty to Warn? [PDF](#) [PDF - 264 KB]
- Premier Inc. Drug Diversion Website [PDF](#)
- Substance Abuse and Mental Health Services Administration [PDF](#)
- National Institute on Drug Abuse (NIDA) [PDF](#)

[www.cdc.gov/infectionssafety/drugdiversion/index.htm](http://www.cdc.gov/infectionssafety/drugdiversion/index.htm) [Top of page](#) [PDF](#)

## Enforcement Agencies:

- Drug Enforcement Administration [PDF](#)
- FDA Office of Criminal Investigations [PDF](#)

[Top of page](#) [PDF](#)

## State Health Department Reports:

- Minnesota Controlled Substance Diversion Prevention Coalition [PDF](#) [PDF - 393 KB] [PDF](#)
- New Hampshire Hepatitis C Outbreak Report [PDF](#) [PDF - 3.93 MB] [PDF](#)
- Public Health Vulnerability Review: Drug Diversion, Infection Risk [PDF](#) [PDF - 1.04 MB] [PDF](#)

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## Dispensing of Medications 501

- Concerns must be clarified before dispensing
  - Medications dispensed are retrieved when recalled and discontinued
    - Discussed previously under tag 491
  - Medications must be available when pharmacy is not open and P&P on who can access
    - Often called the night cabinet standard
    - Can be from automated dispensing cabinets (ADC) outside the pharmacy
    - Contracted services with on-call pharmacists after hours

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## ISMP Guidance on ADCs



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## Locked Storage Areas 502 & 503

- **Standard:** Drugs and biologicals must be kept in a secure and locked area
  - **Standard:** Schedule II-V drugs must be kept locked in secure area
    - Would be considered a secure area if staff actively providing care but not on a weekend when no one is around
    - Only authorized person can get access to locked areas
  - P&P address self administration of drugs
    - See tag 406(drugs and biologicals) and 412 and 413 also (self administered drugs) in nursing section

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## Locked Storage Areas 504

- Persons without legal access to drugs and biologicals can have not have unmonitored access
- They can not have keys to storage rooms, carts, cabinets or containers with unsecured medications
  - Housekeeping (ES), maintenance, or security
- Critical care and L&D area staffed and actively providing care are considered secure
- Setting up for patients in OR is considered secure such as the anesthesia carts but after case or when OR is closed need to lock cart

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## Securing Medications

- So controlled substances must be locked
- Hospitals have greater flexibility in determining which non controlled drugs and biologicals must be kept locked
- Medications should not be stored in areas readily accessible to unauthorized persons such as in a private office unless visitors are not allowed without supervision of staff
- P&P need to address security of any carts containing drugs

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## Securing Medications

- May allow patients to have access to urgently needed drugs such as Nitro and inhalers
- Need P&P on competence of patient, patient education and must meet elements in TJC MM standard on self administration
  - CMS mentioned TJC standard in Federal Register
  - Tag 412 and 413 in nursing on self administered meds
- Measures to secure bedside medications
- Make sure medication carts in OB to do stat C-sections is locked

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## Locked Storage Areas

- If medication cart is in use and unlocked, then someone with legal access must be close by and directing monitoring the cart, like when the nurse is passing meds otherwise locked and in secure area
  - Need policy for safeguarding, transferring and availability of keys
  - Should now have safe injection practice policy and follow CDC 10 requirements
  - CMS gets 50 million dollars to enforce infection control standards and is making infection control visits to hospitals

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## Medications in the OR ASA Position

[www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx](http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx)



**STATEMENT ON SECURITY OF MEDICATIONS IN THE OPERATING ROOM**

(Approved by the ASA Executive Committee in October 2003, and last amended by the ASA House of Delegates on October 16, 2013)

### **Preamble**

**Preamble**  
A secure environment of care is needed for medication safety. Medication safety includes the security of oral, sublingual, parenteral, and inhaled drugs used for elective and emergency patient care. A secure area ensures the integrity of anesthesia machines as well as other equipment and materials. Security of medications in the operating room suite is essential for patient safety.

- Recommended Policies**

  - Access to operating room suites must be strictly limited to authorized persons.
  - All Schedule 3 and 4 narcotic medications must be kept in locked enclosed areas when not in use.
  - Anesthesia professionals must have immediate access to drugs required for emergency patient care. Procedures designed to prevent unauthorized access to such drugs must be used.
  - Anesthesia carts and anesthesia machines may remain unlocked, and non-controlled<sup>\*\*</sup> medications may be left on or top of unlocked anesthesia carts or anesthesia machines under the supervision of an anesthesia professional in an operating room, so long as they are authorized operating room personnel in the OR suite.

