New Pharmacy & Medication Standards

Sue Dill Calloway

RELIAS LEARNING

Speaker

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  hospitalscg@cms.hhs.gov

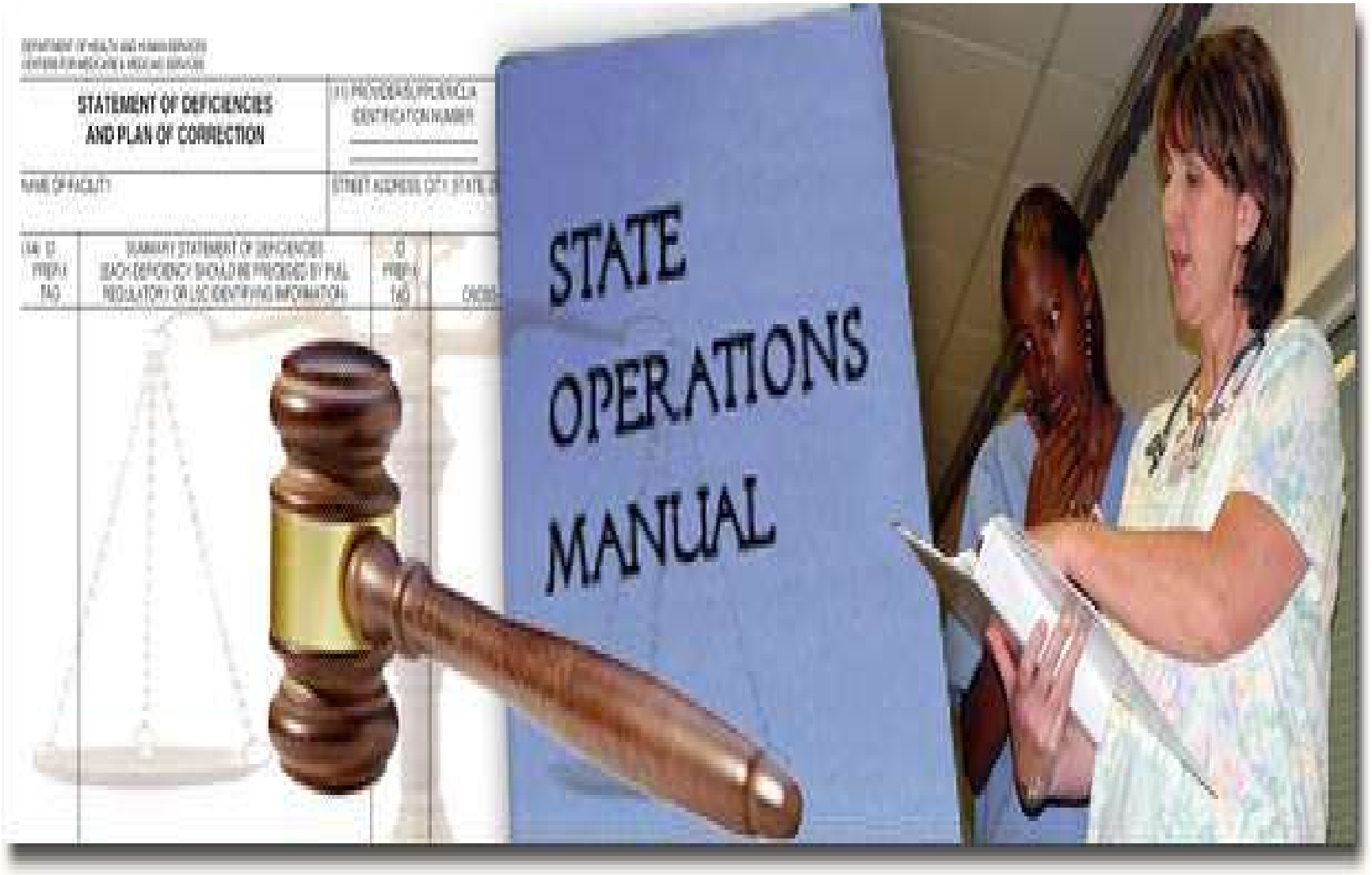
Objectives

- Explain CMS requirements on compounding of medication and beyond-use date.
- Describe CMS policy for high-risk drugs.
- Discuss medication guidelines that CMS outlined.

Introduction to the CMS Hospital Pharmacy CoPs

RELIAS | LEARNING

You Don’t Want One of These From CMS



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 (Added 09.01.01 on antibiotic stewardship)
- 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** [2]
  - Hospitals should check this website once a month for changes

[1] www.gpoaccess.gov/fr/index.html

[2] 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

- 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

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

CoP Manual Also Called SOM

State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Table of Contents
(Rev. 151, 11-20-15)

Transmittals for Appendix A

www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

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

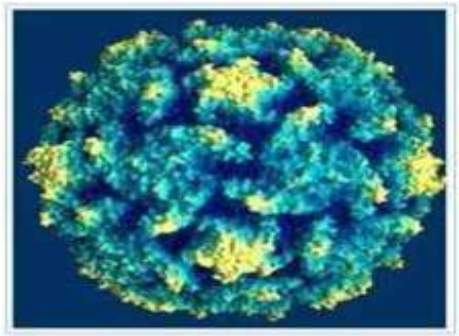
Psychiatric Unit Survey Module

Rehabilitation Hospital Survey Module

Inpatient Rehabilitation Unit Survey Module

Hospital Swing-Bed Survey Module

Email questions
hospitalscg@cms.hhs.gov



CMS Transmittals

Subscribe to the Federal Register

FEDERAL REGISTER

The Daily Journal of the United States Government

www.federalregister.gov/my/sign_up

The Revised Final CoPs

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

[1]www.cms.hhs.gov/transmittals/downloads/R37SOMA.pdf

2 http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf

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

OIG Report January 22, 2015
ISMP Guidelines
ASHP Resources

RELIAS | LEARNING

Surveyor Training on Compounding

- The OIG issued a report regarding a recommendation which called on CMS to ensure hospital surveyors are trained on nationally recognized compounding practices
- Recommended changes to 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

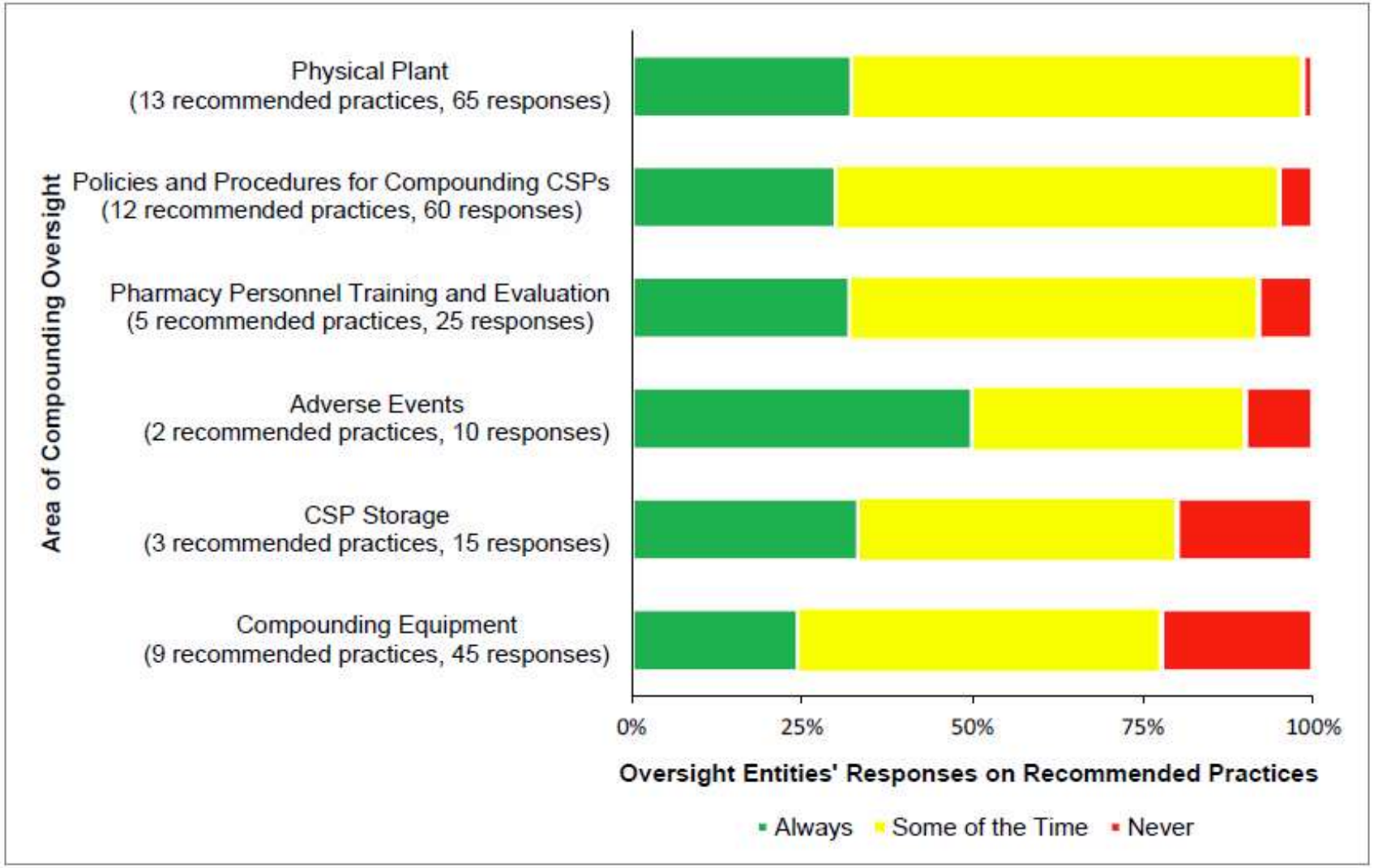
MEDICARE'S OVERSIGHT OF COMPOUNDED PHARMACEUTICALS USED IN HOSPITALS

Daniel R. Levinson
Inspector General

The OIG Report Jan 2015

- The surveyor may review the contracts of the stand alone compounding pharmacy
- This includes surveyors from TJC, DNV, AOA (AAAHC) 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

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 personnel 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 (Revised in 2016)
  - Goal is to provide procedures and safe practices for reducing errors in CSP preparation
  - Addresses drug storage, compounding, labeling, and staff management
- Also ASHP issued guidelines on contracting for sterile compounding services
  - Suggested contract language

ASHP Guidelines on Outsourcing

www.ashp.org/DocLibrary/BestPractices/MgmtGdlOutsourcingSterileComp.aspx

ASHP Guidelines on Outsourcing Sterile Compounding Services

Purpose

The purpose of these guidelines is to provide an overview of factors and processes for healthcare organizations to consider when contracting with compounding pharmacies or outsourcing facilities to obtain sterile compounding services. These guidelines describe services available from compounding pharmacies or outsourcing facilities, reasons for outsourcing and reasons for not outsourcing, the outsourcing process and outsourcing arrangements, and recommendations for evaluating a contractor's performance. The guidelines also provide a topical list of contract provisions, some of which relate to practices that are the subject of other ASHP guidelines. Organizations should refer to pertinent ASHP guidelines for additional information on which to base their contract provisions, agreements, and decisions.[1-3] The concepts presented in this document could be used for strategic planning with the organization's decision-makers, assisting in assessing the quality of compounded sterile preparations or products, drafting contract provisions, comparing prospective contractors, preparing for contract negotiations, and evaluating contractor performance.

This document addresses representative outsourcing options and contract agreements and is not intended to cover all situations. Managers of pharmacy and healthcare organizations should use their professional judgment about applicability to their own needs and circumstances.

Compounding Pharmacies. Section 503A clarified the FD&C Act for activities described as traditional patient-specific compounding (sometimes now called "503A compounding"). Healthcare organization pharmacies fall into this category, as do other pharmacies that fill prescriptions or medication orders within a prescriber–pharmacist–patient professional relationship. All 503A compounding pharmacies, except those in federal facilities, are regulated by state boards of pharmacy; however, they may also be subject to Food and Drug Administration (FDA) inspection under the agency's authority to enforce section 503A of the FD&C Act. The agency's expectations for compliance are specified in the FDA *Compliance Policy Guide* (CPG) *on Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.*[5] In addition to current regulatory requirements, such as prescriptions or medication orders for compounded preparations and compliance with applicable *United States Pharmacopeia* (*USP*) chapters on compounding (i.e., *USP* chapters 795 and 797),[8,9] inspectors may look for implementation of additional CPG recommendations. The services provided by compounding pharmacies are limited by the existing requirement for individual prescriptions or medication orders and may be further limited by forthcoming regulation of distribution across state lines,[7] state and federal restrictions on office-use preparations, and other limitations of section 503A.

Outsourcing Facilities. Section 503B outsourcing facilities

http://apic.org/Resource_/TinyMceFileManager/Academy/ASC_101_resources/Sterilization/ASHP_Outsourcing_Sterile_Compounding_2010.pdf

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, at the least, an internal needs assessment, a cost analysis, 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 outcomes expected during a contract's performance 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 for strategic planning with the organization's 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. The appendix provides a topical list of contract provisions, some of which relate to practices that are 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

- Restricted 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 regulations.

Governmental and Regulatory

- Reductions of federal, state, and local government reimbursement for health care.
- Increased numbers of individuals dependent on federal, state, and local governments for health care.
- Increased federal and state interest in standards for sterile compounding (i.e., *United States Pharmacopeia* [*USP*] chapter 797[4]).

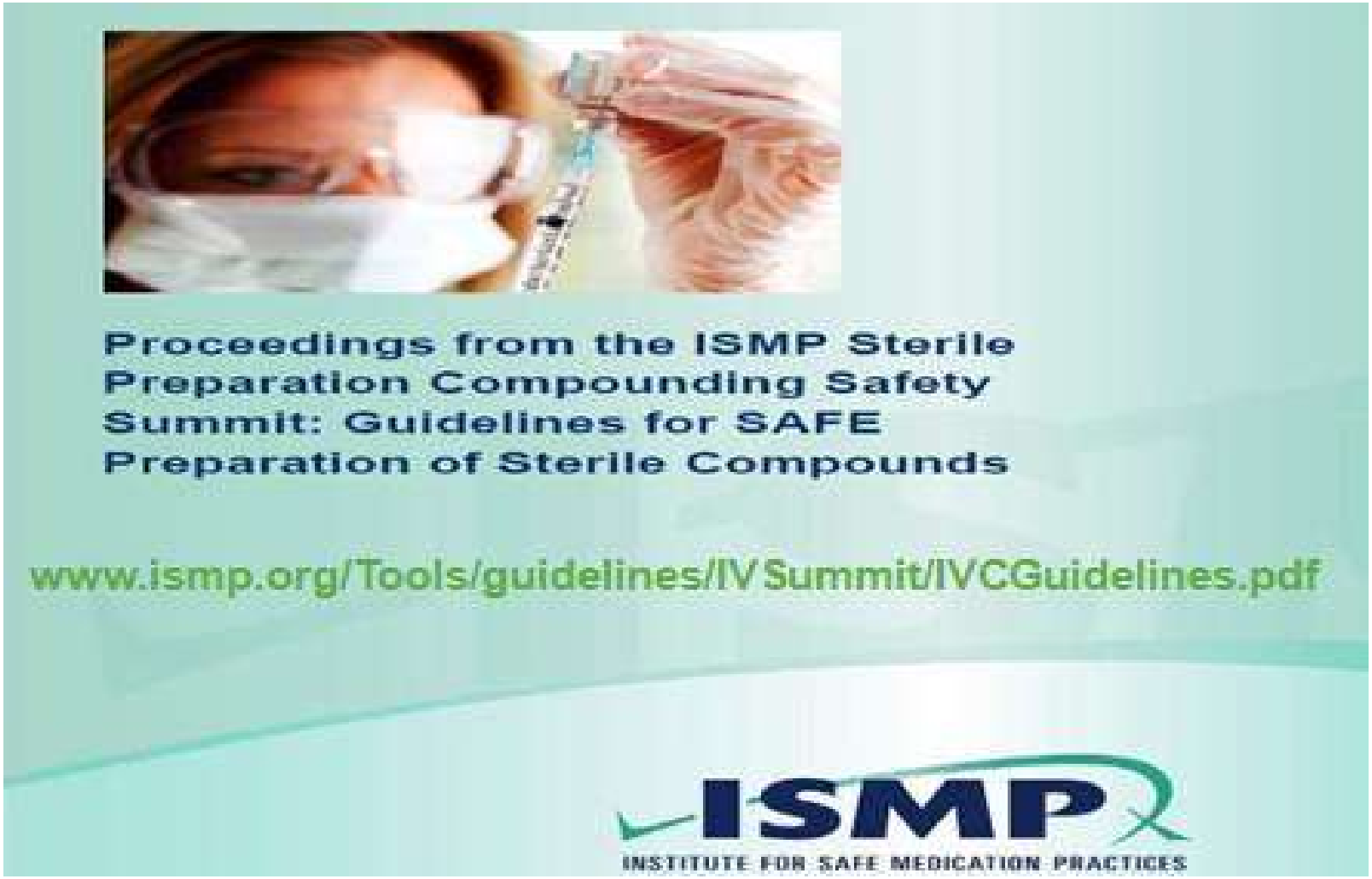
ASHP Has Compounding Resource Center

www.ashp.org/sterilecompounding

Compounding Assessment Tool

www.ashpfoundation.org/InsourcingTool

ISMP's Guidelines 2013



ISMP Revised 2016 22 Pages

Institute for Safe Medication Practices

ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations

Original Publication: 2013
Revised: 2016

www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.pdf

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 (registered pharmacies) 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

- So standalone compounding pharmacies can voluntarily register with the FDA as CSP outsourcing facility
- 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's Compounding Website

Use a Company that is Registered

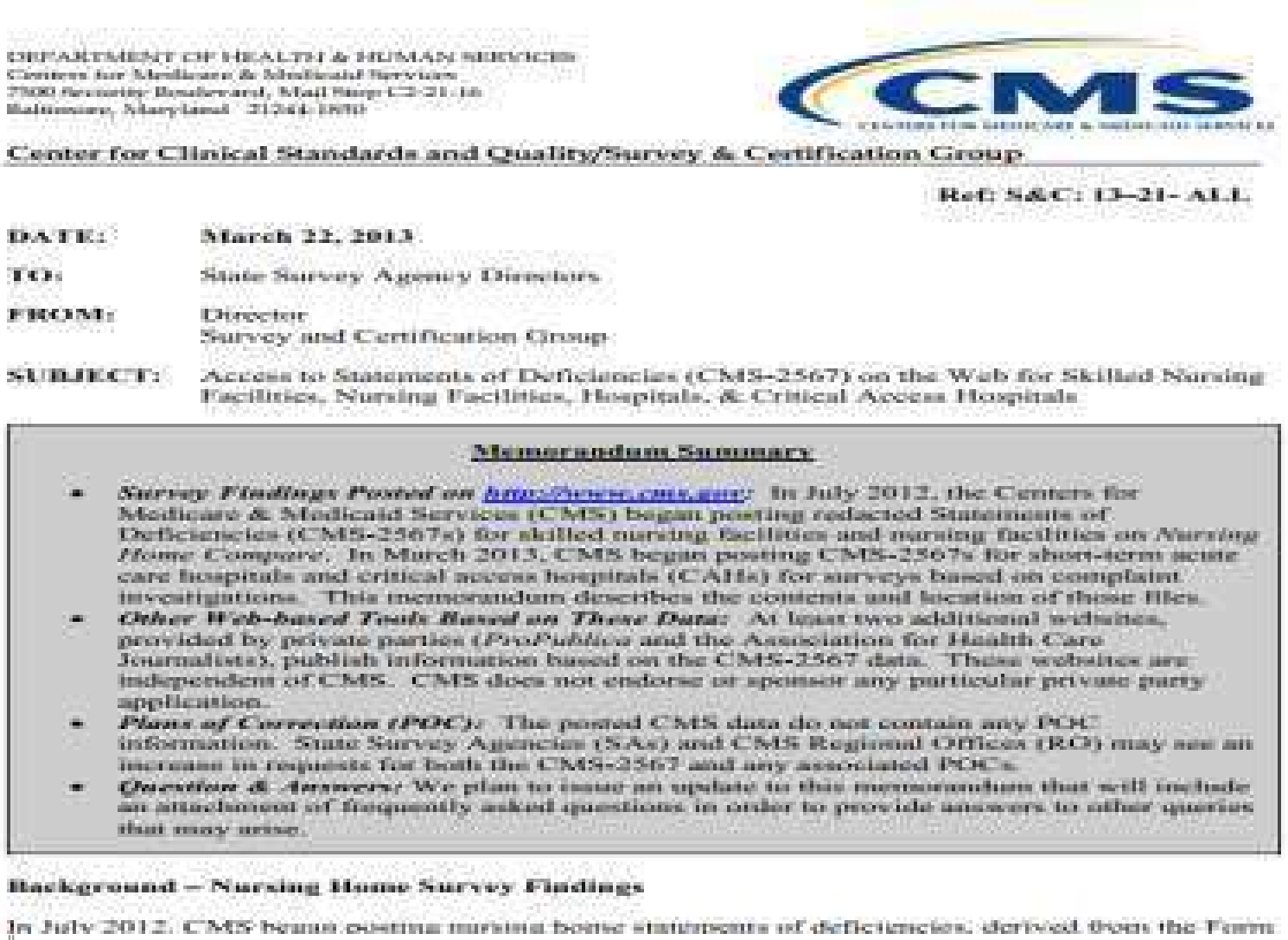
CMS Data On Hospital Pharmacy Deficiencies