Digitized by srujanika@gmail.com

- Rationale**

  - A. Because the operating room suite is a limited-access secure location, it is safe practice for anesthesia professionals to leave non-controlled\* medications on the top of their anesthesia carts or anesthesia machines for brief periods (e.g., while going to a nearby holding area to bring a patient into the operating room).
  - B. At the end of anesthesia cases, when patients are particularly vulnerable, anesthesia

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ASA Standards, Guidelines, Statements

- This position statement is from American Society of Anesthesiologists
  - Security of Medications in the Operating Room
    - All hospitals should also have a copy of the annual book published by AORN on Perioperative Standards and Recommended Practices and has Medication Safety section
  - These are available off the ASA website<sup>1</sup>
  - Security of medications in the operating room

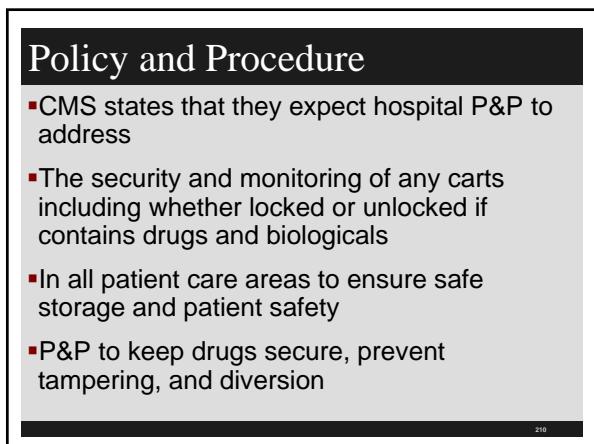
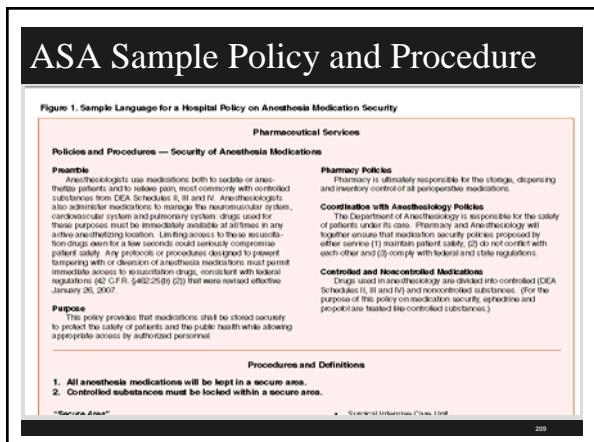
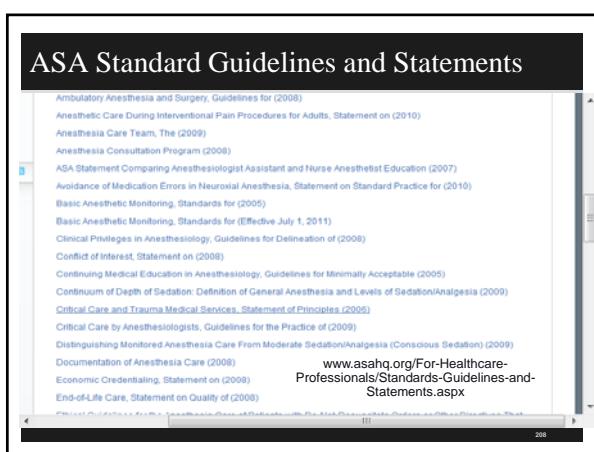
<sup>1</sup><http://www.asahq.org/publicationsAndServices /sgstoc.htm>

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The screenshot shows the ASA Guidelines and Statements page. At the top, there's a navigation bar with links for 'myASA', 'ASA CALENDAR', 'ASA/PAC', 'EDUCATION CENTER', 'JOIN ASA', 'ASA-RELATED ORGANIZATIONS', and 'SHOP ASA'. Below the navigation is a banner stating 'Notice: ASA is now accepting 2013 Committee Nominations - Deadline: January 15, 2012' and a link to 'http://asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx'. The main content area has a blue header 'Standards, Guidelines, Statements and Other Documents'. Under this, there's a sidebar titled 'In This Section' with links to 'About ASA', 'Meetings and Events', 'Publications', 'Practice Management', 'Patient Quality and Safety', and 'Career Opportunities'. The main content area contains text about ASA Standards, Guidelines, and Statements, followed by a section on 'Standards' which defines them as providing rules or minimum requirements for clinical practice.

The screenshot shows the 'APSF NEWSLETTER' from Spring 2010. The title is 'The Official Journal of the Anesthesia Patient Safety Foundation'. The main article is 'APSF Hosts Medication Safety Conference' by John H. Eichhorn, MD. It discusses the 'Consensus Group Defines Challenges and Opportunities for Improved Practice'. The article includes sections on 'Overview', 'Defaults Turn Off CO<sub>2</sub> and Apneic Oxygen', 'Q&A—Exposure to Ultraviolet Radiation in the Operating Room', 'Hospital Coalition Group Endorses APSF Recommendations for PCA Monitoring', and 'Letters to the Editor: Accidental Intratrical Injection of Thiamine Acid'. The newsletter also features a 'Standardization' section with recommendations for high-alert drugs and a 'Technology' section.