RELIAS | LEARNING

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

Access to Hospital Complaint Data



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: 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

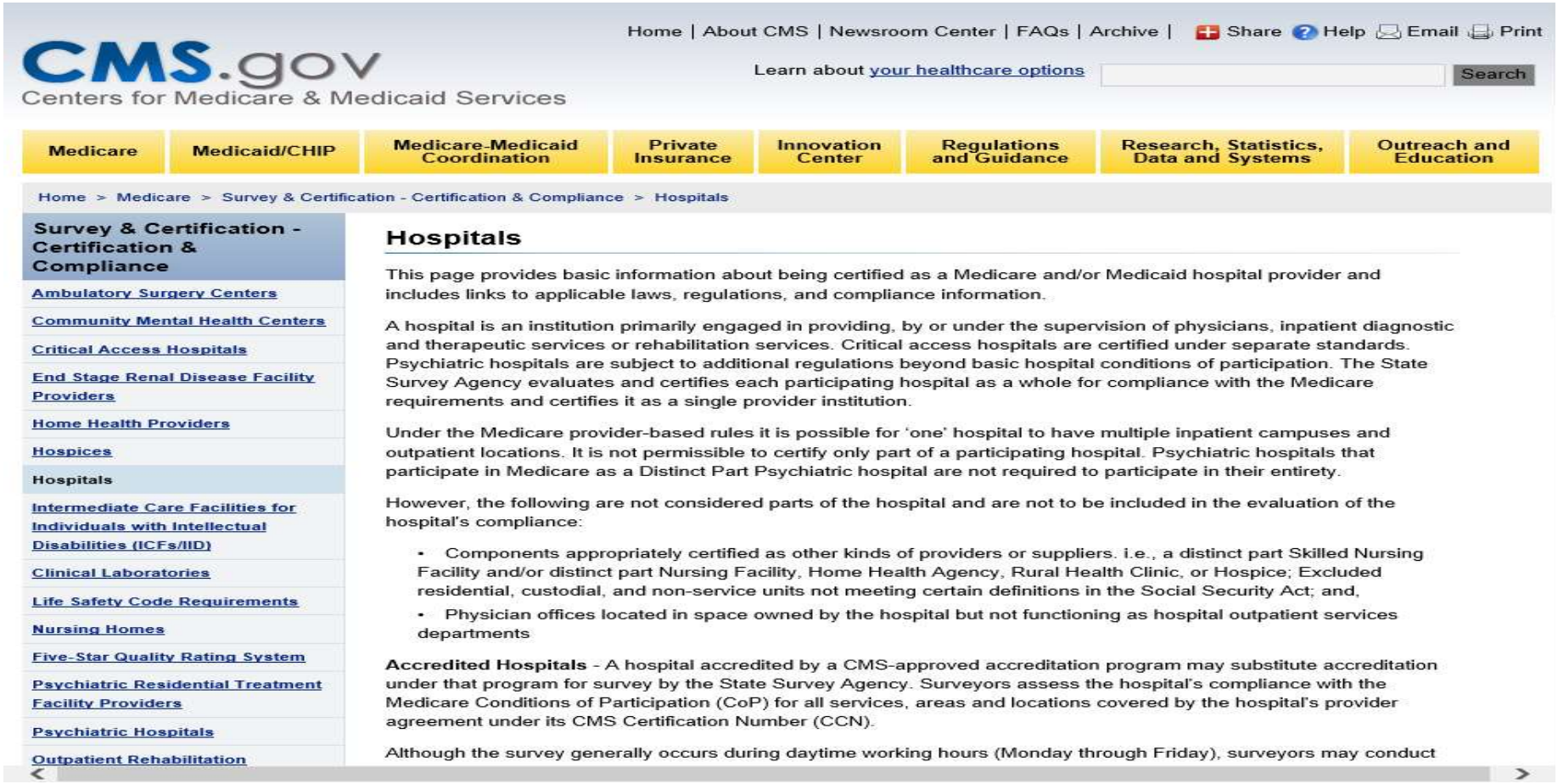
Memorandum Summary

- ***Survey Findings Posted on*** *http://www.cms.gov:* In July 2012, the Centers for Medicare & Medicaid Services (CMS) began posting redacted Statements of Deficiencies (CMS-2567s) for skilled nursing facilities and nursing facilities on *Nursing Home Compare*. In March 2013, CMS began posting CMS-2567s for short-term acute care hospitals and critical access hospitals (CAHs) for surveys based on complaint investigations. This memorandum describes the contents and location of these files.
- ***Other Web-based Tools Based on These Data:*** At least two additional websites, provided by private parties (*ProPublica* and the Association for Health Care Journalists), publish information based on the CMS-2567 data. These websites are independent of CMS. CMS does not endorse or sponsor any particular private party application.
- ***Plans of Correction (POC):*** The posted CMS data do not contain any POC information. State Survey Agencies (SAs) and CMS Regional Offices (RO) may see an increase in requests for both the CMS-2567 and any associated POCs.
- ***Question & Answers:*** We plan to issue an update to this memorandum that will include an attachment 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

Updated Deficiency Data Reports



Deficiency reports available at www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals.html

Pharmacy Deficiencies April 17, 2017

Section	Tag Number	Number
Pharmacy Services Pharmacy Administration	490 491	96 75
Delivery of Drugs Pharmacy Drug Records	500 494	102 34
Formulary/Access to Drug Info	511	6
Reporting Losses	509	3
Pharmacist Responsibility	492	**31**
Pharmacy Personnel	493	7
Pharmacist Supervision Locked Controlled Drugs	501 503	42 7

Pharmacy Deficiencies

Section	Tag Number	Deficiencies
Access to Locked Area Reporting Adverse Events	504 508	7 40
After Hours Access to Drugs Secure Storage	506 502	6 51
Unusable Drug Stop Orders	505 507	85 4
Total	**650**	

CDC Vaccine Storage and Handling

RELIAS | LEARNING

CDC Vaccine Storage and Handling Toolkit

- Make sure you have a copy of this 82 page document
- Published June 2016 and maintain the cold chain
- Do not store vaccines in dorm like refrigerators
- Temperature revised to range between 36 and 46 degrees (previously 35-46 degrees F)
  - State may also have specific requirements
- Use a medical (biological) refrigerator that monitors temperature and set at mid range (40 degrees)
- E-mail specific questions to CDC: **NIPInfo@cdc.gov**

Vaccine Storage & Handling Toolkit

June 2016

www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

CDC Vaccine Storage and Handling Toolkit

- Make sure staff familiar with storage and handling P&Ps and document training
  - Train in orientation and annually
  - When new vaccines added to inventory
  - CDC has online training programs
- Keep standard operating procedures (SOP) for storage and handling near storage units
- Written storage and handling plan can help staff to ensure vaccines are properly managed

Immunization: You Call the Shots-Module Ten-Storage and Handling—2016
WB2596

PROGRAM DESCRIPTION:
This module is the tenth in a series titled Immunization: You Call the Shots and focuses on storage and handling requirements for vaccines.

The series has been available since the mid-nineties in various formats. Previously available as a CDrom, it is now presented in web-based format. The series is designed to provide key immunization knowledge in a very basic step-by-step manner. It presents practice-oriented content about immunization. It does not discuss the denser more complex material regarding epidemiology, disease transmission, etc.

It addresses an important audience for immunization training: the new provider or the medical or nursing student. It is also an excellent review for a seasoned healthcare provider. It has often been used by nursing schools to introduce their students to the comprehensive core knowledge about immunization.

Since it presents a simpler version of the core knowledge about immunization it is a needed alternative to the faster-paced denser core course that NCIRD provides, titled Epidemiology and Prevention of Vaccine-Preventable Diseases. It is a multi-session course of 12 to 15 hours. Evaluation of that course revealed that immunization providers sought a primer or more basic course for newcomers to the immunization field. The You Call The Shots series directly responds to that evaluation feedback.

OBJECTIVES:
At the conclusion of the session, the participant will be able to:

www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp

1. Define and explain cold chain management.
2. Describe the components of routine and emergency plans for vaccine storage and handling.
3. Describe the roles of the primary and back-up coordinators and other staff in the storage and handling of vaccines.
4. Describe proper storage equipment use and monitoring.
5. Describe correct vaccine and diluent storage and handling for routinely recommended vaccines.
6. Describe correct vaccine storage, handling, and disposal of routinely recommended vaccines.
7. Identify actions that should be taken if vaccines have not been stored properly.
8. Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

FACULTY/CREDENTIALS:
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M. Suzanne Johnson-DeLeon MPH; Health Education and Information Specialist, CDC/NCIRD
Raymond Strikas, MD, MPH, Medical Officer, CDC/NCIRD
Donna Weaver, RN, MN, Nurse Educator, CDC/NCIRD

ORIGINATION DATE: 1/15/2016
EXPIRATION DATE: 1/15/2017

URL:http://www.cdc.gov/vaccines/ed/youcalltheshots.htm
HARDWARE/SOFTWARE: Computer Hardware; Internet connection; Browser
MATERIALS: Internet connection and computer

TARGET AUDIENCE: Administrators, CHES certified health educators, Physicians, Epidemiologists, LPNs, LVNs, Medical assistants, medical students, NPs, nurse technicians, other health educators.

CDC Vaccine Storage and Handling Toolkit

- Vaccine cold chain is temperature controlled environment to maintain and distribute vaccine in optimal condition
  - Too much exposure to heat, cold, or light can damage vaccine
- Designate person to be primary vaccine coordinator
- Has a document called at a glance resource guide
- http://www.cdc.gov/vaccines/hcp/admin/downloads/vacc-admin-storage-guide.pdf

AT-A-GLANCE RESOURCE GUIDE

VACCINE ADMINISTRATION AND STORAGE AND HANDLING

IMMUNIZATION AND VACCINES (GENERAL)

General Recommendations on Immunization – Recommendations of the Advisory Committee on Immunization Practices (ACIP)
Guidance about vaccination and vaccines for health care providers.
www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm

Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book), 13th Edition: Course Textbook (2015)
Comprehensive information on routinely used vaccines and the diseases they prevent.
www.cdc.gov/vaccines/pubs/pinkbook/index.html

The Pink Book Webinar Series
One-hour webinars with CDC experts exploring chapters of the Pink Book.
www.cdc.gov/vaccines/ed/webinar-epv/index.html

"You Call the Shots" Online Training Modules

VACCINE STORAGE AND HANDLING

- **Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book): Storage and Handling Chapter**
  www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html
- **Vaccine Storage and Handling Guidelines and Recommendations**
  Resources on vaccine storage and handling recommendations and guidelines.
  www.cdc.gov/vaccines/recs/storage/default.htm
- **Vaccine Storage and Handling Toolkit**
  Comprehensive guidance for health care providers on vaccine storage and handling recommendations and best practices.
  www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
- **"Keys to Storing and Handling Your Vaccine Supply" Training Video**
  This training outlines vaccine storage and handling best practices, and provides helpful tips for preventing errors and preserving vaccine supply and integrity.
  www2.cdc.gov/vaccines/ed/shvideo/

VACCINE ADMINISTRATION

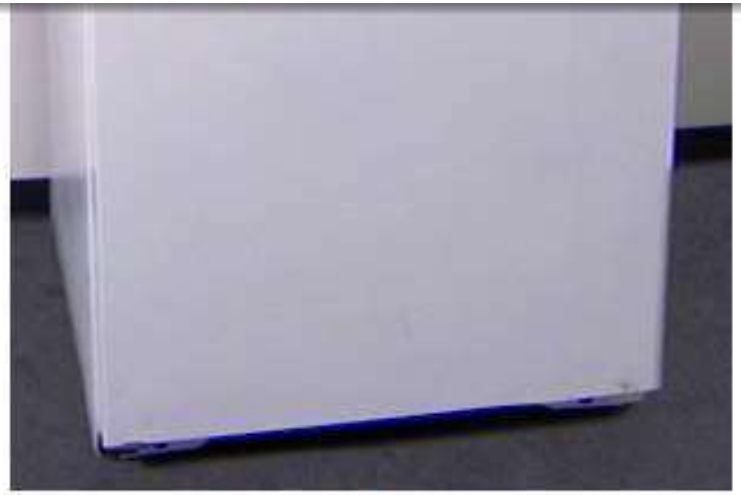
- **Skills Checklist for Immunization**
  A self-assessment tool from the Immunization Action Coalition for health care staff who administer vaccines.
  www.immunize.org/catg.d/p7010.pdf
- **Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book): Vaccine Administration Chapter**

CDC Vaccine Storage and Handling Toolkit

- Use stand alone refrigerator or freezer with enough space to accommodate without crowding
- Use digital data logger with current and valid certificate of calibration testing
  - Have back up in case one breaks or malfunctions
- Pharmacy grade units are designed to store biologics and have fan forced air circulation that promote uniform temperatures
  - Have microprocessors with digital temperature sensor
  - Don’t use dormitory style refrigerators but not all small storage units are dormitory units

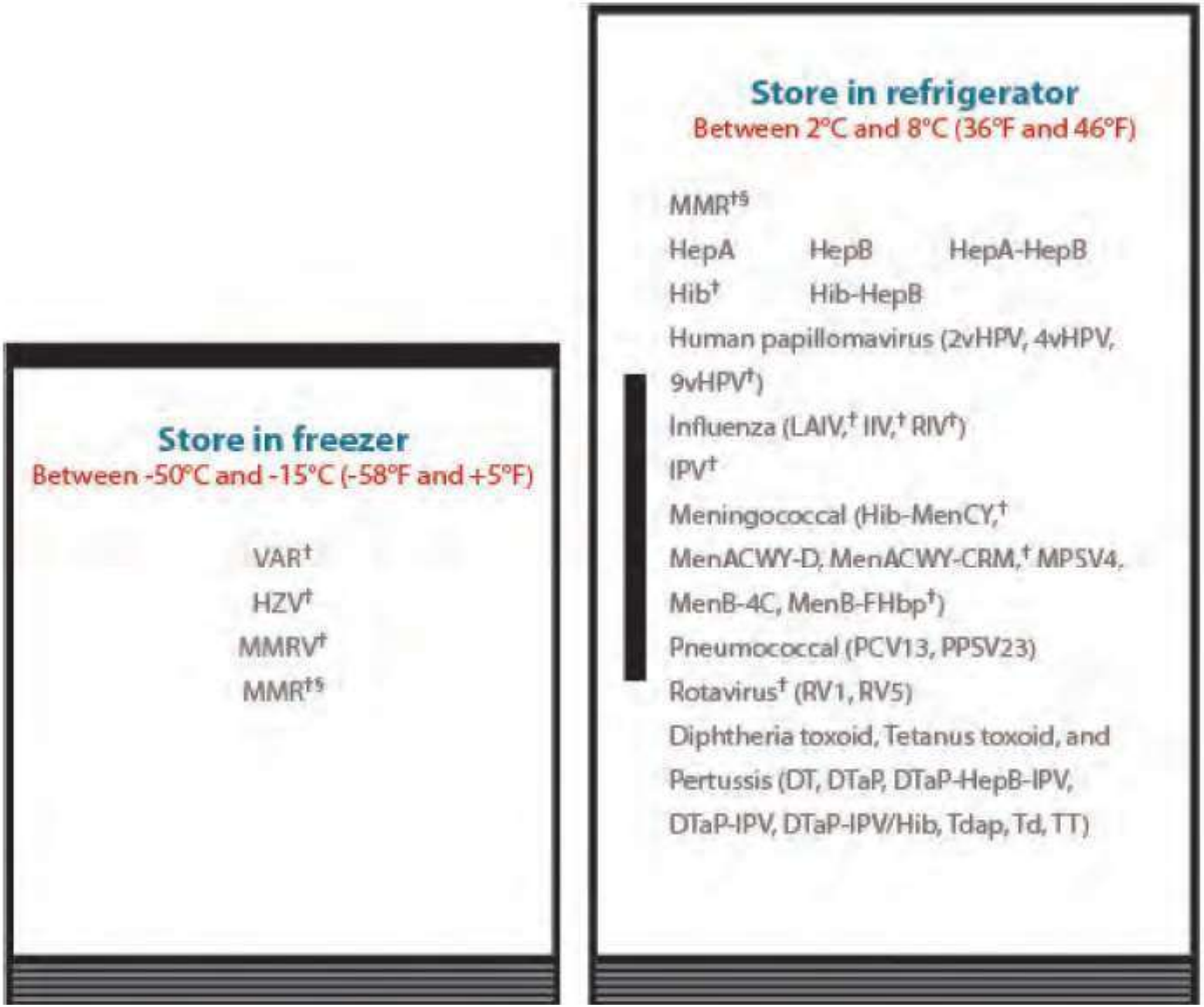
CDC makes the following recommendations for vaccine storage units:

- Use purpose-built units designed to either refrigerate or freeze (can be compact, under-the counter-style or large units).
- If a purpose-built unit is not available, use a stand-alone household unit.
- If you must use a household-grade combination refrigerator/freezer unit, only use the refrigerator compartment for storing vaccines. These units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing temperatures. Use a separate stand-alone freezer to store frozen vaccines.
- **Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.** These units have a single exterior door and an evaporator plate/cooling coil, usually located in



Household combination refrigerator/freezer

Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.


Store in freezer
Between -50°C and -15°C (-58°F and +5°F)
VAR†
HZV†
MMRV†
MMR†§
Store in refrigerator
Between 2°C and 8°C (36°F and 46°F)
MMR†§
HepA
HepB
HepA-HepB
Hib†
Hib-HepB
Human papillomavirus (2vHPV, 4vHPV, 9vHPV†)
Influenza (LAIV,† IIV,† RIV†)
IPV†
Meningococcal (Hib-MenCY,† MenACWY-D, MenACWY-CRM,† MPSV4, MenB-4C, MenB-FHbp†)
Pneumococcal (PCV13, PPSV23)
Rotavirus† (RV1, RV5)
Diphtheria toxoid, Tetanus toxoid, and Pertussis (DT, DTaP, DTaP-HepB-IPV, DTaP-IPV, DTaP-IPV/Hib, Tdap, Td, TT)

Hospital Pharmacy CoPs

RELIAS | LEARNING

CMS Hospital CoPs

- Hospital Conditions of Participation are called the CoPs for short
- It is Appendix A and is 525 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_Appendicestoc.pdf

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.

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
- Medical Staff (such as the MEC) is responsible for developing P&P to minimize drug error
- Function may be delegated to the pharmacy service

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

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, re-packaging, 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.

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

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 delays 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

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 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 a problematic CMS standard

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, USP 800 hazardous drugs), standards by nationally recognized organizations (ASHP, FDA, NIH, USP, ISMP, etc.)