Table I: Consensus Recommendations for Improving Medication Safety in the Operating Room	
<b>Standardization</b>	<b>Pharmacy/Prefilled/Premixed</b>
1. High alert drugs (such as phenylephrine and epinephrine) should be available in standardized concentrations/dilutions prepared by pharmacy in a ready-to-use (bolus or infusion) form that is appropriate for both adult and pediatric patients. Infusions should be delivered by an electronically-controlled smart device containing a drug library.	1. Routine preoperatively prepared medications should be discontinued whenever possible.
2. Ready-to-use syringes and infusions should have standardized fully compliant machine-readable labels.	2. Clinical pharmacies should be part of the perioperative/operating room team.
3. Additional ideas:	3. Standardized pre-repared medication kits by case type should be used wherever possible.
a. Interdisciplinary and uniform curriculum for medication administration safety to be available to all training programs and facilities.	4. Additional ideas:
b. No concentrated versions of any potentially lethal agents in the operating room.	a. Interdisciplinary and uniform curriculum for medication administration safety for all anesthesia professionals and pharmacists.
c. Required read-back in an environment for extremely high alert drugs such as heparins.	b. Enhanced training of operating room pharmacists specifically as perioperative consultants.
d. Standardized placement of drugs within all anesthesia workstations in an institution.	c. Deployment of ubiquitous automated dispensing machines in the operating room suite (with communication to central pharmacy and its information management system).
e. Convenient required method to save all used syringes and drug containers until case concluded.	
f. Standardized infusion libraries/protocols throughout an institution.	
g. Standardized route-specific connectors for tubing (IV, arterial, epidural, enteral).	
<b>Technology</b>	<b>Culture</b>
1. Every anesthetizing location should have a mechanism to identify medications before drawing up or administering them (bar code reader) and a mechanism to	1. Establish a "just culture" for reporting errors (including near misses) and discussion of lessons learned.
	2. Establish a culture of education, understanding, and accountability via a required curriculum and CME and dissemination of dramatic stories in the APSF Newsletter and educational videos.



## Outdated or Mislabeled Drugs 505

- **Standard:** Outdated, mislabeled or otherwise unusable drugs and biologicals must not be available for patient use
- Hospital has a system to prevent outdated or mislabeled drugs
- This include drugs that are recalled
- Drug can become unstable prior to expiration date if subject to conditions inconsistent with manufacturer's labeling

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## Outdated or Mislabeled Drugs 505

- Drug can be outdated before the BUD which can occur after the container is opened or while preparing during process if compounded
  - BUD is different from the expiration date
  - Expiration dates are given in years for commercial products
  - BUD is given or compounded preparations and are generally in hours or days
  - If compounded formulation is an official USP/NF the BUD in the monograph can be used or may be provided by manufacturer
  - BUD is the date and time after which a preparation must not be used or transported so use on patient before this date

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### Assigning Beyond Use Dates

<http://pharmlabs.unc.edu/labs/prescriptions/beyond.htm>

Beyond use dates are different from expiration dates. Expiration dates are required on all commercially manufactured products and are determined after a extensive study of the product's stability. Most expiration dates are given in years for commercial products. Beyond use dates are used for compounded preparations and are generally in days or months.

The major problem for pharmacists is that the stability of compounded formulations often is not known. Also,

- Many instabilities cannot be detected without the use of analytic equipment. This is in contrast to incompatibilities that can be visually observed.
- It is not possible to use the manufacturer's expiration date and extrapolate or estimate a beyond use date for a compounded formulation. The compounded formulation probably will not be identical to the manufactured product; it may have a different drug concentration, use different diluents, be a different fill volume, and be packaged in a different container type.

If the compounded formulation is an official monograph in the USP/NF, the beyond use date given in the monograph can be used provided the procedure in the monograph was followed.

When an official monograph isn't present, a systematic approach to assigning the date can be as follows:

**Step 1.** Beyond use dates should be in accordance with the manufacturer's approved labeling. This means that the product was formulated according to the manufacturer's directions, or that the formulation contains the same concentration of drug, in the same diluent, in the same packaging, for the same intended period of use, and so on.

**Step 2.** When this is not possible, a pharmacist ideally consults with the manufacturer to establish a beyond use date. The USP/NF Section <1206> Sterile Drug Products for Home Use: Storage and Beyond Use Dating directs that:

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 Beyond-Use Dating  
By Lou Dierlo, RPh, and Dave Thomas, RPh, MBA  
[http://ldhealthsolutions.com/\\_articles/2009\\_09AssigningBeyondUseDates.pdf](http://ldhealthsolutions.com/_articles/2009_09AssigningBeyondUseDates.pdf)

## Assigning Beyond-Use Dates for Compounded Sterile Preparations: Evaluating Stability Data

**A**ssigning beyond-use dates (BUDs) to compounded sterile preparations (CSPs) is a complex process, fraught with responsibility and risk. To mitigate this risk and provide the highest quality products to patients, one must fully understand the risk of non-sterility and then identify and carefully interpret available resources on chemical stability.