USP Hazardous Drugs in Hospitals

- February 1, 2016 USP published the new standards
- Will apply to hospitals effective July 1, 2018
- That handle drugs identified as hazardous or potentially hazardous by NIOSH
- Done to help protect healthcare workers
  - For more information go to www.usp.org/news/usp-publishes-standard-handling-hazardous-drugs-healthcare-settings
  - FAQ at www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

USP 800 Hazardous Drugs

BRIEFING

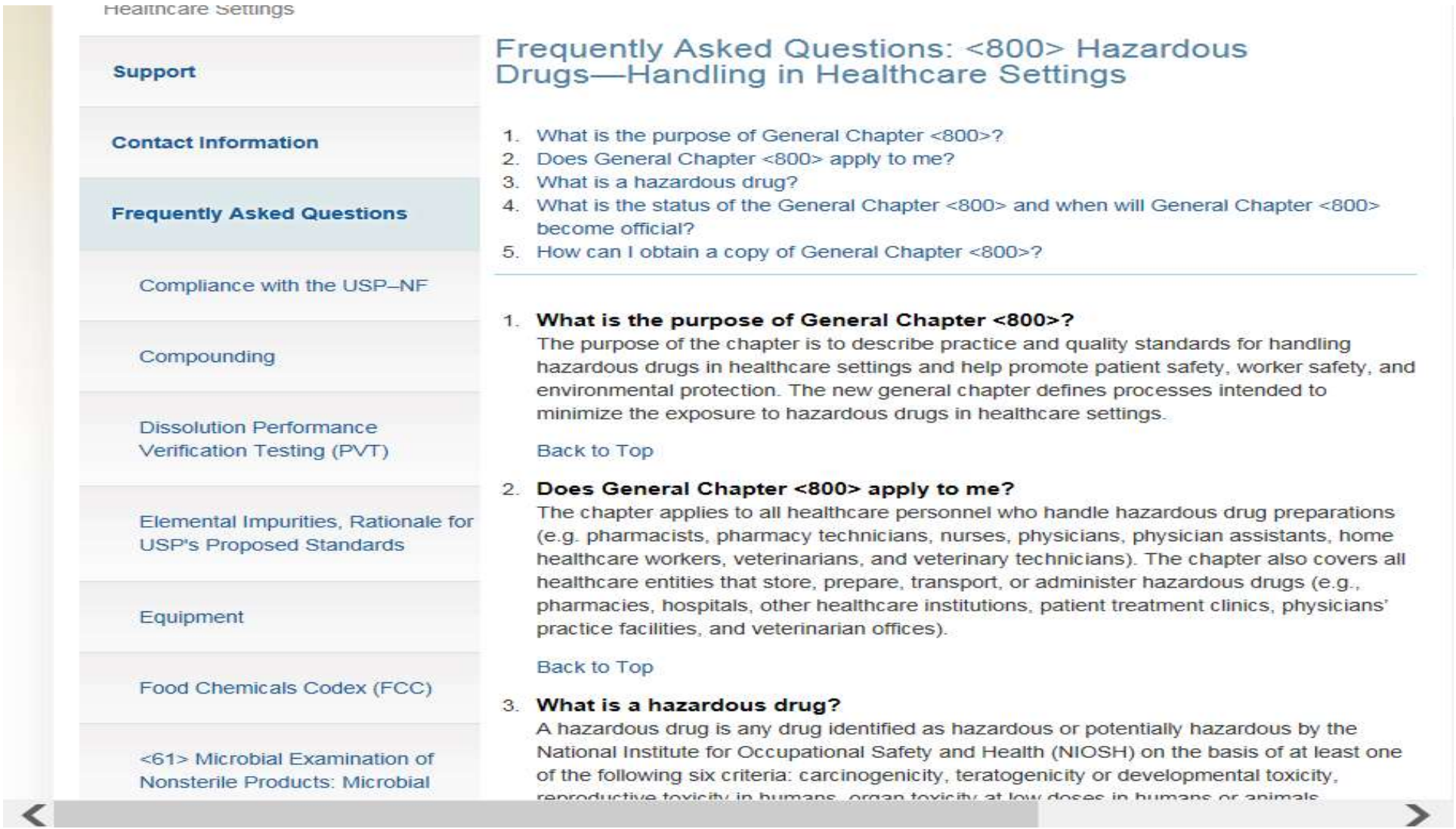
《800》 Hazardous Drugs—Handling in Healthcare Settings. Because there is no existing *USP* chapter for this topic, the Compounding Expert Committee and the Compounding with Hazardous Drugs Expert Panel propose this new general chapter to guide the handling of hazardous drugs in healthcare settings. This new general chapter has been created to identify the requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs to protect the patient, healthcare personnel, and environment. Facility requirements that differ from general chapter 《797》 *Pharmaceutical Compounding—Sterile Preparations* and this chapter will be harmonized. These differences include the following:

1. Elimination of the current allowance in 《797》 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 area designated 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 CSP may be prepared in a BSC located in a C-SCA, provided the beyond-use date of the CSP does not exceed 12 hours. A CACI that meets the requirements in 《797》 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 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 *CompoundingSL@usp.org*.

www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf

USP 800 Hazardous Drugs



Healthcare Settings

Support

Contact Information

Frequently Asked Questions

Compliance with the USP–NF

Compounding

Dissolution Performance Verification Testing (PVT)

Elemental Impurities, Rationale for USP's Proposed Standards

Equipment

Food Chemicals Codex (FCC)

<61> Microbial Examination of Nonsterile Products: Microbial

Frequently Asked Questions: <800> Hazardous Drugs—Handling in Healthcare Settings

1. What is the purpose of General Chapter <800>?
2. Does General Chapter <800> apply to me?
3. What is a hazardous drug?
4. What is the status of the General Chapter <800> and when will General Chapter <800> become official?
5. How can I obtain a copy of General Chapter <800>?

1. **What is the purpose of General Chapter <800>?**
The purpose of the chapter is to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection. The new general chapter defines processes intended to minimize the exposure to hazardous drugs in healthcare settings.

Back to Top

2. **Does General Chapter <800> apply to me?**
The chapter applies to all healthcare personnel who handle hazardous drug preparations (e.g. pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians). The chapter also covers all healthcare entities that store, prepare, transport, or administer hazardous drugs (e.g., pharmacies, hospitals, other healthcare institutions, patient treatment clinics, physicians' practice facilities, and veterinarian offices).

Back to Top

3. **What is a hazardous drug?**
A hazardous drug is any drug identified as hazardous or potentially hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals

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

List of Hazardous Drugs in Healthcare

CDC Home

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

NIOSH
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The National Institute for Occupational Safety and Health (NIOSH)

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

DHHS (NIOSH) Publication Number 2014-138 (Supersedes 2012-150) September 2014

The National Institute for Occupational Safety and Health (NIOSH) Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings was published in September 2004. In Appendix A of the Alert, NIOSH identified a sample list of major hazardous drugs. The list was compiled from information provided by four institutions that had generated lists of hazardous drugs for their respective institutions, as well as a list from the Pharmaceutical Research and Manufacturers of America (PhRMA). The 2004 list was updated in 2010 and 2012. The current update (2014) adds 27 drugs and includes a review of the 2004 list and the consequent removal of 12 drugs that did not meet the NIOSH criteria for hazardous drugs. In addition, a new format has been developed for the list of hazardous drugs, as described below. The review process for the addition of the new listings is described in the Federal Register: http://www.cdc.gov/niosh/docket/review/docket233/pdf/CDC-2013-0007.pdf.

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

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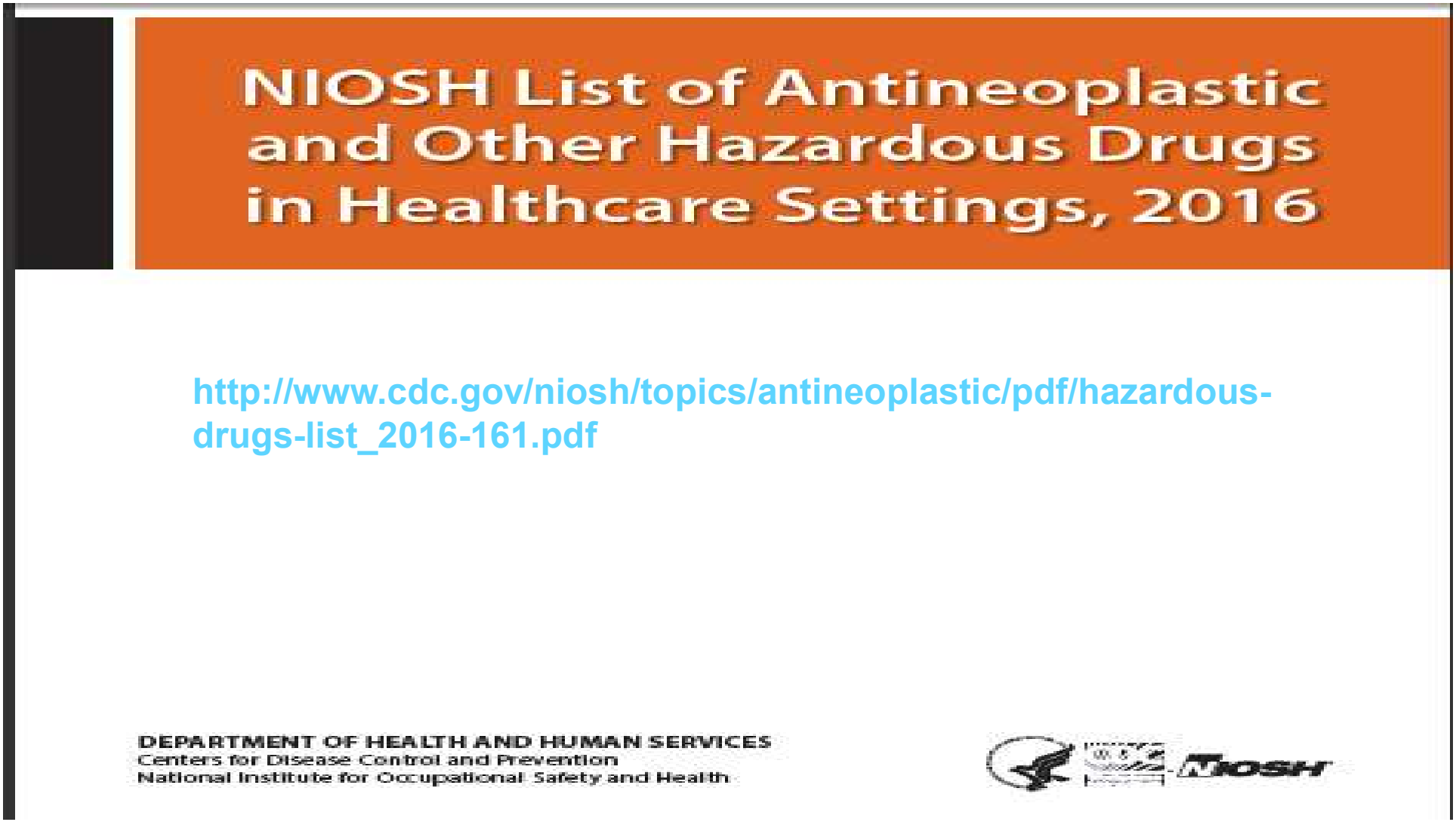
Contact Us:

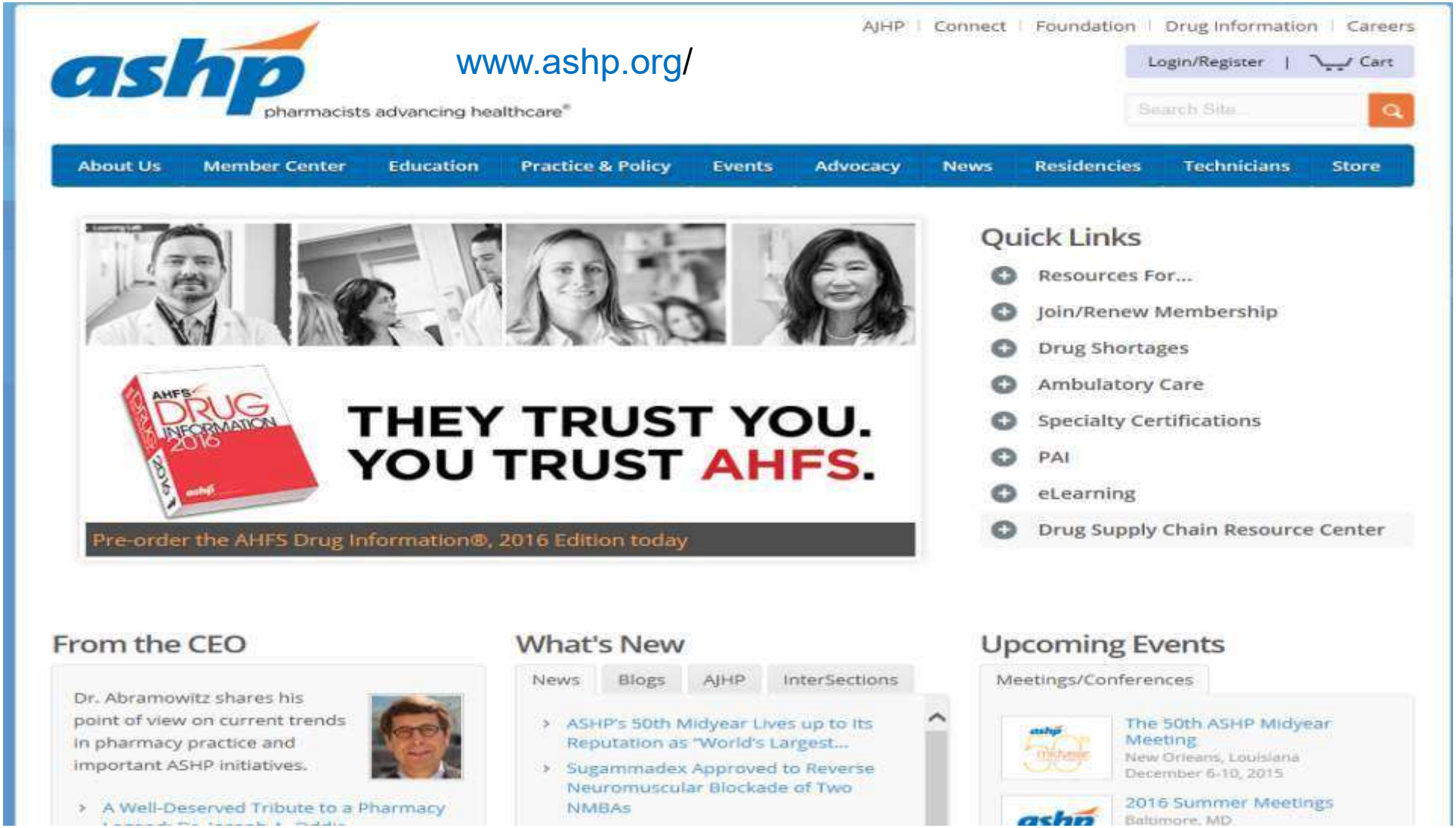
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention
800-CDC-INFO (800-232-4636)
TTY: (888) 232-6348
New Hours of Operation
8am-8pm ET/Monday-Friday
Closed Holidays
Contact CDC-INFO

2016 NIOSH Hazardous Drugs



ISMP Institute for Safe Medication Practices

American Society of Healthsystem Pharmacist



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Quality Matters Blog
What the Letters "USP" Mean on the Label of Your Medicine
USP–NF Excipients: Challenges &

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

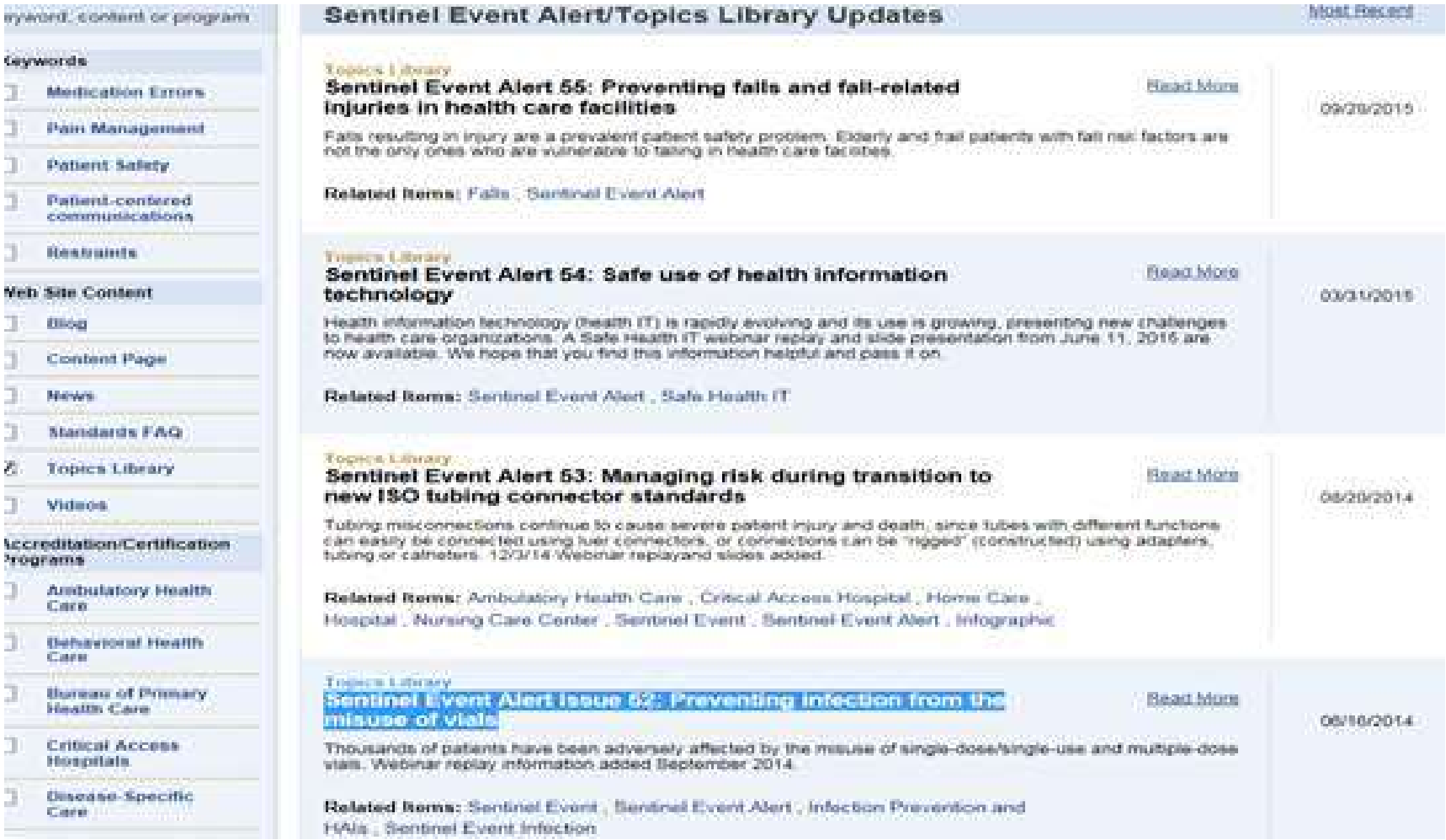
P&Ps for Minimizing Drug Errors

- 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

National Coordinating Council

Pharmacy Alerts NAN

Many TJC SEAs are Medication Related



FDA Website Has Many Resources

ASHP Foundation

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

Institute for Safe Medication Practices (ISMP)

ISMP List of *High-Alert* Medications in Acute Care Settings

Printer friendly version

www.ismp.org/Tools/institutionalhighAlert.asp

...sing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies like improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; standardizing the ordering, storage, preparation, and administration of these products; and employing redundancies such as automated or independent doublechecks when necessary. (Note: manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list).

Classes/Categories of Medications	Specific Medications
adrenergic agonists, IV (e.g., **EPINEPH**rine, phenylephrine, norepinephrine)	**EPINEPH**rine, subcutaneous
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)	epoprostenol (Flolan), IV
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)	insulin U-500 (special emphasis)*
antiarrhythmics, IV (e.g., lidocaine, amiodarone)	magnesium sulfate injection
antithrombotic agents, including:	methotrexate, oral, nononcologic use
■ anticoagulants (e.g., warfarin, low molecular weight heparin, IV unfractionated heparin)	opium tincture
	oxytocin, IV
	nitroprusside sodium for injection

So What's In Your Policy?

WISCONSIN PATIENT SAFETY INSTITUTE

PO Box 1551
Madison, WI 53701
Voice: 608.442.3789
800.362.8976
Fax: 608.263.5402
www.WPSI.org

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, thereby improving patient safety.