USP defines an expiration date as the date placed by the manufacturer on the container and label of a drug product designating the time frame a product is expected to remain within the approved specifications of its identity,

2) Excessive bacterial endotoxins (pyrogens)  
3) Viscosity in the intended strength of the correct ingredients (outside compendial limits)  
4) Unintended chemical and physical contaminants  
5) Ingredients of inappropriate quality in CSPs

BUDs for compounded preparations must be assigned with all these variables in mind. Although this concept is straightforward, ensuring an effi-

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## Common Sources for Determining BUD

before determining a BUD for any preparation. The most common sources for such data are:

- The package insert
- The United States Pharmacopeia (USP/NF)
- USP dispensing information
- Remington's Pharmaceutical Sciences (current edition)
- The Journal of Pharmaceutical Sciences
- AHFS Drug Information
- American Journal of the Health-System Pharmacy
- The International Journal of Pharmaceutical Compounding
- Trissel's 2 Clinical Pharmaceutics Database (electronic form - continually updated)
- Handbook on Injectable Drugs by Lawrence A. Trissel (current edition)
- King Guide to Parenteral Admixtures (current edition)
- Extended Stability for Parenteral Drugs edited by Caryn Bing (current edition)

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## Outdated or Mislabeled Drugs 505

- Hospital must have P&P to give clear direction to pharmacy staff on how to determine BUD if not available from the manufacturer
- P&P must be based on accepted professional principles equivalent to USP National Formulary
- Section in USP 797 entitled "Determining BUD"
  - Can be obtained through product specific experimental studies
  - Provides examples of issues a pharmacist can use to determine BUD in evaluating current literature

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## Outdated or Mislabeled Drugs 505

- Surveyor will spot check individual drug containers to make sure have all the required information including lot and control number, expiration date, strength, etc.
- Surveyor will ask for one or more examples in which BUD had to be determined for compounded sterile medication based on P&P
- Will look to see if consistent with P&P
- Surveyor will check to make sure P&P is consistent with or more stringent than USP standards

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## No Pharmacist on Duty 0506

- If no pharmacist on duty, drugs removed from storage area are allowed only by personnel designated in policies of MS and pharmacy service
- Must be in accordance with state and federal law
- Routine access to pharmacy by non-pharmacist for access should be minimized and eliminated as much as possible
  - E.g. night cabinet for use by nurse supervisor
  - Need process to get meds to patient if urgent or emergent need
  - TJC does not allow nurse supervisor in pharmacy so would need to call the on call pharmacist

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## No Pharmacist on Duty 0506

- Access is limited to set of medications that has been approved by the hospital and only trained prescribers and nurses are permitted access
- Quality control procedures are in place like second check by another or secondary verification like bar coding
- Pharmacist reviews all medications removed and correlates with order first thing in the morning

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## Joint Commission

- The Joint Commission (TJC) has a similar standard in the hospital manual
- It is located in PC.02.01.01 EP 15
- This section says the hospital must provide care and treatment for each patient
- This section requires that blood transfusions and IV medication must be administered in accordance with state law and approved medical staff policies and procedures
- This is for hospitals that use TJC for deemed status

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## Automatic Stop Orders 507

- Standard: Drugs not specifically prescribed as to time and number must automatically be stopped after a reasonable time
- Commonly known as automatic stop orders
- Must follow acceptable SOP
- MS and pharmacy services determine automatic stop orders
- Hospital must monitor and enforce
- In EHR can have dose and time parameters build into the CPOE screens

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## Pharmaceutical Services 0508

- Standard: Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician
  - If appropriate also to the QAPI program
- Hospitals are required to make sure the attending doctor is immediately aware of the following:
  - Medication errors or drug errors
  - Adverse drug reactions (ADRs)
  - Drug incompatibilities (DI)

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## Pharmacy CoP Tag 508

- If attending physician is unavailable can notify covering physician
  - However, important to note that when covering physician is notified, the attending must still be notified as soon as he or she is available
- Hospital must have P&P on reporting to the attending physician and to the PI program
  - Hospitals have incident reporting systems which often go to risk management and to the hospital wide PI committee
- CMS has a definition of all 3 and hospitals should include definition in their P&P

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## Medication Error

- The National Coordinating Council Medication Error Reporting and Prevention definition is
- Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.
- In this context drug error is **limited** to those errors that actually reach the patient

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## Tag 508 2013

The hospital must adopt policies and procedures that identify the types of events that must be reported immediately to the attending physician, as well as those to be reported to the QAPI program.

- Drug administration error:

The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use." *In the context of this regulation, however, "drug administration error" is limited to those errors in administration that actually reach the patient, i.e., a medication actually is administered to a patient who did not need it, a medication is administered, or the wrong route of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, as discussed in the medication administration standard at 42 CFR 482.23(c).*

- Adverse drug reaction:

The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as "Any unexpected, unintended, undesired, or excessive response to a drug that:

- Requires discontinuing the drug (therapeutic or diagnostic)
- Requires changing the dosage regimen

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## ADR Definition by ASHP

An ADE is any unexpected, unintended, undesired, or excessive response to a drug that:

1. Requires discontinuing the drug (therapeutic or diagnostic)
2. Requires changing the drug therapy
3. Requires modifying the dose (except for minor dosage adjustments)
4. Necessitates being admitted to the hospital
5. Prolongs stay in a health care facility

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## ADR Definition by ASHP (Continues)

6. Necessitates supportive treatment
7. Significantly complicates diagnosis
8. Negatively affects prognosis, or
9. Results in temporary or permanent harm, disability, or death
  - Also includes an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug)
  - And an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual)

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## Drug Incompatibilities Definition

- A drug incompatibility (DI) occurs when drugs interfere with one another chemically or physiologically
- Drugs known to be incompatible must not be mixed or administered together
  - Or administered within a timeframe where they will interfere with each other
- If IV medications are administered with known incompatibility then a medication errors has occurred
  - Therefore, it must be reported to the physician

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## Drug Incompatibilities

- Any unexpected reaction that occurs between the IV medications must also be reported
- CMS said hospitals can minimize risk by having resources available such as
  - Drug incompatibility (DI) chart
  - Online incompatibility references
- Incompatibility information must be readily available to staff
  - Must be kept up-to-date as information is frequently updated by manufacturer

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## Reporting to the Attending

- An immediate report must be made to the attending if medication error, ADE, or DI harmed or has the potential to harm the patient
- If outcome of medication error is unknown then physician must be notified
  - Be sure the incident report is filled out and document in the incident report that the attending physician was notified
  - Document notification of the attending physician in the patient's medical record

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## Medication Errors With No Harm 0508

- Medication errors that do not result in harm or insignificant harm to the patient must be documented in the medical record
- These do not require immediate reporting to the attending physician
- Example, nurse forgets to give an analgesic dose during the night shift
  - It can be reported first thing in the morning
  - No need to wake up the physician during the night since no harm done

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## Drug Administration Errors

- CMS says hospital staff are expected to use their best clinical judgment in determining whether immediate reporting is required
  - Based on patient's presentation and assessment
  - This must be done in accordance with the hospital P&P
- PI program must track and report medication errors and near misses
  - Must also track suspected ADRs
  - To determine system errors and prevent future errors

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## Drug Interactions Checker

The screenshot shows the Drugs.com website interface. At the top, there's a navigation bar with links like 'Drugs A to Z', 'Pill Identifier', 'Interactions Checker', 'News & Alerts', and 'Health'. Below the navigation, there's a search bar with the placeholder 'enter a search term' and a link to 'Browse all medications A B C D E F G H I J K L M N O P Q R S T U V W'. Underneath the search bar, there are several links: 'Medicines - Personal Medication eRecords', 'Side Effects', 'Pregnancy', and 'Breastfeeding'. The main content area is titled 'Drug Interactions Checker'. It contains a text input field labeled 'Drug Name:' with a placeholder 'www.drugs.com/drug\_interactions.php', a button labeled 'Add', and a message: 'Your interactions list is empty. Type a drug name in the box above to get started.' At the bottom of the page, there's a footer with a link to 'www.drugs.com/drug\_interactions.php'.

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## Drug Interaction Checker

The screenshot shows the Medscape Reference website interface. At the top, there's a navigation bar with links for 'NEWS', 'REFERENCE', 'EDUCATION', 'Drugs, Diseases & Procedures', and a search bar with the placeholder 'Search Medscape Reference'. Below the navigation, there's a section titled 'Bisphosphonate Dosing' with a sub-section 'Examine the evidence supporting the proven dosing schedule'. On the left, there's a sidebar for 'Drug Interaction Checker' with a 'Add a Drug' input field and a note: 'Use the search field to add a drug, OTC, or herbal.' On the right, there's a small graphic with the text 'When should you order stress testing?' and 'Learn about the uses for stress MRI'. At the bottom of the page, there's a footer with the URL 'http://reference.medscape.com/drug-interactionchecker'.

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The screenshot shows the homepage of the Pediatric Drug Interaction Checker. The title 'Pediatric Drug Interaction Checker' is at the top. Below it is a search bar with placeholder text 'Search'. To the left is a sidebar with links like 'Ask the Expert', 'Diagnose Tools', 'Patient (PM)', 'Interactions', and 'Submit'. The main content area has tabs for 'Doctor Corner', 'Parents Corner', and 'Child Corner'. A large central box contains a 'Drug Interaction Calculator' with a note: 'Enter upto 10 generic drugs in a prescription and see the various drug interactions that can occur.' On the right side, there are sections for 'Forgot Password', 'Patient Management', 'Research', 'Apply for Research PDF', 'Search' (with sub-links for Hospitals, Pediatricians, Special Schools, Medical Colleges, and Pediatric Residency), and a 'Feedback' section.