DEFINITION

High Alert Medications are drugs that bear a higher risk of causing significant patient harm when they are used in error.[1]

POLICY

A. The following medications are appropriate for inclusion in a High Alert Medications policy.

- Epidural infusions
- Fentanyl
- Heparin (>100 units, flushes exempt)
- Insulin (including regular, aspart, NPH, and glargine)
- Lidocaine with epinephrine vials
- Neuromuscular blocking agents (atracurium, cisatracurium, mivacurium, pancuronium, rapacuronium, rocuronium, succinylcholine, vecuronium, etc)
- Patient Controlled Analgesia (PCA) infusions of any medication
- Total Parenteral Nutrition (TPN) and Total Nutrient Admixture (TNA) solutions
- Oncologic agents
- Moderate sedation agents (e.g., midazolam)

B. The following medications may also be appropriate for inclusion in a High Alert Medication policy in addition to the medications above:

- Glycoprotein IIb/IIIa inhibitors (eptifibatide, abciximab, tirofiban)
- Iron Dextran
- Adrenergic antagonists agents (e.g., esmolol)
- Anticonvulsants

C. Concentrated electrolyte vials (e.g., potassium chloride) should not be stocked in patient care areas.

PROCEDURES

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

Prescribing

A. Verbal orders for High Alert Medications should be discouraged.

B. If possible, prescribing for High Alert Medications should be standardized using preprinted orders.

Preparation and dispensing

A. All storage locations should be clearly labeled and separated from regular stock. If High Alert Medications must be kept in patient care areas, locked storage areas should be used with a distinct High Alert Medication warning label visibly placed on the storage bin.

High Alert How to Guide IHI

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 five million incidents of medical harm between December 2006 and December 2008. The How-to

www.ihi.org/NR/rdonlyres/8B2475CD-56C7-4D9B-B359-801F3CC3A8D5/0/HighAlertMedicationsHowToGuide.doc

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

ASHP Sterile Compounding Resources

Outsourcing Vendor Assessment Tool

www.ashpfoundation.org/sterileproductstool

Safety Concerns of Investigational Meds

Institute for Safe Medication Practices
1800 Byberry Road, Suite 810, Huntingdon Valley, PA 19006
www.ismp.org

FOR IMMEDIATE RELEASE
November 7, 2007

CONTACT: Renee Brehio, Media Relations
704-831-8822
rbrehio@ismp.org

Product-Related Issues Lead to Potential Errors with Investigational Drugs

Huntingdon Valley, Pa.—Routine practices used to name, label, package, and store investigational drugs raise serious patient safety concerns, warns the Institute for Safe Medication Practices (ISMP). In the most recent issue of the *ISMP Medication Safety Alert!* newsletter, the Institute outlines some of those concerns and provides recommendations for safe use.

Safety Concerns www.ismp.org/pressroom/PR20071107_2.pdf

- **Drug names.** Investigational drugs are often identified by a number preceded by an abbreviation of the sponsoring company's name. This may lead to mistakes, including similar names due to participation in multiple studies by same sponsor and truncation of long letter/number designations by pharmacy computer systems. Other mistakes could be due to products receiving a generic or common name during a study that remains on the product label, and changes in code names.
- **Drug labels.** Many investigational drugs are labeled using a very small font size with little use of bold type, color, tall-man letters, or other strategies to help differentiate products. This can lead to confirmation bias when products are selected from the shelf, since the packaging looks so similar.
- **Drug packaging.** Many oral investigational drugs are not supplied in unit-dose packages. Some parenteral drugs may require dozens of vials to prepare a single dose, which sensitizes practitioners to expect to use multiple vials during preparation and makes recognition of overdoses less likely.
- **Tablet markings.** Tablet strengths often look identical and have no markings to help differentiate the strengths. While this may be essential for blinded studies, the same batches of look-alike tablets may be used for open label studies where the tablet strength is known to all participants.

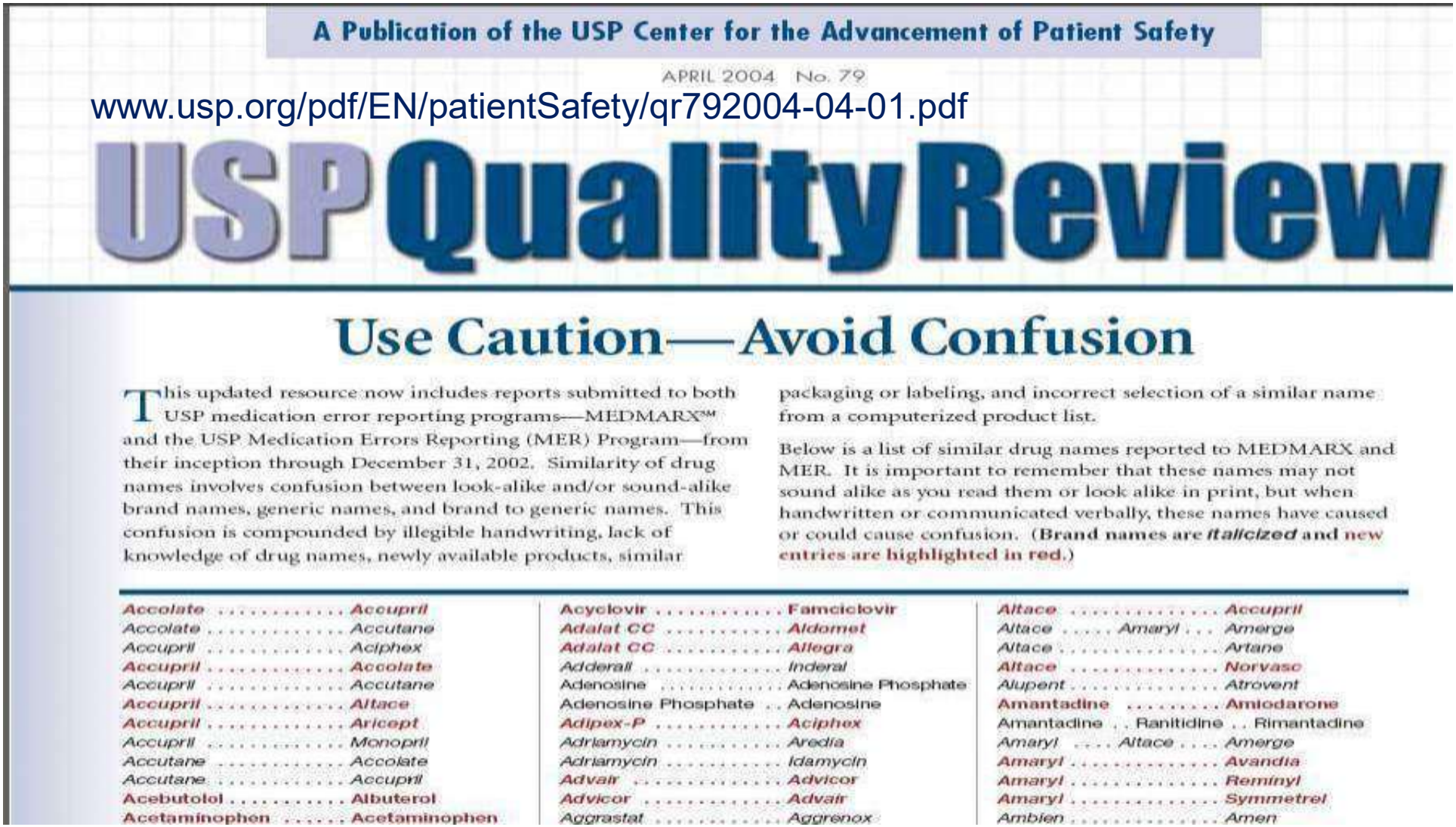
Required Policies and Procedures 491

- Standardize equipment and medication related devices
- CMS says can't have more than 1 or 2 types of equipment such as infusion or PCA 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.)

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
  - 8th 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

USP Confused Name List



A Publication of the USP Center for the Advancement of Patient Safety

APRIL 2004 No. 79

www.usp.org/pdf/EN/patientSafety/qr792004-04-01.pdf

USP Quality Review

Use Caution—Avoid Confusion

This updated resource now includes reports submitted to both USP medication error reporting programs—MEDMARX℠ and the USP Medication Errors Reporting (MER) Program—from their inception through December 31, 2002. Similarity of drug names involves confusion between look-alike and/or sound-alike brand names, generic names, and brand to generic names. This confusion is compounded by illegible handwriting, lack of knowledge of drug names, newly available products, similar packaging or labeling, and incorrect selection of a similar name from a computerized product list.

Below is a list of similar drug names reported to MEDMARX and MER. It is important to remember that these names may not sound alike as you read them or look alike in print, but when handwritten or communicated verbally, these names have caused or could cause confusion. (**Brand names are *italicized* and new entries are highlighted in red.**)

Accolate . . . . . *Accupril*	*Acyclovir* . . . . . Famciclovir	*Altace* . . . . . *Accupril*
Accolate . . . . . *Accutane*	*Adalat CC* . . . . . *Aldomet*	*Altace* . . . . . *Amaryl* . . . *Amerge*
Accupril . . . . . *Aciphex*	*Adalat CC* . . . . . *Allegra*	*Altace* . . . . . *Artane*
Accupril . . . . . *Accolate*	*Adderall* . . . . . *Inderal*	*Altace* . . . . . *Norvasc*
Accupril . . . . . *Accutane*	Adenosine . . . . . Adenosine Phosphate	*Alupent* . . . . . *Atrovent*
Accupril . . . . . *Altace*	Adenosine Phosphate . . Adenosine	*Amantadine* . . . . . *Amiodarone*
Accupril . . . . . *Aricept*	*Adipex-P* . . . . . *Aciphex*	Amantadine . . Ranitidine . . Rimantadine
Accupril . . . . . *Monopril*	*Adriamycin* . . . . . *Aredia*	*Amaryl* . . . . *Altace* . . . . *Amerge*
Accutane . . . . . *Accolate*	*Adriamycin* . . . . . *Idamycin*	*Amaryl* . . . . . *Avandia*
Accutane . . . . . *Accupril*	*Advair* . . . . . *Advicor*	*Amaryl* . . . . . *Reminyl*
Acebutolol . . . . . *Albuterol*	*Advicor* . . . . . *Advair*	*Amaryl* . . . . . *Symmetrel*
Acetaminophen . . . . . *Acetaminophen*	*Aggrastat* . . . . . *Aggrenox*	*Ambien* . . . . . *Amen*

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).

The Joint Commission (TJC) established a National Patient Safety Goal that requires each accredited organization to identify a list of look-alike or sound-alike drugs used in the organization. Those names that appear on TJC's list of look-alike or sound-alike names have been noted with a double asterisk (**) below.

Drug Name	Confused Drug Name	*ISMP Medication Safety Alert!®* Acute Care Edition
ABELCET**	amphotericin B**	Vol. 8, Issue 13, 6/26/03
ACCUPRIL	ACIPHEX	Vol. 5, Issue 9, 5/3/00
acetazolamide**	acetohexamide**	Vol. 5, Issue 12, 6/14/00
acetohexamide**	acetazolamide**	Vol. 5, Issue 12, 6/14/00
ACIPHEX	ARICEPT	Vol. 5, Issue 24, 11/29/00
ACIPHEX	ACCUPRIL	Vol. 5, Issue 9, 5/3/00
ACTIVASE	TNKase	Vol. 8, Issue 11, 5/29/03
ACTONEL	ACTOS	Vol. 9, Issue 13, 7/1/04
ACTOS	ACTONEL	Vol. 9, Issue 13, 7/1/04
ADDERALL	INDERAL	Vol. 1, Issue 4, 2/28/96
ADVICOR	ALTOCOR	Vol. 7, Issue 9, 5/1/02

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
  - RCA (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

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 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

ASHP Website on Shortages

FDA has a List of Drug Recalls

FDA Drug Recalls Website

Sign Up to Get Recall Alerts from FDA

FDA MedWatch Program

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

Use Kg and Not Pounds for Children

Acetaminophen Dosing Chart

Acetaminophen (Tylenol) Dose every 4 to 6 hours *Maximum 5 doses in 24 hours*		Infants' Concentrated Drops 80 mg/0.8 mL	Children's Suspension Liquid 160 mg/5 mL	Children's Soft Chews Chewable 80 mg each	Junior Strength Chewable 160 mg each	Adult Regular Strength 325 mg each
		Dropperful (Use only the dropper provided)	Teaspoon (tsp)	Tablet	Tablet	Tablet
Weight	Age					
6-11 lbs	0-3 mos	½ = 0.4 mL				
12-17 lbs	4-11 mos	1 = 0.8 mL	½ tsp			
18-23 lbs	12-23 mos	1 ½ = 0.8+ 0.4mL	¾ tsp			
24-35 lbs	2-3 yrs	2 = 0.8 + 0.8 mL	1 tsp	2	1	
36-47 lbs	4-5 yrs		1 ½ tsp	3	1 ½	
48-59 lbs	6-8 yrs		2 tsp	4	2	
60-71 lbs	9-10 yrs		2 ½ tsp	5	2 ½	1
72-95 lbs	11 yrs		3 tsp	6	3	1 ½
96 lbs +	12 yrs +		4 tsp	8	4	2

Ibuprofen Dosing Chart

Ibuprofen (Motrin, Advil) Dose every 6 to 8 hours *Maximum 4 doses in 24 hours*		Infants' Concentrated Drops 50 mg/1.25 mL	Children's Suspension Liquid 100 mg/5 mL	Children's Chews Chewable 50 mg each	Junior Strength 100 mg each	Adult Regular Strength 200 mg each
		Dropperful (Use only the dropper provided)	Teaspoon (tsp)	Tablet	Tablet	Tablet
Under 6 mos		*Consult Your Child's Provider*				
Weight	Age					
12-17 lbs	6-11 mos	1=1.25 mL				
18-23 lbs	12-23 mos	1 ½ =1.875 mL				
24-35 lbs	2-3 yrs		1 tsp	2		
36-47 lbs	4-5 yrs		1 ½ tsp	3		
48-59 lbs	6-8 yrs		2 tsp	4	2	
60-71 lbs	9-10 yrs		2 ½ tsp	5	2 ½	
72-95 lbs	11 yrs		3 tsp	6	3	
96 lbs +	12 yrs +		4 tsp	8	4	2

Acetaminophen& Ibuprofen Dosing Charts

Fever Medication: Dosage Charts

Acetaminophen Dosage Chart

Dosages may be repeated every four hours, but should not be given more than five times in twenty- four hours. (Note Milliliter is abbreviated as mL; 5 mL equals 1 teaspoon [tsp]. Don't use household teaspoons, which can vary in size.) Be sure to read the label to make sure you are using the right product.

Age*	Weight†	Infant Drops 80 mg/0.8 mL	Children's Elixir 160 mg/5 mL	Chewable Tablets 80 mg tabs
0-5 mos.	6-11 lbs. (2.7-5 kg)	0.4 mL	-	-
6-11 mos.	12-17 lbs. (5.5-7.7 kg)	0.8 mL	½ tsp	1 tab
1-2 yrs.	18-23 lbs. (8.2-10.5 kg)	1.2 mL	¾ tsp	1½ tabs
2-3 yrs.	24-35 lbs. (10.9-15.9 kg)	1.6 mL	1 tsp	2 tabs
4-5 yrs.	36-47 lbs. (16.3?21.4 kg)	2.4 mL	1½ tsps	3 tabs

*: Note: Age is provided as a convenience only. Dosing for fever should be based on current weight.

†: Weight given is representative of the age range.

www.healthychildren.org/Documents/tables/Fever-Med-Dosage.html

Ibuprofen Dosage Chart

Dosages may be repeated every six to eight hours, but should not be given more than four times in twenty- four hours. (Note: Milliliter is abbreviated as mL; 5 mL equals 1 teaspoon [tsp]. Don't use household teaspoons, which can vary in size.) Be sure to read the label to make sure you are using the right product.

Age*	Weight†	Infant Drops 50 mg/1.25 mL	Children's Elixir 100 mg/5 mL	Chewable Tablets 50 mg tabs
6-11 mos.	12-17 lbs. (5.5-7.7 kg)	1.25 mL	2.5 mL	-
	18-?? lbs.			

CDC Dosing Charts HIV Meds

Peds Dosing Guide 22" x 10" 112706 11/27/06 11:30 AM Page 1

www.cdc.gov/globalaids/docs/program-areas/pmtct/peds-dosing-guide.pdf

Weight range (kg)	Abacavir (Ziagen®, ABC)		Didanosine (Videx®, DDI)			Lamivudine (Epivir®, 3TC)		Stavudine (Zerit®, d4T)		Zidovudine (Retrovir®, ZDV, AZT)		
	8 mg/kg/dose TWICE daily		90-120 mg/m^2/dose TWICE daily	120 mg/m^2/dose TWICE daily	180-240 mg/m^2/dose ONCE daily	4 mg/kg/dose TWICE daily		1 mg/kg/dose TWICE daily		180-240 mg/m^2/dose TWICE daily		
	20 mg/ml solution	300 mg tablets	10 mg/ml suspension	25, 50, 100 mg chewable tablets	125, 200, 250, 400 mg EC capsules	10 mg/ml solution	150 mg tablets	1 mg/ml solution	15, 20, 30 mg capsules	10 mg/ml syrup	100 mg capsules	300 m tablet
5 - 5.9	2 ml		4 ml	25 mg + 25 mg tabs		3 ml		6 ml		6 ml		
6 - 6.9	3 ml		5 ml	25 mg + 25 mg tabs		3 ml		7 ml	10 mg (as 0.5 x 20 mg)	7 ml		
7 - 7.9	4 ml		6 ml	25 mg + 25 mg tabs		4 ml		8 ml	10 mg (as 0.5 x 20 mg)	8 ml		
8 - 8.9	4 ml		6 ml	25 mg + 25 mg tabs		4 ml		9 ml	10 mg (as 0.5 x 20 mg)	9 ml	1 cap	
									10 mg			

Significance of Accurate Patient Weight

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 a 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

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

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

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

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

So What's In Your Policy?

POLICY AND PROCEDURE MANUAL

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 of 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) Storage – 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 of products received and their security.

Specifically, JDH will ensure proper handling of medications by allowing only Pharmacist/Pharmacist 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=3f3fe330fb5d2d63e8a6f7b1c6bb933f&mc=true&tpl=/ecfrbrowse/Title21/21cfrv9_02.tpl#0

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 1303.37	QUOTAS
1304	1304.01 to 1304.55	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 1307.31	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 LIST I CHEMICALS
1310	1310.01 to 1310.21	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

USP's National Formulary Blue Box

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

According to the Federal Food, Drug and Cosmetic Act (FCDA), the official compendia of the United States for excipients, drug substances, and drug products is the USP/NF. It is published every year in November by the United States Pharmacopeial Convention (http://www.usp.org/) and includes two supplements published in February and June.

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.

APA American Pharmacists Association

www.pharmacist.com/

ACCP Website

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

So What's In Your High Risk Med Policy?

General Hospital MEDICAL CENTER

HIGH ALERT MEDICATIONS

I. 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.

II. 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.

III. EQUIPMENT: A. High Alert Medication List
B. Medication Administration Record

IV. WHO DOES IT: A. Two licensed nurses, one being an RN

V. PROCEDURE: A. The high-alert list includes the medication groups that we determined were our highest risk medications. The list may be altered as necessary.

1. **Insulin, (subcutaneous,IV)**
2. **Heparin (LMWH, subcutaneous, IV)**
3. **Potassium chloride for injection concentrate**

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

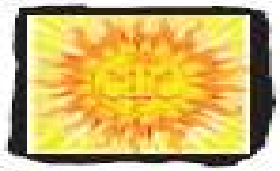
Pharmacy Delivery of Service 500

- 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
- 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

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

Medication List From RED



What medicines do I need to take?

Each day, follow this schedule:

Morning Medicines			
Medicine name (generic and name brand) and amount	Why am I taking this medicine?	How much do I take?	How do I take this medicine?

TJC Medication Reconciliation

Reconciling Medication Information

Hospital Accreditation Program

NPSG.03.06.01

Maintain and communicate accurate patient medication information.