The screenshot shows the Epocrates Online Checker website. At the top, there's a navigation bar with links for DRUGS, DISEASES, MEDICAL, and TABLES. Below the header, a search bar contains the placeholder text "e.g.: amoxicillin dosing or acne vulgaris". To the right of the search bar is a "Search" button. Underneath the search bar, there's a section titled "Search. Diagnose. Treat." followed by a "Search" button. Below this, a "Other tools:" section lists "Check Drug Interactions", "Pill Identifier", and "Epocrates Toolbar". At the bottom of the page, there's a large call-to-action button with the URL "https://online.epocrates.com/home". The footer features a "Product Tour" link and a "Epocrates Online Premium" section.

**Hospital Policies and Procedures (P&P) 508**

- Hospital must establish P&P for the reporting of medication errors, ADRs, and incompatibilities
- Hospital must make sure staff are aware of the reporting requirements
  - Hospital should add this information to orientation for new employees
  - Hospital should consider periodic CNE
- Immediate reporting must be required in the P&P with timeframes for reporting that are based on the clinical effects of harm on the patient

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**Non-punitive Environment 0508**

- Hospitals are encouraged by CMS to adopt a non-punitive environment
  - Non-punitive environment so staff will report
  - Many hospitals balance the non-punitive environment with Just Culture
- Should focus on system analysis theory and system issues and not individual staff
  - The majority of medication errors are made by long term employees with unblemished records
  - It is a system that allows the error to occur

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**Hospital Requirements 508**

- The hospital can not just rely on incident reports
- Additional steps must be taken besides
  - Encouraging reporting
  - Adopting a broad definition of medication error and
  - PI reporting
- Incident reports fail to identify most errors and ADEs

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# Proactive Identification

- Proactive identification could include
    - Observe medication passes by nurse
    - Concurrent and retrospective review of patient medical record
    - ADR surveillance team
    - Implementation of medication usage evaluations for high-alert drugs
    - Identification of indicator drugs (trigger drugs)

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### IHI Has Three Trigger Tools for ADEs

Rated by Users:	☆☆☆☆☆	<a href="#">Rate This</a>
<b>Trigger Tool for Measuring Adverse Drug Events (IHI Tool)</b>		
A method for using "triggers," or clues, in patient records to identify ADEs that may not have been reported through standard methods developed by the Institute for Healthcare Improvement (Boston, Massachusetts, USA) and Premier, Inc.		(San Diego, California, USA)
This item has not yet been rated		<a href="#">Rate This</a>
<b>Pediatric Trigger Tool for Measuring Adverse Events (UK version)</b>		
This trigger tool is a structured case notes review tool that measures the number of harm (adverse events) in the organisation using pediatric-specific triggers to identify adverse events; developed by the Safer Care Team, NHS Institute for Innovation and Improvement (Coventry, England).		
This item has not yet been rated		<a href="#">Rate This</a>
<b>Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting</b>		
The Trigger Tool, developed for use with mental health inpatients, includes a list of known adverse drug event triggers in mental health settings and provides instructions for conducting a retrospective review of patient records to identify triggers to identify possible ADEs; developed by the Institute for Healthcare Improvement (Cambridge, Massachusetts, USA).		
This item has not yet been rated		<a href="#">Rate This</a>

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## Trigger Tool for ADE

## Trigger Tool for Measuring Adverse Drug Events

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# Mental Health ADE Trigger Tool

## Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting

[www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/#Trigger](http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/#Trigger)

Institute for Healthcare Improvement  
November 2008  
Version 2

# Pediatric Trigger Tool for ADE



NICU Trigger Tool:  
Measuring Adverse Events in the Neonatal Intensive Care Unit



## Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit

The use of "triggers," or cues, to identify adverse events (ADEs) is an effective method for measuring the overall level of harm in a health care organization. This Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit provides instructions for conducting a retrospective review of patient records using triggers to identify possible AEs in the **Neonatal Intensive Care Unit (NICU)**. This tool includes a list of potential AEs, triggers to identify each AE, the number of admissions with at least one AE in your NICU (the total number of AEs per 100 admissions), and the percentage of admissions with an AE in your NICU. A full test of these triggers was conducted in order to construct a valid neonatal Trigger Tool. The details of this study can be found in the following article:

Sharek PJ, Horbar JG, Mason W, et al. Adverse events in the neonatal intensive care unit: Development, testing, and findings of a NICU-focused Trigger Tool to identify harm in North American NICUs. *Pediatrics*. 2005;118(4):1332-1340.  
<http://pediatrics.aappublications.org/cgi/content/abstract/118/4/1332>

## Measure of Effectiveness 508

- Hospital must have a method to evaluate the effectiveness of its systems for identifying and reporting medication errors and ADEs to the PI program
- Methods could include the use of standardized benchmarks for size and scope of services provided
  - Or studies on reporting rate published in peer review journals
- CMS encourages hospitals to report ADE, medication errors, and incompatibilities

## Medication Error Reporting 0508

- Reporting is not limited to
- The Food and Drug Administration's (FDA) MedWatch program
  - <http://www.fda.gov/Safety/MedWatch/default.htm>
- The Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program (USP-ISMP MERP)
  - <https://www.ismp.org/orderforms/reportterrotoismp.asp>
- Any reports required by any specific state law requirement

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## FDA Med Watch Program

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## ISMP Medication Error Reporting Program

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### Survey Procedure 0508

- Surveyor is suppose to pull the policy and make sure there is a definition of medication errors, ADR, and DI
- P&P must discuss when to report these immediately to the attending physician and to PI program
- Surveyor to make sure all medication errors and suspected ADEs are documented in the medical record
- Will ask staff what they do when they become aware of the above 3 things

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### Survey Procedure 508

- Surveyor is to make sure staff are aware of the hospital's P&P on reporting and documentation of all medication errors and ADEs
- Will ask how this information gets reported to the hospital PI program
- Surveyor is to make sure the hospital's definition of ADR and medication error is based on national standards
  - These were provided by CMS in the interpretive guidelines

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### Abuses and Losses 509

- Standard: Abuses and losses of controlled substances must be reported pharmacist and CEO and in accordance with any state or federal laws
- Surveyor will interview pharmacist to determine their understanding of controlled substances policies
- What is procedure for discovering drug discrepancies?
- Remember state board of pharmacy rules on abuses and losses

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### Information Available to Staff 510

- Standard: Information must be available to staff
  - Drug interaction, side effects, toxicology, doses, indication for use and routes of administration
- Pharmacy must be a resource for medication related information to optimize outcomes
- Pharmacy may assist staff with following medication related functions;
  - Collect specific information such as allergies, height, and weight
  - Pharmacy therapeutic goals

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### Pharmacy Can Help Staff 510

- Identify any problems such as drug-drug interactions or excessive doses
- Monitor and adjust dose based on lab values such as Warfarin dosing
- Monitoring the plan as needed
- Practitioner may write pharmacy to dose and would calculate dose required
- CPOE may have build in functions for dosing, interactions but pharmacy responsible for accurate up to date information

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### Information Available to Staff 510

- Needs to have up to date resources whether in electronic or hard copy
- Pharmacist needs to be readily available by phone to respond to questions from nursing and other practitioners
- Surveyors will ask staff whether needed reference material is available to them
- Surveyors will ask nursing staff if reference material available when monitoring patients for medication therapies

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## Formulary 0511

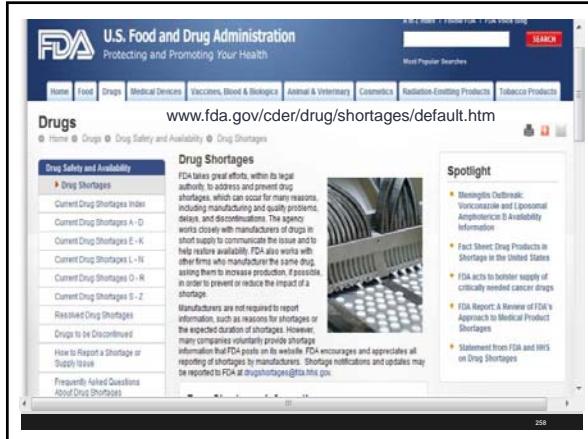
- Formulary system must be established by the MS to ensure quality pharmaceuticals at reasonable cost
  - Formulary lists the drugs that are available
  - Processes to monitor patient responses to newly added medication
  - Process to approve and procure meds not on the list
  - Process to address shortages and outages including communication with staff, approving substitution and educating everyone on this, and how to obtain medications in a disaster

1

## Medications Shortages

- FDA has a website on current shortages and can sign up to get this information sent via email
  - FDA drug shortage program designated by Center for Drug Evaluation and Research (CDER) Center Director
  - FDA also has list of drugs to be discontinued
  - Sign up to get email notification at [www.fda.gov/cder/drug/shortages/default.htm](http://www.fda.gov/cder/drug/shortages/default.htm)

1



## Sign Up To Get Drug Shortage Information

The screenshot shows a web page from the U.S. Food and Drug Administration (FDA). At the top, there's a blue header bar with the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below the header, the URL [https://public.govdelivery.com/accounts/USFDA/subscriber/new?pop=&topic\\_id=USFDA\\_22](https://public.govdelivery.com/accounts/USFDA/subscriber/new?pop=&topic_id=USFDA_22) is displayed. The main content area has a heading "Email Updates" and a paragraph explaining the service: "Welcome to the U.S. Food & Drug Administration (FDA) free e-mail subscription service. When you subscribe to this service, you will receive an e-mail message each time there is an update on the FDA page(s) you select." It also includes a note about privacy: "We have a strict privacy policy. FDA does not collect personally identifiable information other than your e-mail address which is needed in order to provide the service. FDA will not use or share your e-mail address for any other purpose. The GovDelivery service FDA employs to provide this e-mail subscription service is not a government entity. Information you provide may be made available to GovDelivery and other non-governmental parties." A form field for "Email Address" is present, along with "Submit" and "Cancel" buttons. Below the form, a note states: "Your contact information is used to deliver requested updates or to access your subscriber preferences." At the bottom, there are links for "Privacy Policy" and "Help".