Elements of Performance for NPSG.03.06.01

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.
   Note 1: Current medications include those taken at scheduled times and those taken on an as-needed basis. See the Glossary for a definition of medications.
   Note 2: It is often difficult to obtain complete information on current medications from a 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.
2. Define the types of medication information to be collected in non–24-hour settings and different patient circumstances.
   Note 1: Examples of non–24-hour settings include the emergency department, primary care, outpatient radiology, ambulatory surgery, and diagnostic settings.
   Note 2: Examples of medication information that may be collected include name, dose, route, frequency, and purpose.
3. Compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies.
   Note: Discrepancies include omissions, duplications, contraindications, unclear information, and changes. A qualified individual, identified by the hospital, does the comparison. (See also HR.01.06.01, EP 1)
4. Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose).
   Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications. For more information about communications to other providers of care when the patient is discharged or transferred, refer to Standard PC.04.02.01.
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.
   Note: Examples include 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 in 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.)

CMS Proposed Discharge Planning

FEDERAL REGISTER

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

www.gpo.gov/fdsys/pkg/FR-2015-11-03/pdf/2015-27840.pdf

Part IV

Department of Health and Human Services

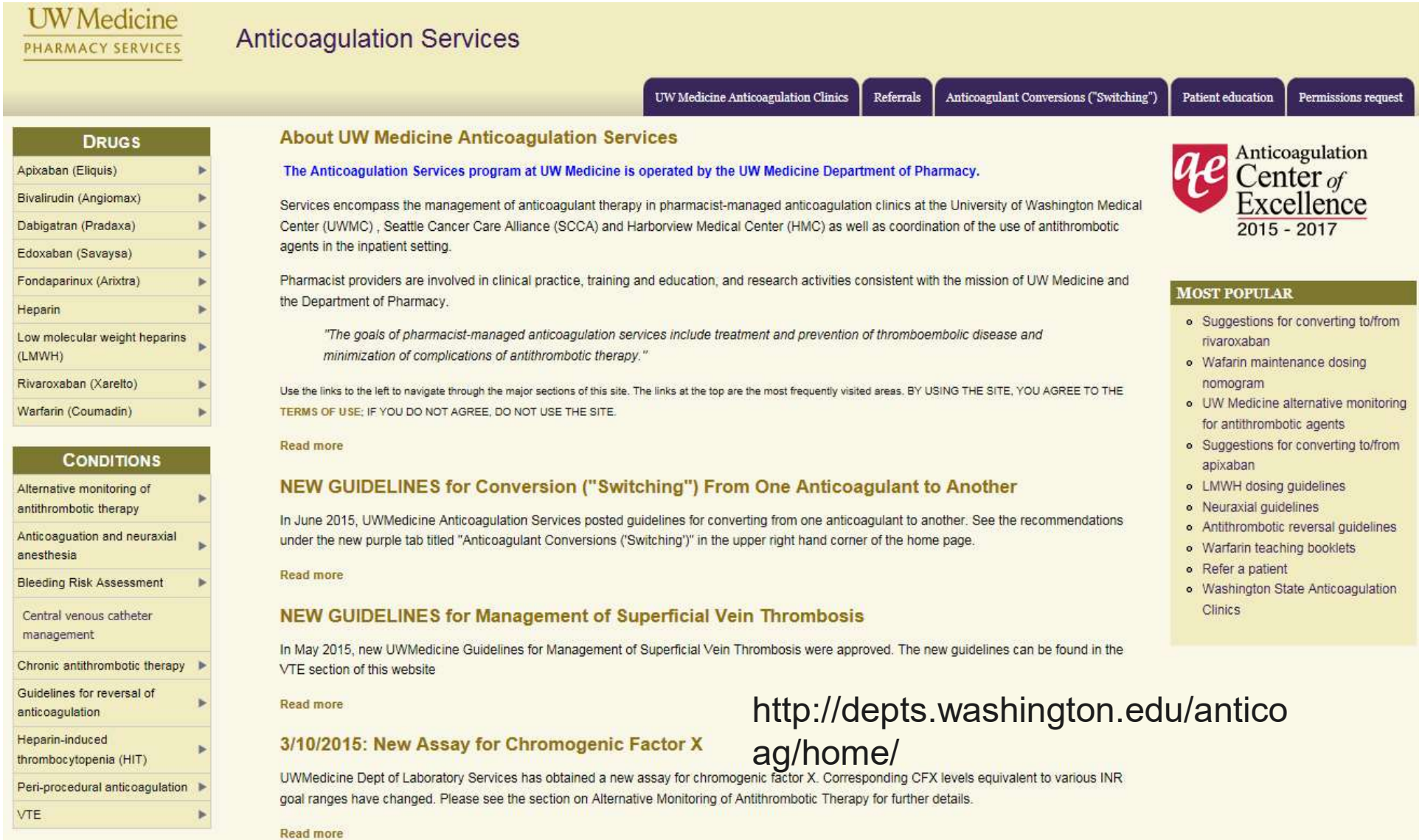
Centers for Medicare and Medicaid Services

42 CFR Parts 482, 484, 485
Medicare 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 request 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

Anticoagulant Resources UM



http://depts.washington.edu/anticoag/home/

Warfarin Maintenance Dosing Nomogram

Guidelines for warfarin maintenance dosing adjustments

For Goal INR 2-3	Dosing Adjustments	For Goal INR 2.5-3.5
INR < 1.5	• consider a booster dose of 1 ¼ -2 times daily maintenance dose • consider resumption of prior maintenance dose if factor causing decreased INR is transient [eg: missed warfarin dose(s)] • if adosage adjustment is needed, increase maintenance dose by 10%–20%	INR < 2.0
INR 1.5–1.7	• consider a booster dose of 1 ¼ – 2 times daily maintenance dose • consider resumption of prior maintenance dose if factor causing decreased INR is considered [eg: missed warfarin dose(s)] • if a dosage adjustment is needed, increase maintenance dose by 5–15%	INR 2.0–2.3
INR 1.8–1.9	• *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 in the judgment of the clinician, the INR does not represent an increased risk of thromboembolism for the patient* • consider a booster dose of 1 ¼ – 2 times daily maintenance dose • consider resumption of prior maintenance dose if factor causing decreased INR is transient [eg: missed warfarin dose(s)] • if a dosage adjustment is needed, increase maintenance dose by 5%–10%	INR 2.3–2.4
2.0-3.0	**Desired range**	2.5-3.5
3.1-3.2	• 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 in the judgment of the clinician, the INR does no represent an increased risk of hemorrhage for the patient • consider continuation of prior maintenance dose if factor causing elevated INR is transient [eg: acute alcohol ingestion] • if a dosage adjustment is needed, decrease maintenance dose by 5%–10%	3.6-3.7
	• consider holding ¼ to 1 dose • consider resumption of prior maintenance dose if factor causing elevated INR is	

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

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

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

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

FDA's Compounding Website

Use a Company that is Registered

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

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

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."*

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

Proposed USP Changes to 797

- Note that in September 2015, USP proposed some changes to USP 797
- Some of the major revisions included reorganizing the previous microbial risk categories from three (low, medium, and high) to two (Category 1 and 2)
  - They are distinguished by the BUD and the environment you compound in
- Also introducing new "in-use time" terminology to better define the time frame in which compound sterile preparations (CSP) must be used after it has been opened or punctured

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 CSPs 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.*

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

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

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.

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

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

FDA Resources on Drug Diversions

Prevention Resources:

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

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www.cdc.gov/injectionsafety/drugdiversion/index.html

Enforcement Agencies:

- Drug Enforcement Administration
- FDA Office of Criminal Investigations

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State Health Department Reports:

- Minnesota Controlled Substance Diversion Prevention Coalition [PDF - 391 KB]
- New Hampshire Hepatitis C Outbreak Report [PDF - 3.93 MB]
- Public Health Vulnerability Review: Drug Diversion, Infection Risk [PDF - 1.04 MB]

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

ISMP Guidance on ADCs

Institute for Safe Medication Practices (ISMP)

Guidance on the Interdisciplinary Safe Use of Automated Dispensing Cabinets

www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf

- Limit over rides
- Link ADC to pharmacy computer for profiling
- Use biometric use identification
- Return all meds in secure one-way bin
- Document the destruction of medication waste

Institute for Safe Medication Practices

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

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

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 in a private office unless visitors are not allowed without supervision of staff
- P&P need to address security of any carts containing drugs

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

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

Medications in the OR ASA Position

www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

American Society of Anesthesiologists®

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

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

1. Access to operating room suites must be strictly limited to authorized persons.
2. All Schedule 3 and 4 narcotic medications must be kept in locked enclosed areas when not under the direct control of an anesthesia professional.
3. Anesthesia professionals must have immediate access to drugs required for emergency patient care. Procedures designed to prevent unauthorized access to such drugs must be consistent with this imperative for patient safety.
4. Anesthesia carts and anesthesia machines may remain unlocked, and non-controlled* medications may be left in or on top of unlocked anesthesia carts or anesthesia machines immediately prior to, during, and immediately following surgical cases in an operating room, so long as there are authorized operating room personnel in the OR suite.

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

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[1]
- Security of medications in the operating room

[1]http://www.asahq.org/publicationsAndServices/sgstoc.htm

ASA Guidelines and Statements

Recommendation on Medications in the OR

The Official Journal of the Anesthesia Patient Safety Foundation

apsf NEWSLETTER Spring 2010

www.apsf.org/newsletters/html/2010/spring/04_conference.htm

In this issue:

APSF Hosts Medication Safety Conference

APSF Funds New Registry

Web Application to Track Patient Safety During Sedation

Dear SIRS—Why Do New Defaults Turn Off CO_2 and Apnea Alarms?

Q&A—Exposure to Ultraviolet Radiation in the Operating Room

Hospital Coalition Group Endorses APSF Recommendations for PCA Monitoring

Letters to the Editor:

Accidental Intrathecal Injection of Tranexamic Acid

APSF Hosts Medication Safety Conference

Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

Overview

On January 26, 2010, the Anesthesia Patient Safety Foundation (APSF) convened a consensus conference of 100 stakeholders from many different backgrounds to develop new strategies for "predictable prompt improvement" of medication safety in the operating room. The proposed new paradigm to reduce medication errors causing harm to patients in the operating room is based on Standardization, Technology, Pharmacy/Prefilled/Premixed, and Culture (STPC). This new paradigm goes far beyond the important but traditional emphasis on medication label format and the admonition to "always read the label." Small group sessions on each of the 4 elements of the new paradigm (STPC) debated and formulated specific recommendations that were organized and prioritized by all the attendees.

The resulting consensus recommendations include:

Standardization

– High-alert drugs (such as phenylephrine and epinephrine) should be available in

Table 1:
Consensus Recommendations for Improving Medication Safety in the Operating Room

Standardization

1. High alert drugs (such as phenylephrine and epinephrine) should be available in standardized concentrations/diluents 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.
2. Ready-to-use syringes and infusions should have standardized fully compliant machine–readable labels.
3. *Additional Ideas:*
   a. Interdisciplinary and uniform curriculum for medication administration safety to be available to all training programs and facilities.
   b. No concentrated versions of any potentially lethal agents in the operating room.
   c. Required read-back in an environment for extremely high alert drugs such as heparin.
   d. Standardized placement of drugs within all anesthesia workstations in an institution.
   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).

Technology

1. Every anesthetizing location should have a mechanism to identify medications before drawing up or administering them (bar code reader) and a mechanism to provide feedback, decision support, and documentation (automated information

Pharmacy/Prefilled/Premixed

1. Routine provider-prepared medications should be discontinued whenever possible.
2. Clinical pharmacists should be part of the perioperative/operating room team.
3. Standardized pre-prepared medication kits by case type should be used whenever possible.
4. *Additional Ideas:*
   a. Interdisciplinary and uniform curriculum for medication administration safety for all anesthesia professionals and pharmacists.
   b. Enhanced training of operating room pharmacists specifically as perioperative consultants.
   c. Deployment of ubiquitous automated dispensing machines in the operating room suite (with communication to central pharmacy and its information management system).

Culture

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.
3. Establish a culture of cooperation and recognition of the

ASA Standard Guidelines and Statements

www.asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx

ASA Sample Policy and Procedure

Figure 1. Sample Language for a Hospital Policy on Anesthesia Medication Security

Pharmaceutical Services

Policies and Procedures — Security of Anesthesia Medications

Preamble

Anesthesiologists use medications both to sedate or anesthetize patients and to relieve pain, most commonly with controlled substances from DEA Schedules II, III and IV. Anesthesiologists also administer medications to manage the neuromuscular system, cardiovascular system and pulmonary system: drugs used for these purposes must be immediately available at all times in any active anesthetizing location. Limiting access to these resuscitation drugs even for a few seconds could seriously compromise patient safety. Any protocols or procedures designed to prevent tampering with or diversion of anesthesia medications must permit immediate access to resuscitation drugs, consistent with federal regulations (42 C.F.R. §462.25(b) (2)) that were revised effective January 26, 2007.

Purpose

This policy provides that medications shall be stored securely to protect the safety of patients and the public health while allowing appropriate access by authorized personnel.

Pharmacy Policies

Pharmacy is ultimately responsible for the storage, dispensing and inventory control of all perioperative medications.

Coordination with Anesthesiology Policies

The Department of Anesthesiology is responsible for the safety of patients under its care. Pharmacy and Anesthesiology will together ensure that medication security policies proposed by either service (1) maintain patient safety, (2) do not conflict with each other and (3) comply with federal and state regulations.

Controlled and Noncontrolled Medications

Drugs used in anesthesiology are divided into controlled (DEA Schedules II, III and IV) and noncontrolled substances. (For the purpose of this policy on medication security, ephedrine and propofol are treated like controlled substances.)

Procedures and Definitions

1. **All anesthesia medications will be kept in a secure area.**
2. **Controlled substances must be locked within a secure area.**

"Secure Area"

- Surgical Intensive Care Unit

Policy and Procedure

- CMS states that they expect hospital P&P to address
- The security and monitoring of any carts including whether locked or unlocked if contains drugs and biologicals
- In all patient care areas to ensure safe storage and patient safety
- P&P to keep drugs secure, prevent tampering, and diversion

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

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 monogram 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

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 commercially manufactured products and are determined after 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 a 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:

Photo courtesy of Baxa

Beyond-Use Dating

By Lou Diorio, RPh, and Dave Thomas, RPh, MBA

http://ldthealthsolutions.com/_articles/200909AssigningBeyondUseDates.pdf

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

Assigning 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 preparations 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) Variability in the intended strength of the correct ingredients (outsi 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 va ables in mind. Although this concept is straightforward, instituting an eff

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)

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

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

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

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

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

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

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)

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

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 content drug error is limited to those errors that actually reach the patient

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 when it should not be, or the wrong dose is administered, or the wrong root 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 drug therapy;

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

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)

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 not 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

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

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

Medication Errors With No Harm 0508

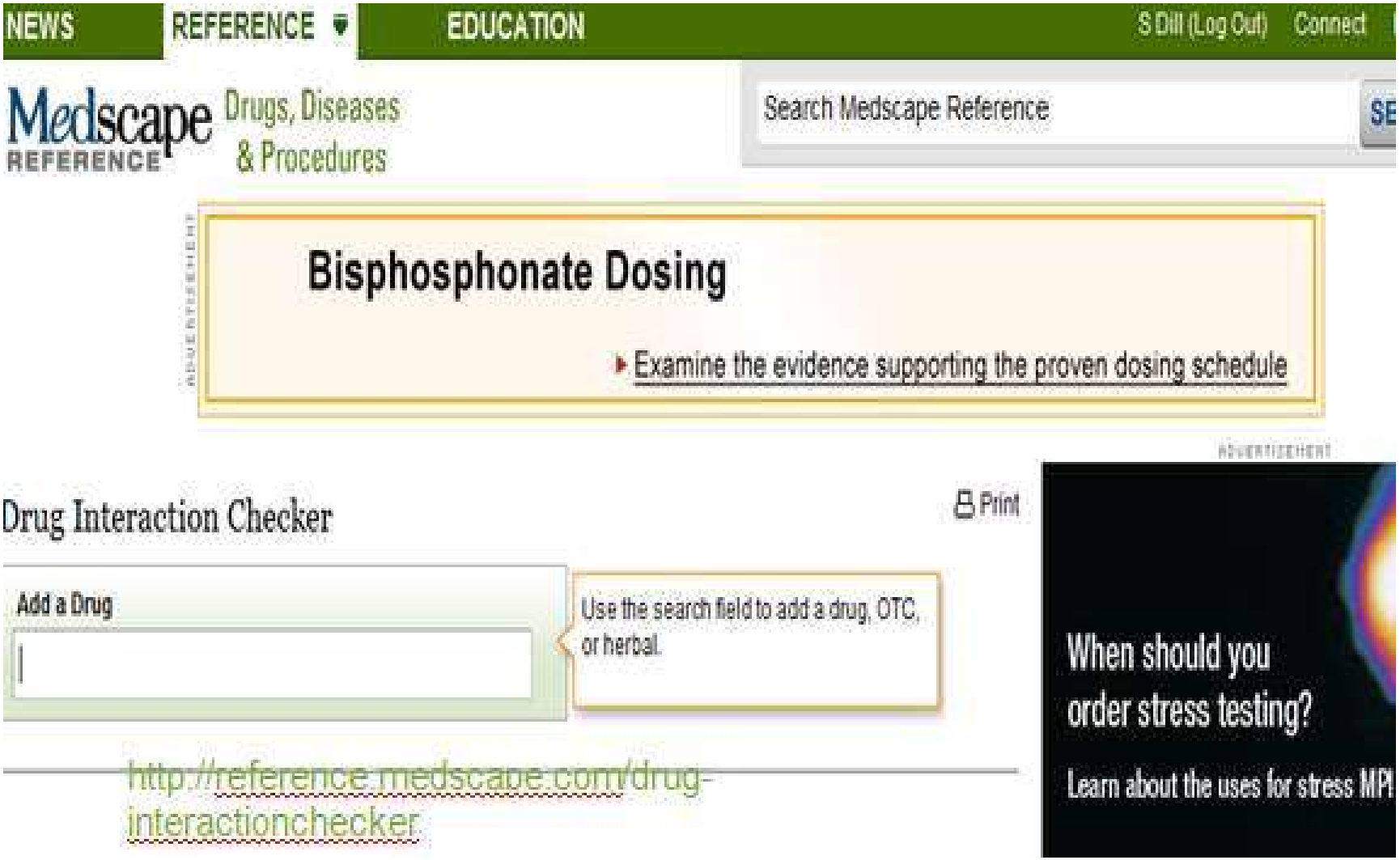
- Medication errors that do not result in harm or insignificant harm to the patient must be documented in the medical record
- These do not require immediate reporting to the attending physician
- Example, nurse forgets to give an analgesic dose during the night shift
  - It can be reported first thing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