## ASHSP Drug Shortage Website

- American Society of Health System Pharmacists has website on current shortages and drugs no longer available
- Has other resources such as articles and news on drug shortages
- Has two articles on understanding and managing drug product shortages which you can use to help draft this required P&P
- <http://www.ashp.org/shortages>

The screenshot shows the homepage of the American Society of Health-System Pharmacists (ASHP) Drug Shortage Resource Center. The top navigation bar includes links for "About Us", "Member Center", "Education", "Practice & Policy", "Meetings", "Advocacy", "News", "Accreditation", "Information For...", and "Login/Register | My Account | Shopping Cart". The main content area features a banner with the text "HOME > DRUG SHORTAGES" and the URL [www.ashp.org/shortages](http://www.ashp.org/shortages). Below the banner, there's a section titled "Drug Shortages" with sub-links for "Current Shortages", "Drugs No Longer Available", "Resolved Shortages", and "Report a Drug Shortage". A sidebar on the left lists "Drug Shortages", "Current Shortages", "Drugs No Longer Available", "Resolved Shortages", "Guidelines and Resources", and "Report a Drug Shortage". The central part of the page contains a "FIND DRUG SHORTAGES" search bar with fields for "Search by Generic Drug Name..." and "Find", and "Search by Drug Shortage List...".

## GAO Drug Shortage Better but Still Continue



United States Government Accountability Office  
Report to Congressional Addressees  
[www.gao.gov/assets/670/660785.pdf](http://www.gao.gov/assets/670/660785.pdf)

February 2014

### DRUG SHORTAGES

**Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability**

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## CMS Manual

- There are other reference to medication besides the pharmacy/medication section
- In the survey process, surveyor should look for outdated medication in the pharmacy
- Mentions psychiatric advance directives and use of medication
- Discusses medications and if a risk for falls or an unsteady gait
- Tag 160 regarding use of medications and when it is a restraint

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## CMS Manual

- Physically holding to give a medication is a restraint (Tag 160)
- Must assess medication in one hour face to face visit for patients who are V/SD (Tag 179)
- Must include medications and allergies in H&P (Tag 358)
- Surveyor to select patients and review all medication order and MARs (Tag 404)
- Drugs must be administered under the supervision of nursing and with approved MS P&Ps (Tag 405)
- Drugs must be administered within **certain time limits** of the scheduled time and nurse must remain with patient until taken (Tag 405, Revised 12-22-2011)

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## CMS Manual

- 3 timeframes to administer medications under 405
- Must monitor medications as part of PI process including errors (Tag 405) and safe use of Opioids
- Any questions on medications is resolved prior to administration (Tag 406)
- Need all elements of a complete drug order (Tag 406 and similar to questions asked on TJC Medication Management tracer)
- Verbal orders used infrequently and pose a risk of medication errors (Tag 407)

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## CMS Manual Other Sections

- Staff must have education on blood and IV medications (Tag 409 and amended June 20, 2011 and changed in FR July 16, 2012 to have P&P and follow state law)
- Medical record must contain response to medications (Tag 449 and 464)
- Medical record must contain all medications given including any unfavorable reactions to drugs (Tag 467)
- Diets must meet needs of patients including patients taking certain medications (Tag 628)
- Adequate lighting in medication preparation areas (Tag 726)

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## CMS Manual Other Sections

- Patients must be counseled in timing and dosage of medications and effects for post hospital care (Tag 822)
- Need policy on storage, access, control, and administration of medications and medications errors (Tag 1160)

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## Storage of Medication Policy

### Storage of Medications

**Pharmacy:**  
JDH seeks to control both access to and storage conditions of medications at all times. Medications should be stored in accordance with manufacturer recommendations and/or based on pharmacist experience and instructions. Pharmacy access should be restricted at all times based on employee identification.

Controlled substances must be secured in a locked room inside the pharmacy and held in a secured device or refrigerator. Personnel gain access to the controlled substance devices via password authentication.

### Transportation and Delivery of Medications

**Transportation:** Medications may only be transported via prescribed manners.

Different types of medications are transported in different ways:

- Controlled substances may be transported in one of three ways:
  - Licensed pharmacists or pharmacists' assistants can be picked up by licensed personnel at the pharmacy and then transported to units.
  - Off site locations may receive medications via JDH transports.

Medications not containing controlled substances medications may be transported by pharmacy staff, Hospital staff, or volunteers.

For additional information on Pharmacy transportation see Pharmacy manual C-011 and C-012

### Delivery:

Controlled substances must be delivered to the appropriate Pyxis machine or double locked facility. (For additional details see Pharmacy manual C-009)

When a pharmacist or pharmacist tech delivers medication it may be delivered to either the

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## The End! Questions?

Sue Dill Calloway RN, Esq.  
CPHRM, CCMSCP  
AD, BA, BSN, MSN, JD  
President



Patient Safety and Healthcare Education  
5447 Fawnbrook Lane  
Dublin, Ohio 43017  
614 791-1468  
sdill1@columbus.rr.com  
(no email question, call)

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