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

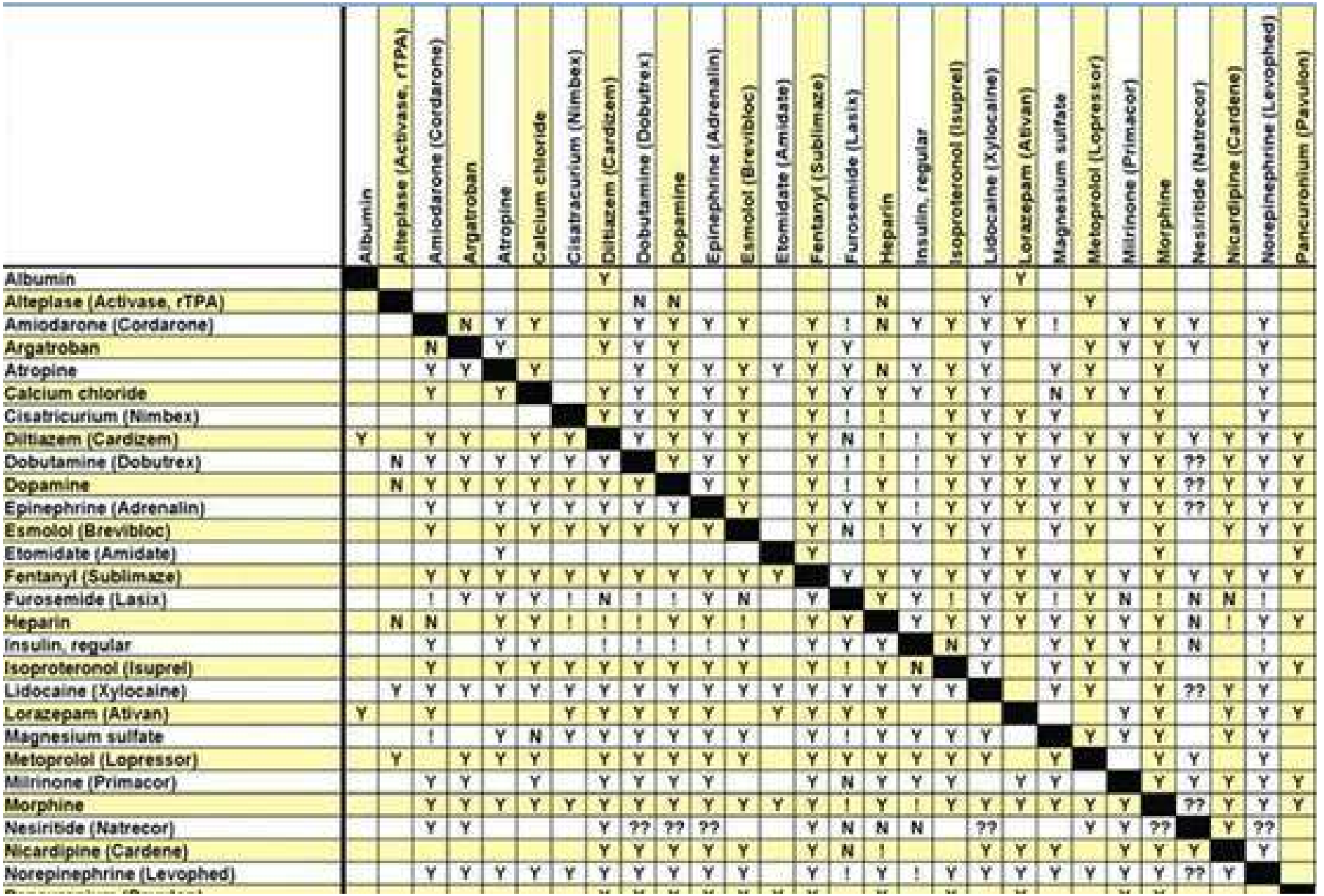
Drug Interactions Checker

Drug Interaction Checker



Pediatric Drug Interaction Checker

Epocrates Online Checker



	Albumin	Alteplase (Activase, rTPA)	Amiodarone (Cordarone)	Argatroban	Atropine	Calcium chloride	Cisatracurium (Nimbex)	Diltiazem (Cardizem)	Dobutamine (Dobutrex)	Dopamine	Epinephrine (Adrenalin)	Esmolol (Brevibloc)	Etomidate (Amidate)	Fentanyl (Sublimaze)	Furosemide (Lasix)	Heparin	Insulin, regular	Isoproterenol (Isuprel)	Lidocaine (Xylocaine)	Lorazepam (Ativan)	Magnesium sulfate	Metoprolol (Lopressor)	Milrinone (Primacor)	Morphine	Nesiritide (Natrecor)	Nicardipine (Cardene)	Norepinephrine (Levophed)	Pancuronium (Pavulon)
Albumin								Y												Y								
Alteplase (Activase, rTPA)									N	N						N			Y			Y						
Amiodarone (Cordarone)				N	Y	Y		Y	Y	Y	Y	Y		Y	!	N	Y	Y	Y	Y	!		Y	Y	Y		Y	
Argatroban			N		Y			Y	Y	Y				Y	Y				Y			Y	Y	Y	Y		Y	
Atropine			Y	Y		Y			Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y		Y	Y		Y			Y	
Calcium chloride			Y		Y			Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y		N	Y	Y	Y			Y	
Cisatricurium (Nimbex)								Y	Y	Y	Y	Y		Y	!	!		Y	Y	Y	Y			Y			Y	
Diltiazem (Cardizem)	Y		Y	Y		Y	Y		Y	Y	Y	Y		Y	N	!	!	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Dobutamine (Dobutrex)		N	Y	Y	Y	Y	Y	Y		Y	Y	Y		Y	!	!	!	Y	Y	Y	Y	Y	Y	Y	??	Y	Y	Y
Dopamine		N	Y	Y	Y	Y	Y	Y	Y		Y	Y		Y	!	Y	!	Y	Y	Y	Y	Y	Y	Y	??	Y	Y	Y
Epinephrine (Adrenalin)			Y		Y	Y	Y	Y	Y	Y		Y		Y	Y	Y	!	Y	Y	Y	Y	Y	Y	Y	??	Y	Y	Y
Esmolol (Brevibloc)			Y		Y	Y	Y	Y	Y	Y	Y			Y	N	!	Y	Y	Y		Y	Y		Y		Y	Y	Y
Etomidate (Amidate)					Y									Y					Y	Y				Y				Y
Fentanyl (Sublimaze)			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Furosemide (Lasix)			!	Y	Y	Y	!	N	!	!	Y	N		Y		Y	Y	!	Y	Y	!	Y	N	!	N	N	!	
Heparin		N	N		Y	Y	!	!	!	Y	Y	!		Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	N	!	Y	Y
Insulin, regular			Y		Y	Y		!	!	!	!	Y		Y	Y	Y		N	Y		Y	Y	Y	!	N		!	
Isoproterenol (Isuprel)			Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	!	Y	N		Y		Y	Y	Y	Y			Y	Y
Lidocaine (Xylocaine)		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y			Y	Y		Y	??	Y	Y	
Lorazepam (Ativan)	Y		Y				Y	Y	Y	Y	Y		Y	Y	Y	Y							Y	Y		Y	Y	Y
Magnesium sulfate			!		Y	N	Y	Y	Y	Y	Y	Y		Y	!	Y	Y	Y	Y			Y	Y	Y		Y	Y	
Metoprolol (Lopressor)		Y		Y	Y	Y		Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y		Y			Y	Y		Y	
Milrinone (Primacor)			Y	Y		Y		Y	Y	Y	Y			Y	N	Y	Y	Y		Y	Y			Y	Y	Y	Y	Y
Morphine			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	!	Y	!	Y	Y	Y	Y	Y	Y		??	Y	Y	Y
Nesiritide (Natrecor)			Y	Y				Y	??	??	??			Y	N	N	N		??			Y	Y	??		Y	??	
Nicardipine (Cardene)								Y	Y	Y	Y	Y		Y	N	!			Y	Y	Y		Y	Y	Y		Y	
Norepinephrine (Levophed)			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	!	Y	!	Y	Y	Y	Y	Y	Y	Y	??	Y		
Pancuronium (Pavulon)																												

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

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

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

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)

IHI Has Three Trigger Tools for ADEs

www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/#Trigger Tools

Trigger Tool for ADE

Trigger Tool for Measuring Adverse Drug Events

The use of "triggers," or clues, to identify adverse drug events (ADEs) is an effective method for measuring the overall level of harm from medications in a health care organization. The Trigger Tool for Measuring Adverse Drug Events provides instructions for conducting a retrospective review of patient records using triggers to identify possible ADEs. This tool includes a list of known ADE triggers and instructions for collecting the data you need to measure the number of ADEs per 1,000 doses and the percentage of admissions with an ADE.

NOTE: You can use this tool in conjunction with the interactive Trigger Tool for Measuring ADEs in the Workspace area on IHI.org. Enter your detailed data from all of your ADE Patient Record Review Sheets into the interactive Trigger Tool for Measuring ADEs. The Tool will automatically calculate and graph two measures: ADEs per 1,000 Doses and Percent of Admissions with an ADE.

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 Tools

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 clues, to identify adverse events (AEs) 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 AE triggers and instructions for collecting the data you need to measure the rate of AEs 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.* 2006;118(4):1332-1340.
http://pediatrics.aappublications.org/cgi/content/abstract/118/4/1332

This NICU Trigger Tool contains:

Measure of Effectiveness 508

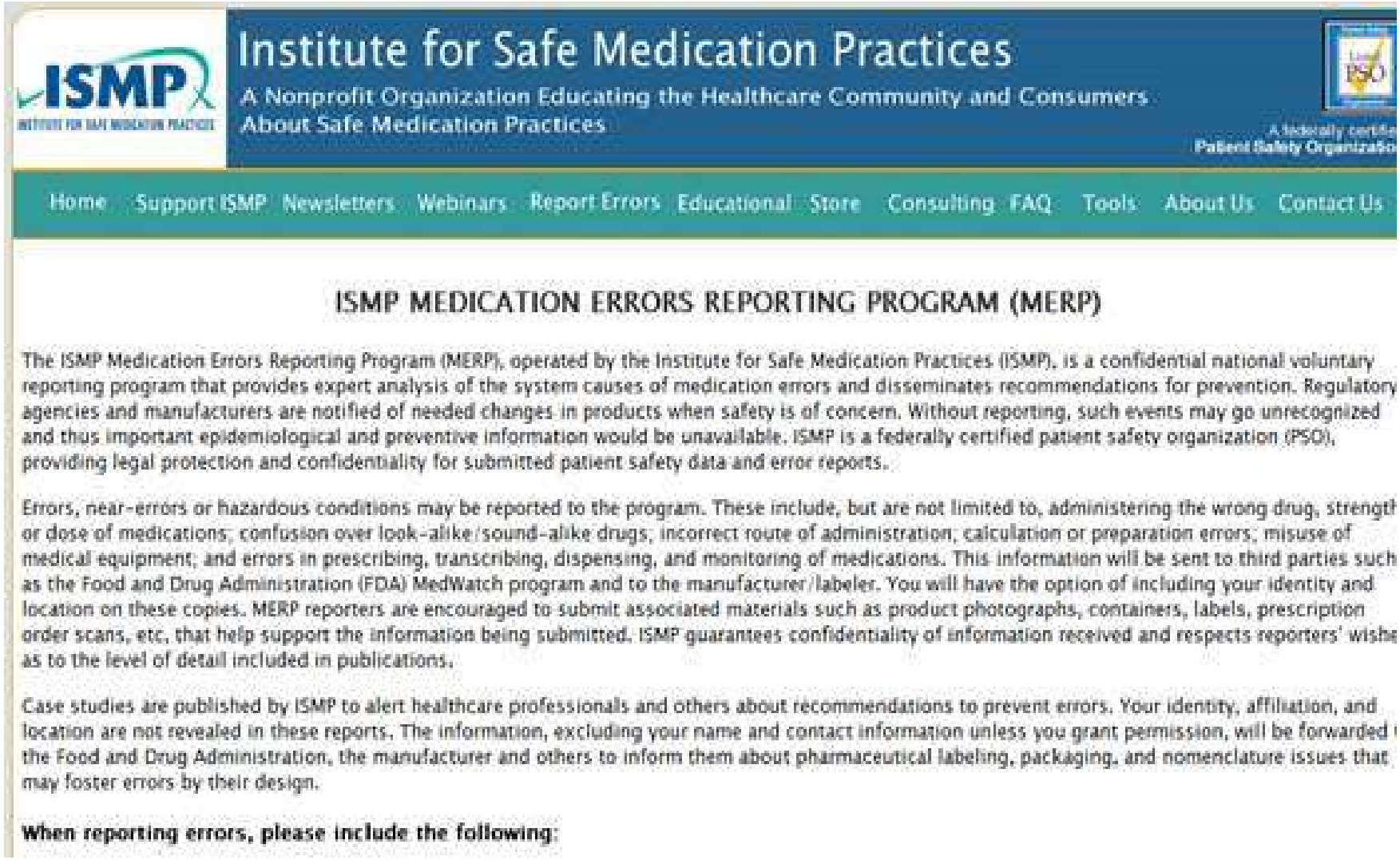
- Hospital must have a method to evaluate the effectiveness of its systems for identifying and reporting medication errors and ADEs to the PI program
- Methods could include the use of standardized benchmarks for size and scope of services provided
  - Or studies on reporting rate published in peer review 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/reporterrortoismp.asp
- Any reports required by any specific state law requirement

FDA Med Watch Program

ISMP Medication Error Reporting Program



Institute for Safe Medication Practices

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

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ISMP MEDICATION ERRORS REPORTING PROGRAM (MERP)

The ISMP Medication Errors Reporting Program (MERP), operated by the Institute for Safe Medication Practices (ISMP), is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern. Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. ISMP is a federally certified patient safety organization (PSO), providing legal protection and confidentiality for submitted patient safety data and error reports.

Errors, near-errors or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications. This information will be sent to third parties such as the Food and Drug Administration (FDA) MedWatch program and to the manufacturer/labeler. You will have the option of including your identity and location on these copies. MERP reporters are encouraged to submit associated materials such as product photographs, containers, labels, prescription order scans, etc, that help support the information being submitted. ISMP guarantees confidentiality of information received and respects reporters' wishe as to the level of detail included in publications.

Case studies are published by ISMP to alert healthcare professionals and others about recommendations to prevent errors. Your identity, affiliation, and location are not revealed in these reports. The information, excluding your name and contact information unless you grant permission, will be forwarded the Food and Drug Administration, the manufacturer and others to inform them about pharmaceutical labeling, packaging, and nomenclature issues that may foster errors by their design.

When reporting errors, please include the following:

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

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

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

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

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

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

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

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

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

SEARCH

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

Drugs

Home > Drugs > Drug Safety and Availability > Drug Shortages

www.fda.gov/cder/drug/shortages/default.htm

Drug Safety and Availability

- Drug Shortages
- Current Drug Shortages Index
- Current Drug Shortages A - D
- Current Drug Shortages E - K
- Current Drug Shortages L - N
- Current Drug Shortages O - R
- Current Drug Shortages S - Z
- Resolved Drug Shortages
- Drugs to be Discontinued
- How to Report a Shortage or Supply Issue
- Frequently Asked Questions

Drug Shortages

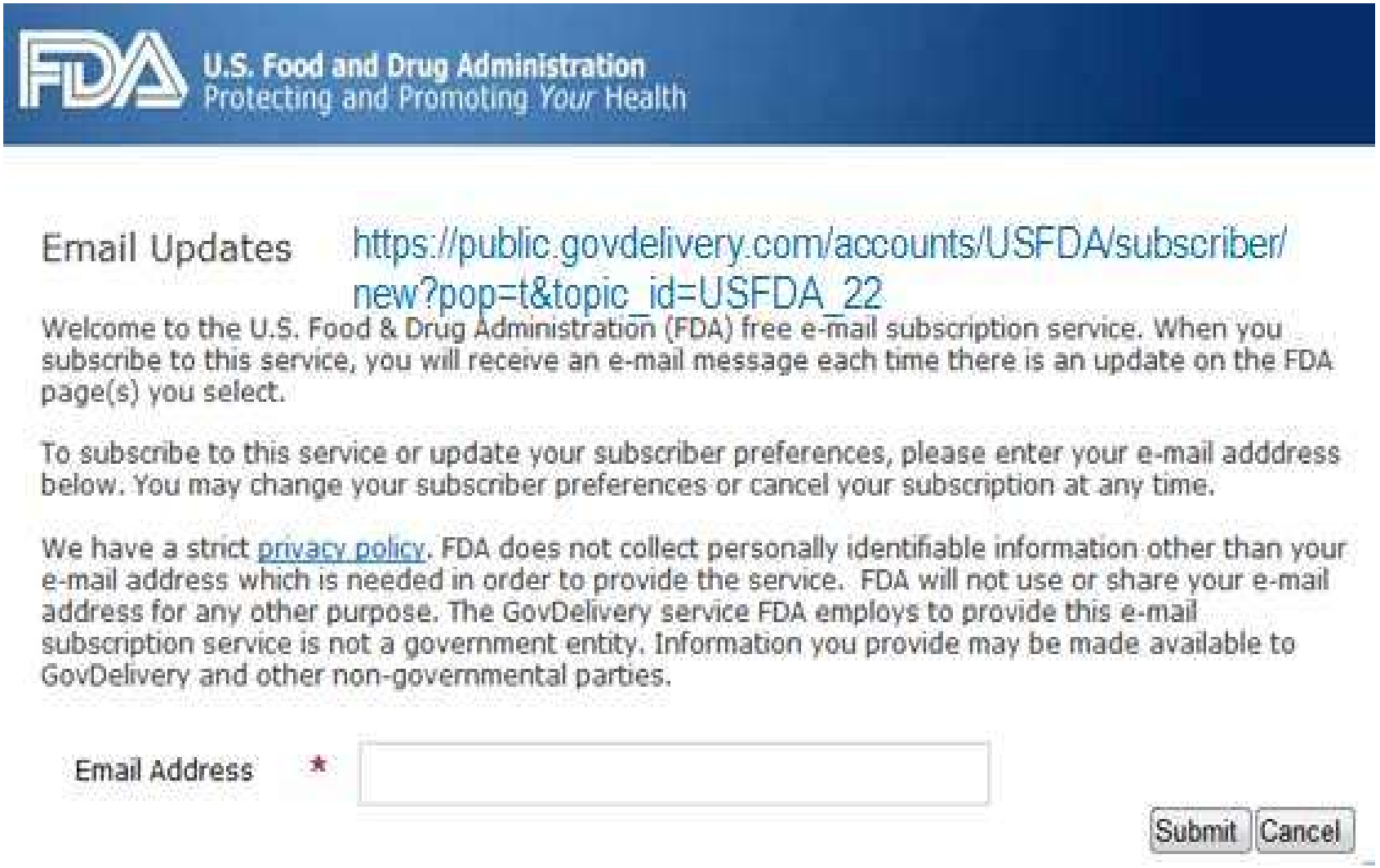
FDA takes great efforts, within its legal authority, to address and prevent drug shortages, which can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. The agency works closely with manufacturers of drugs in short supply to communicate the issue and to help restore availability. FDA also works with other firms who manufacturer the same drug, asking them to increase production, if possible, in order to prevent or reduce the impact of a shortage.

Manufacturers are not required to report information, such as reasons for shortages or the expected duration of shortages. However, many companies voluntarily provide shortage information that FDA posts on its website. FDA encourages and appreciates all reporting of shortages by manufacturers. Shortage notifications and updates may be reported to FDA at drugshortages@fda.hhs.gov.

Spotlight

- Meningitis Outbreak: Voriconazole and Liposomal Amphotericin B Availability Information
- Fact Sheet: Drug Products in Shortage in the United States
- FDA acts to bolster supply of critically needed cancer drugs
- FDA Report: A Review of FDA's Approach to Medical Product Shortages
- Statement from FDA and HHS on Drug Shortages

Sign Up To Get Drug Shortage Information



ASHSP Drug Shortage Website

- American Society of Health System Pharmacist 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

American Society of Health-System Pharmacists
TOGETHER WE MAKE A GREAT TEAM
STORE | AJHP | COMMUNITY | eLEARNING | JOBS | ASHP FOUNDATIC
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Practice & Policy
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HOME > DRUG SHORTAGES
www.ashp.org/shortages
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Current Shortages
Drugs No Longer Available
Resolved Shortages
Guidelines and Resources
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Welcome to the ASHP Drug Shortages Resource Center, the first stop for information and resources on drug product shortages and management. Drug shortages can adversely affect drug therapy, compromise or delay medical procedures, and result in medication errors. ASHP and its partners work to keep the public informed of the most current drug shortages.
Subscribe to RSS | Report a Drug Shortage
FIND DRUG SHORTAGES
Search by Generic Drug Name...
Find
OR
Search by Drug Shortage List...

GAO Drug Shortage Better but Still Continue

United States Government Accountability Office

GAO

Report to Congressional Addressees

www.gao.gov/assets/670/660785.pdf

February 2014

DRUG SHORTAGES

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

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

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)

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)

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)

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)

Storage of Medication Policy

Storage of Medications

Pharmacy:
JDH should seek 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:

- By pharmacist or pharmacist tech
- Controlled substances 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

Additional Resources

- CMS Proposed Changes to CoP Manual & Antibiotic Stewardship
  - CMS proposed standards and
  - TJC requirements under MM.09.01.01
- CMS Survey Memos
  - Safe injection practices
  - infection control breaches
  - fingerstick devices
  - insulin pens and
  - luer misconnections

Additional Resources

- Nursing CoPs affecting Pharmacy and Medication
  - 3 time frames
  - safe opioid use
  - compounding,
  - self-administration
- ISMP IV Push guidelines
- CMS Infection Control Worksheet
  - Safe injection practices
  - MDRO

The End! Questions????

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AD, BA, BSN, MSN, JD
President

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sdill1@columbus.rr.com
(no email question, call)

THANK YOU

RELIAS | LEARNING

Additional Resources

RELIAS | LEARNING

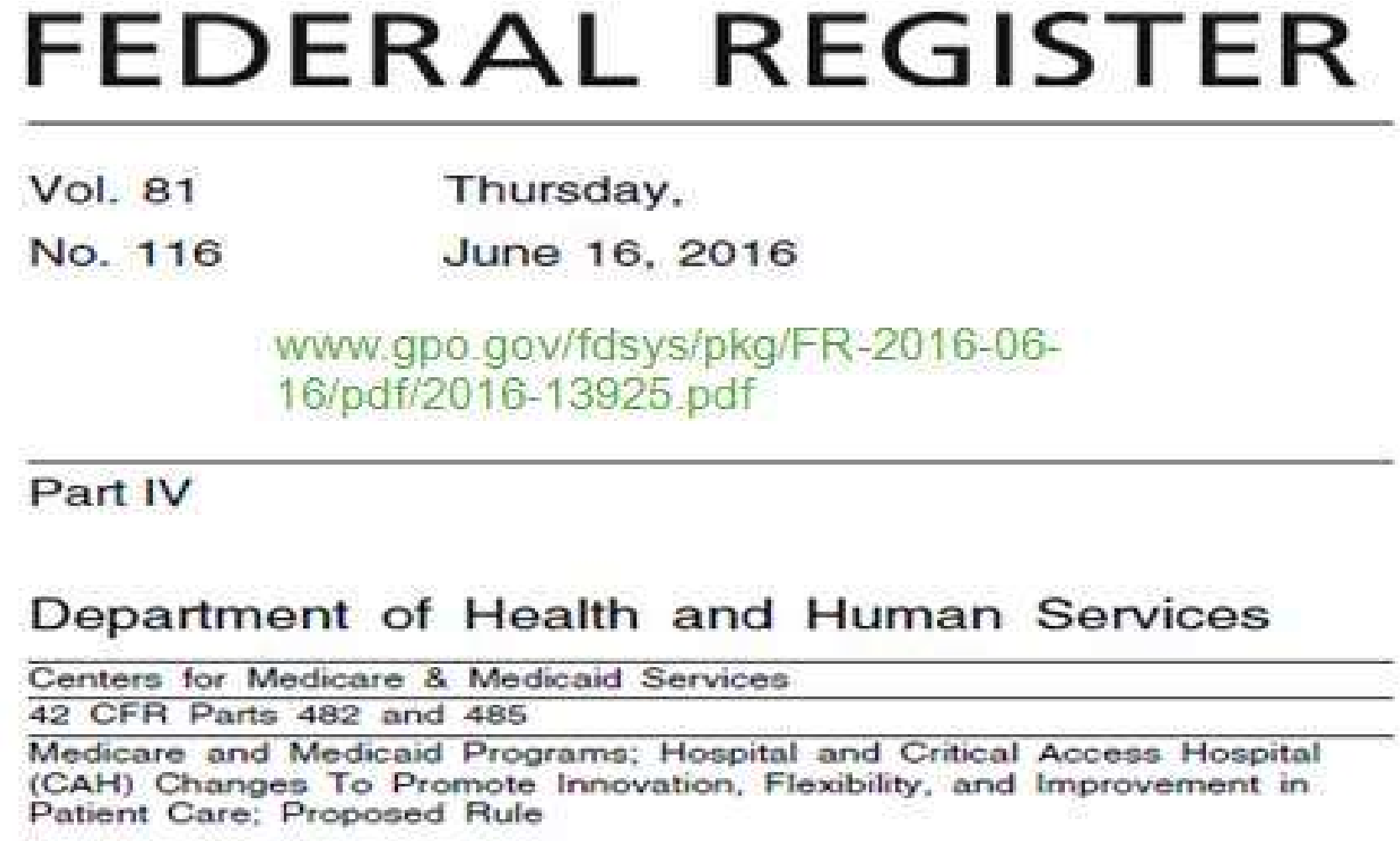
CMS Proposed Changes to CoP Manual & Antibiotic Stewardship

RELIAS | LEARNING

CMS Antimicrobial Stewardship Program

- CMS has a section on this located in the Infection Control worksheet
  - This is discussed in more detail later
- CMS proposed changes on June 16, 2016 in the Hospital Improvement Act
- Has a section on antibiotic stewardship program and what elements has to be present
- Will change chapter name to “Infection Prevention and Control and Antibiotic Stewardship Program (ASP)

June 16, 2016 CMS Hospital Proposed Changes



FEDERAL REGISTER

Vol. 81 Thursday,
No. 116 June 16, 2016

www.gpo.gov/fdsys/pkg/FR-2016-06-16/pdf/2016-13925.pdf

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 482 and 485

Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care; Proposed Rule

CMS Antimicrobial Stewardship Program

- Hospital required to develop and maintain ASP to improve prescribing and to reduce C-diff risk
- ASP must be active and hospital wide to prevent and control HAI and to optimize antibiotic use
- Program must demonstrate and adhere to **nationally recognized standards** to decrease antibiotic resistance
- Must use best practices related to antibiotic use
- Specifically mentions SHEA, IDSA and CDC guidelines

TJC Antibiotic Stewardship Program

- Standards effective January 1, 2017
- Added new Medication Management standard
- MM.09.01.01 was developed after the White House Forum on Antibiotic Stewardship which occurred June 2, 2015
- TJC shows a commitment to slow the emergence of antibiotic resistance bacteria, detect resistant strains, and prevent the spread of resistant infections
  - CDC says 20-50% of all antibiotics in the US are unnecessary

TJC Antibiotic Stewardship Program

- Standard: The hospital has an antimicrobial stewardship program based on evidence-based national guidelines
- Has 8 elements of performance
- EP1 Leaders establish antimicrobial stewardship as a priority for the hospital
  - Accountability for leadership can be evidenced by the IC plan, PI plan, strategic plans, budgeting resources, using the EHR to collect data, accountability documents

Joint Commission

Requirement

New Antimicrobial Stewardship Standard

www.jointcommission.org/assets/1/6/HAP-CAH_Antimicrobial_Prepub.pdf

APPLICABLE TO HOSPITALS AND CRITICAL ACCESS HOSPITALS

Effective January 1, 2017

Medication Management (MM)

Standard MM.09.01.01

The [critical access] hospital has an antimicrobial stewardship program based on current scientific literature.

Elements of Performance for MM.09.01.01

1. Leaders establish antimicrobial stewardship as an organizational priority. (*See also* LD.01.03.01, EP 5)

   Note: *Examples of leadership commitment to an antimicrobial stewardship program are as follows:*

   - *Accountability documents*
   - *Budget plans*
   - *Infection prevention plans*
   - *Performance improvement plans*
   - *Strategic plans*
   - *Using the electronic health record to collect antimicrobial stewardship data*

2. The [critical access] hospital educates staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices. Education occurs upon hire or granting of initial

   Note: *An example of an educational tool that can be used for patients and families includes the Centers for Disease Control and Prevention's Get Smart document, "Viruses or Bacteria—What's got you sick? at http://www.cdc.gov/getsmart/community/downloads/getsmart-chart.pdf.*

4. The [critical access] hospital has an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting:

   - Infectious disease physician
   - Infection preventionist(s)
   - Pharmacist(s)
   - Practitioner

   Note 1: *Part-time or consultant staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.*

   Note 2: *Telehealth staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.*

5. © The [critical access] hospital's antimicrobial stewardship program includes the following core elements:

   - Leadership commitment: Dedicating necessary human, financial, and information technology resources.
   - Accountability: Appointing a single leader responsible for program outcomes. Experience with successful programs shows that a physician leader is effective.
   - Drug expertise: Appointing a single pharmacist leader responsible for working to improve antibiotic use.
   - Action: Implementing recommended actions, such as

TJC Antibiotic Stewardship Program

- EP2 Educate staff and LIPs involved in the ordering of antibiotics, dispensing, administrating, and monitoring for antimicrobial resistance and antimicrobial stewardship practices
  - Education occurs upon hire or granting of privileges and periodically after that as needed
- EP3 Educate patients, and their families regarding the appropriate use of antimicrobial medications, including antibiotics, as needed
  - An example of an article you can use is the CDC's Get Smart document, "Viruses or Bacteria-What's got you sick?
    www.cdc.gov/getsmart/community/downloads/getsmart-chart.pdf

Viruses or Bacteria
What's got you sick?

Antibiotics only treat bacterial infections. Viral illnesses cannot be treated with antibiotics. When an antibiotic is not prescribed, ask your healthcare professional for tips on how to relieve symptoms and feel better.

Illness	Usual Cause		Antibiotic Needed
	Viruses	Bacteria	
Cold/Runny Nose	✓		NO
Bronchitis/Chest Cold (in otherWise healthy children and adults)	✓		NO
Whooping Cough		✓	Yes
Flu	✓		NO
Strep Throat		✓	Yes
Sore Throat (except strep)	✓		NO
Fluid in the Middle Ear (otitis media With effusion)	✓		NO
Urinary Tract Infection		✓	Yes

Antibiotics Aren't Always the Answer

www.cdc.gov/getsmart

GET SMART
Know When Antibiotics Work

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

TJC Antibiotic Stewardship Program

- EP 4 The hospital has an antimicrobial stewardship multidisciplinary team that includes the following:
- Pharmacist, Infection disease physician, and Infection preventionist,
  - Part-time or consultant staff are acceptable
- EP 5 The hospital's antimicrobial stewardship program includes the following core elements:
- Leadership commitment-having dedicated people, and financial and IT resources

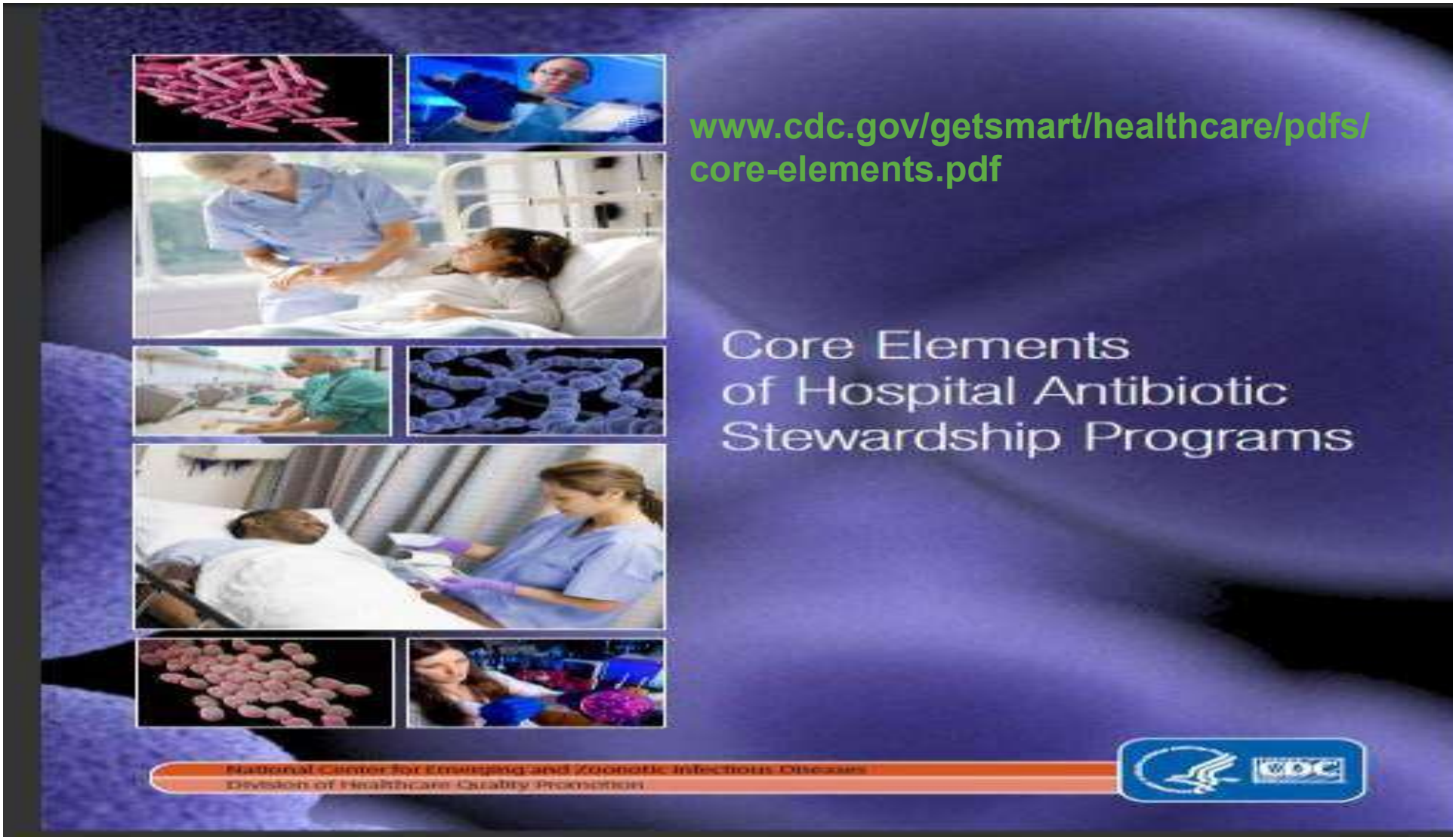
TJC Antibiotic Stewardship Program

- Accountability-single leader responsible for outcomes and experience with successful programs show a physician leader is effective
- Drug expertise-appointing a single pharmacist leader responsible for improving antibiotic use
- Action-implement recommended action such as systematic review of ongoing treatment need after a certain period like antibiotic time out after 48 hours
- Tracking-monitor the program which may include information on antibiotic prescribing and resistance patterns

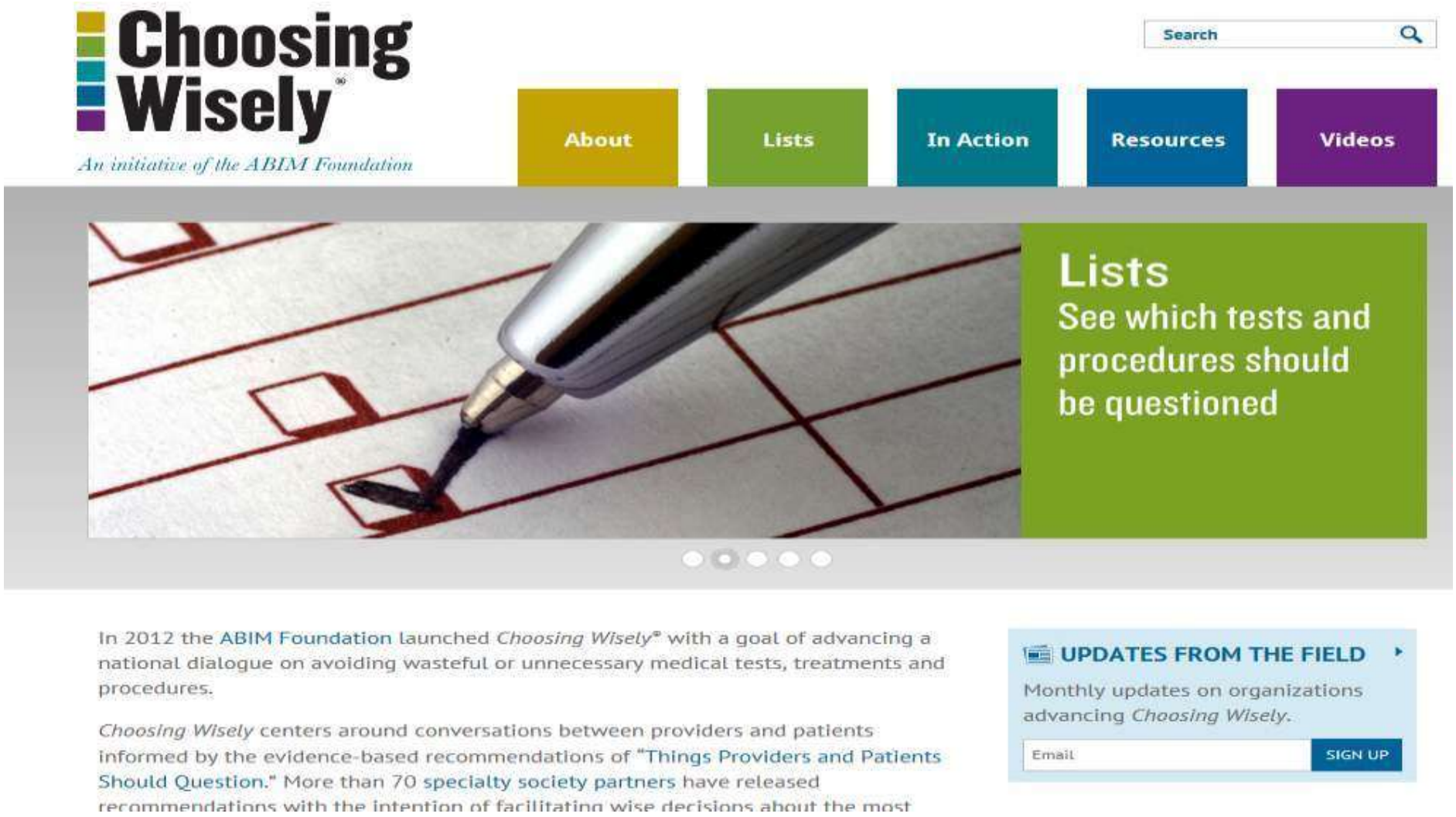
TJC Antibiotic Stewardship Program

- Reporting-regularly report information on the program to MD/DOs, nurses, and staff which may include information on use and resistance patterns
- Education- educate staff, practitioners, and patients on the program which may include information about resistance and optimal prescribing
  - Mentions the CDC core elements
  - TJC recommends that hospitals use this document when designing their program
- Choosing wisely also have24 organizations that have recommendations on prescribing antibiotics

CDC Core Elements of Hospital ASP



Choosing Wisely Website



24 Recommendations from Organizations

Society for Healthcare Epidemiology of America	Don't continue antibiotics beyond 72 hours in hospitalized patients unless patient has clear evidence of infection.
Society for Healthcare Epidemiology of America	Don't use antibiotics in patients with recent *C. difficile* without convincing evidence of need. Antibiotics pose a high risk of *C. difficile* recurrence.
American Academy of Dermatology	Don't routinely use antibiotics to treat bilateral swelling and redness of the lower leg unless there is clear evidence of infection.
American Academy of Pediatrics – Section on Perinatal Pediatrics	Avoid routine continuation of antibiotic therapy beyond 48 hours for initially asymptomatic infants without evidence of bacterial infection.
American Society for Metabolic and Bariatric Surgery	Avoid routine postoperative antibiotics.
American Urogynecologic Society	Avoid using a fluoroquinolone antibiotic for the first-line treatment of uncomplicated urinary tract infections (UTIs) in women.
AMDA – The Society for Post-Acute and Long-Term Care Medicine	Don't obtain a C. difficile toxin test to confirm "cure" if symptoms have resolved.
Infectious Diseases	Avoid prophylactic antibiotics for the

TJC Antibiotic Stewardship Program

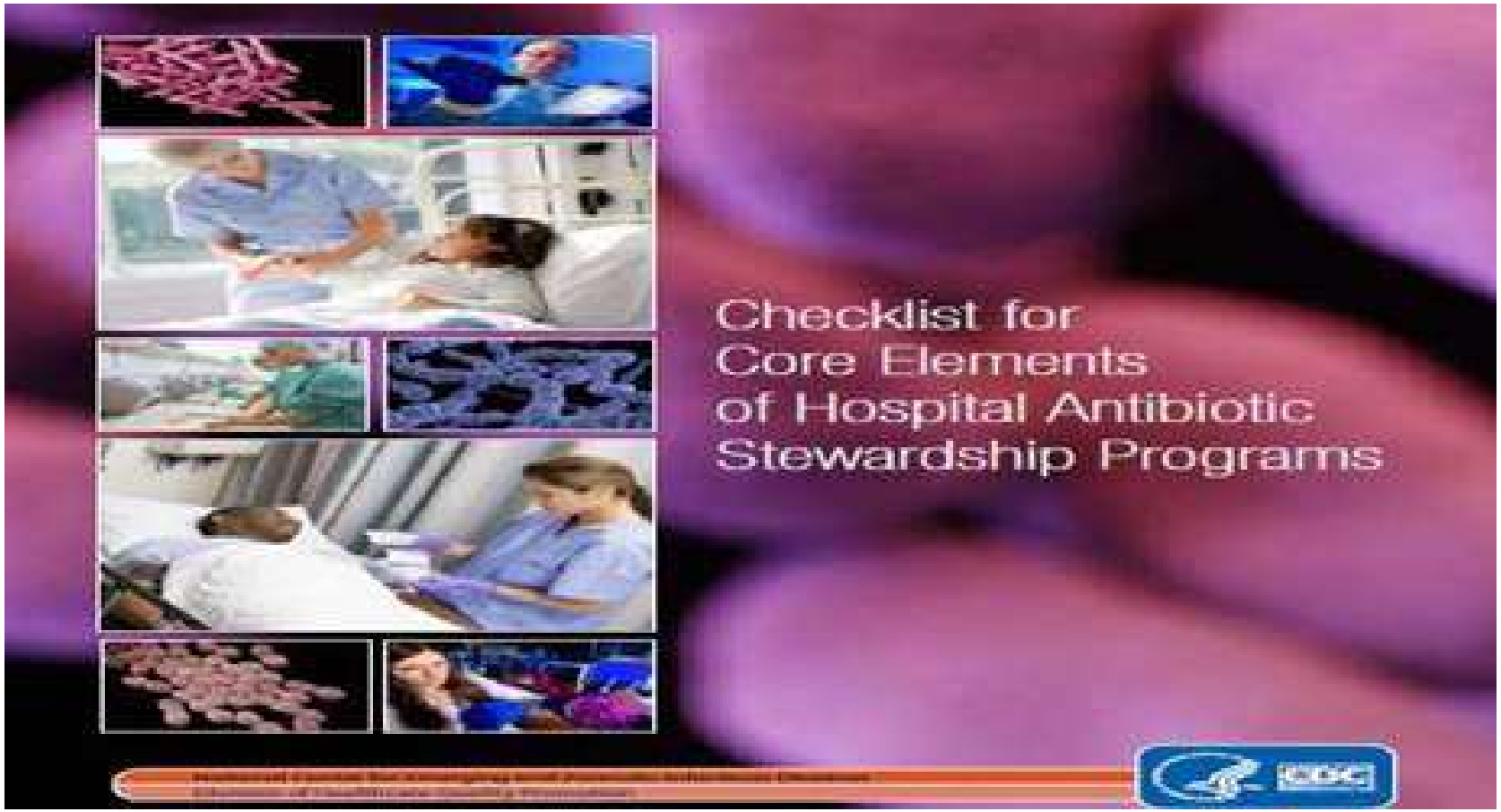
- EP 6 The hospital's program uses hospital approved multidisciplinary protocols such as policies
- Examples of protocols are as follows:
  - Antibiotic Formulary Restriction
  - Plan for Parenteral to Oral Antibiotic Conversion
  - Guidelines for Antimicrobial Use in Adults
  - Guidelines for Antimicrobial Use in Pediatrics
  - Care of the patient with C-diff
  - Preauthorization Requirements for Specific Antimicrobials
  - Use of prophylactic antibiotics

TJC Antibiotic Stewardship Program

- Assessment of Appropriateness of Antibiotics for Community Acquired Pneumonia, skin and soft tissue infection, and UTI
- EP 7 The hospital collects and analyzes data on its antimicrobial stewardship program, including antimicrobial prescribing and resistance patterns
- EP 8 The hospital takes action on improvement opportunities identified in its antimicrobial stewardship program

Antimicrobial Stewardship Toolkits

CDC Toolkit Core Elements



www.ahaphysicianforum.org/resources/appropriate-use/antimicrobial/content%20files%20pdf/CDC%20checklist.pdf

CDC Outpatient Core Elements

http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6506.pdf

Core Elements of Outpatient Antibiotic Stewardship

SHEA Toolkit

SHEA IDSA Guidelines for ASP

Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship

hwww.ahaphysicianforum.org/resources/appropriate-use/antimicrobial/content%20files%20pdf/Guidelines-Institutional-Program.pdf

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[1]Harborview Medical Center and the University of Washington, Seattle; [2]Maine Medical Center, Portland; [3]Emory University, Atlanta, Georgia; [4]Hines Veterans Affairs Hospital and Loyola University Stritch School of Medicine, Hines, and [5]Stroger (Cook County) Hospital and Rush University Medical Center, Chicago, Illinois; [6]University of Utah, Salt Lake City; [7]Mayo Clinic College of Medicine, Rochester, Minnesota; [8]University of Pittsburgh Medical Center, Pittsburgh, and [9]University of Pennsylvania, Philadelphia, Pennsylvania; [10]William Beaumont Hospital, Royal Oak, Michigan; [11]Ochsner Health System, New Orleans, Louisiana; and [12]University of Miami, Miami, Florida

EXECUTIVE SUMMARY

This document presents guidelines for developing institutional programs to enhance antimicrobial stewardship, an activity that includes appropriate selection, dosing, route, and duration of antimicrobial therapy. The multifaceted nature of antimicrobial stewardship has led to collaborative review and support of these recommendations by the following organizations: American Academy of Pediatrics, American Society of

and deserves careful oversight and guidance. Given the association between antimicrobial use and the selection of resistant pathogens, the frequency of inappropriate antimicrobial use is often used as a surrogate marker for the avoidable impact on antimicrobial resistance. The combination of effective antimicrobial stewardship with a comprehensive infection control program has been shown to limit the emergence and transmission of antimicrobial-resistant bacteria. A secondary goal of

ASHP Practice Guidelines

www.ashpadvantage.com/podcasts/handouts/07568.pdf

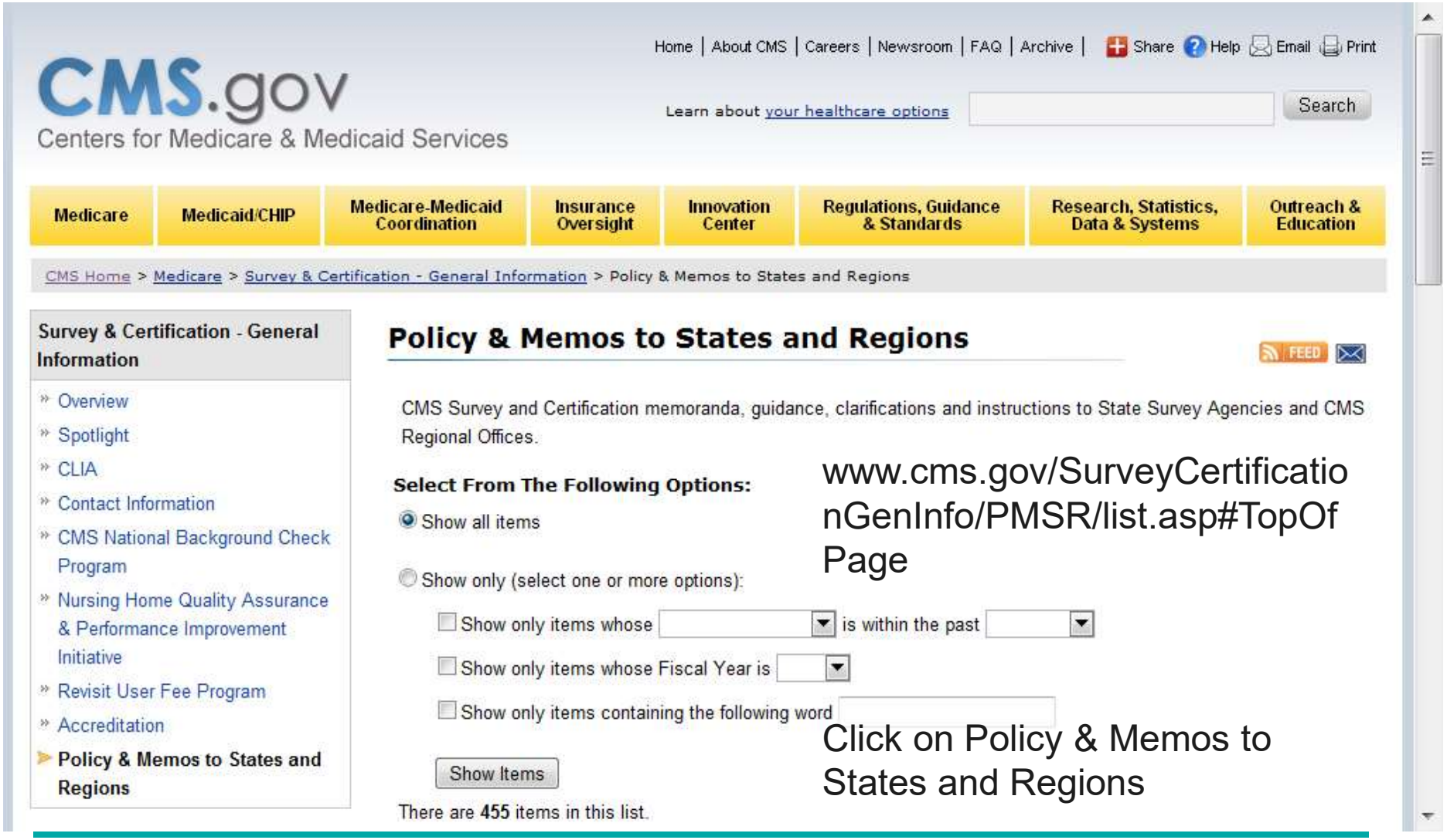
Practice Guidelines for Implementing Antimicrobial Stewardship

Conducted during the 41st ASHP Midyear Clinical Meeting
Anaheim, California

Important CMS Memos Related to Pharmacy and Medications

RELIAS | LEARNING

CMS Survey and Certification Website



www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

Click on Policy & Memos to States and Regions

CMS Survey Memos

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:

Title	Memo #	Posting Date	Fiscal Year
Implementation Issues, Long-Term Care Regulatory Changes: Substandard Quality of Care (SQC) and Clarification of Notice before Transfer or Discharge Requirements	17-27-NH	2017-05-12	2017
Psychiatric Residential Treatment Facilities (PRTF) Frequently Asked Questions (FAQs)	17-28-PRTF	2017-05-12	2017
Notice of Proposed Regulation Changes to Requirements Related to Survey Team Composition and Investigation of Complaints	17-26-NH	2017-04-28	2017
Electronic Staffing Submission - Payroll-Based Journal Update	17-25-NH	2017-04-21	2017
Notice of Proposed Regulation Changes for Accrediting Organizations (AOs) Transparency and Termination Notices	17-24-ALL	2017-04-14	2017

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 retains 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

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-01-Hospital

DATE: **October 30, 2015**

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 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,

Pharmacy Changes Final

State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

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(Rev. 151, 11-20-15)

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Psychiatric Unit Survey Module

Rehabilitation Hospital Survey Module

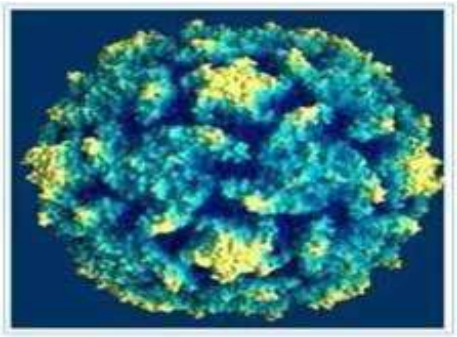
Inpatient Rehabilitation Unit Survey Module

Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines

www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

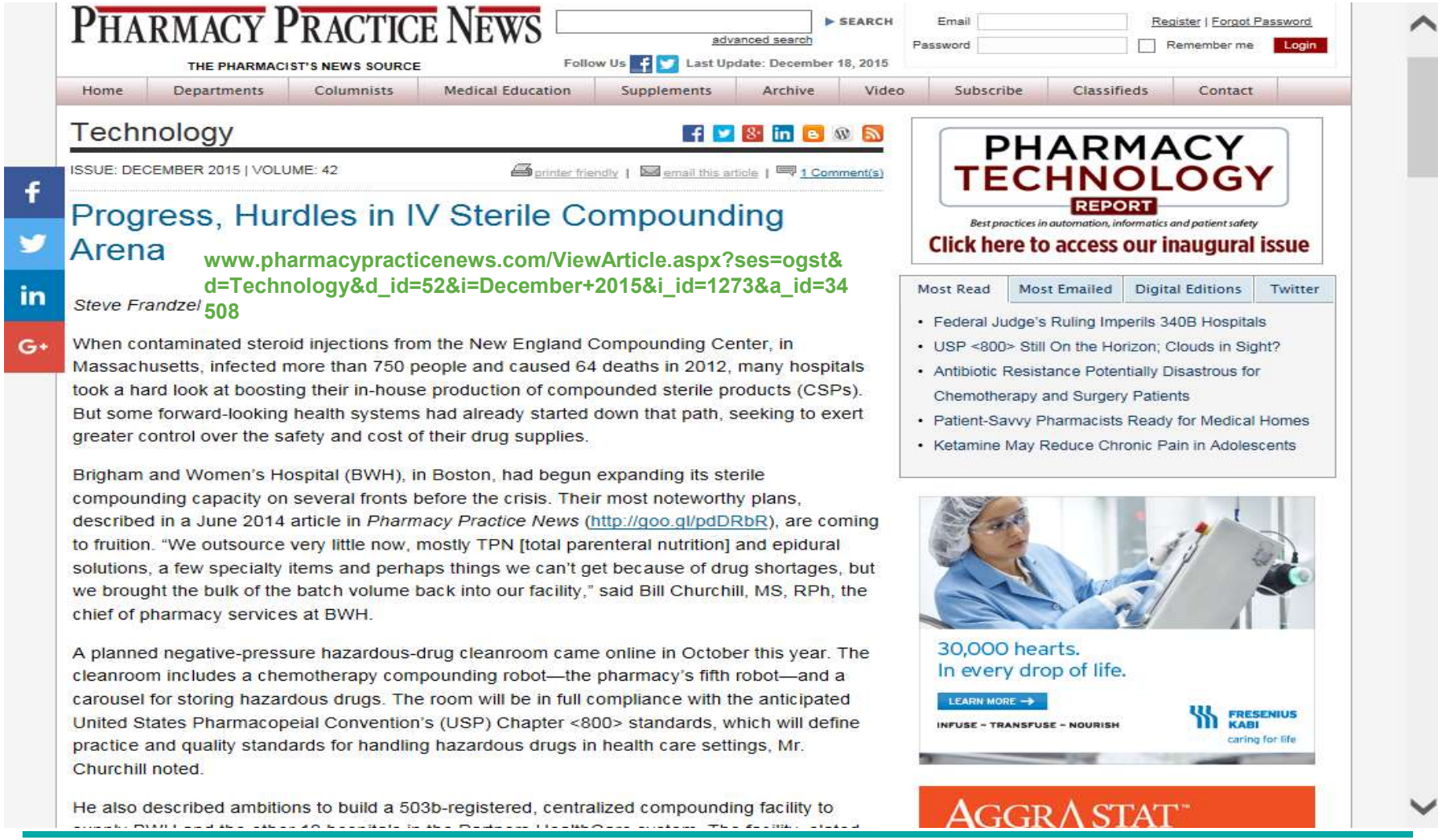
Email questions hospitalscg@cms.hhs.gov



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

CMS Adds Section on Compounding



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Technology

ISSUE: DECEMBER 2015 | VOLUME: 42

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Progress, Hurdles in IV Sterile Compounding Arena

www.pharmacypracticenews.com/ViewArticle.aspx?ses=ogst&d=Technology&d_id=52&i=December+2015&i_id=1273&a_id=34508

Steve Frandzel

When contaminated steroid injections from the New England Compounding Center, in Massachusetts, infected more than 750 people and caused 64 deaths in 2012, many hospitals took a hard look at boosting their in-house production of compounded sterile products (CSPs). But some forward-looking health systems had already started down that path, seeking to exert greater control over the safety and cost of their drug supplies.

Brigham and Women's Hospital (BWH), in Boston, had begun expanding its sterile compounding capacity on several fronts before the crisis. Their most noteworthy plans, described in a June 2014 article in *Pharmacy Practice News* (http://goo.gl/pdDRbR), are coming to fruition. "We outsource very little now, mostly TPN [total parenteral nutrition] and epidural solutions, a few specialty items and perhaps things we can't get because of drug shortages, but we brought the bulk of the batch volume back into our facility," said Bill Churchill, MS, RPh, the chief of pharmacy services at BWH.

A planned negative-pressure hazardous-drug cleanroom came online in October this year. The cleanroom includes a chemotherapy compounding robot—the pharmacy's fifth robot—and a carousel for storing hazardous drugs. The room will be in full compliance with the anticipated United States Pharmacopeial Convention's (USP) Chapter <800> standards, which will define practice and quality standards for handling hazardous drugs in health care settings, Mr. Churchill noted.

He also described ambitions to build a 503b-registered, centralized compounding facility to

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- Federal Judge's Ruling Imperils 340B Hospitals
- USP <800> Still On the Horizon; Clouds in Sight?
- Antibiotic Resistance Potentially Disastrous for Chemotherapy and Surgery Patients
- Patient-Savvy Pharmacists Ready for Medical Homes
- Ketamine May Reduce Chronic Pain in Adolescents

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Sue Dill Calloway
Sdill1@columbus.rr.com
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, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-01-Hospital

DATE: October 30, 2015

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

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 medication 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

Single Dose Medication Memo

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

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-35-ALL

DATE: **June 15, 2012**

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 vials (collectively referred to in this memorandum as "SDVs") into smaller doses, each intended for a single patient:*** The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, *Pharmaceutical Compounding - Sterile Preparations* ("USP <797>"). Under USP <797>, healthcare facilities may repackage SDVs into smaller doses, each intended for use with one patient. Among other things, these standards currently require that:
  - The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
  - All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process.

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 under 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.

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

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/PracticeTools/SterileProductsTool.aspx
- Click on starting using sterile products outsourcing tool now

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Safe Injection Practices www.empsf.org

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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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EPIX Patient Safety Briefs
(Previously known as EPIX Email Alerts)

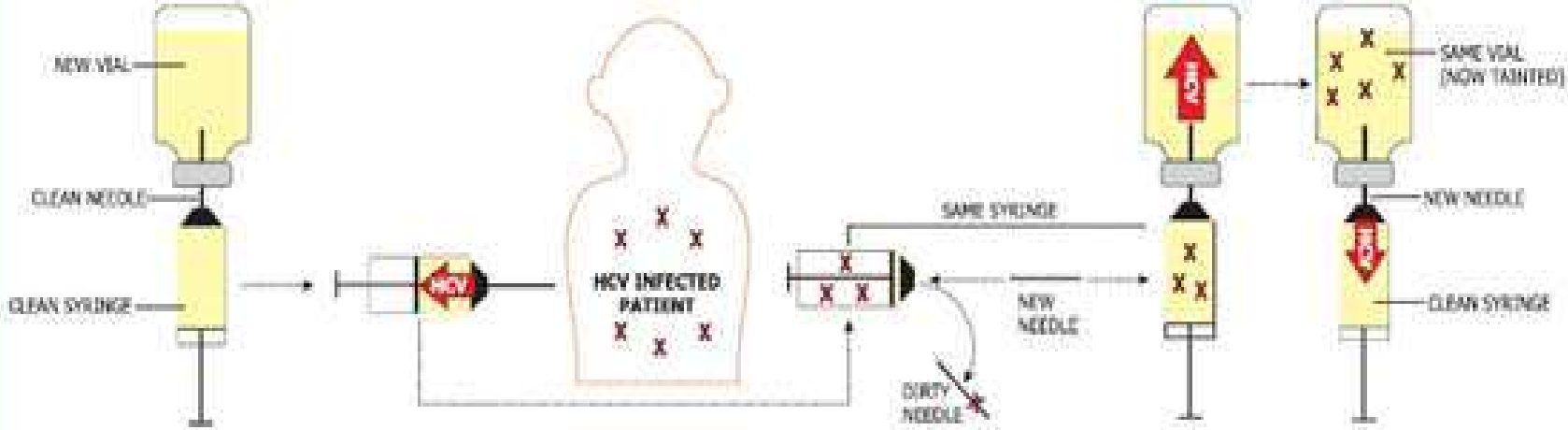
Safe Injection Practices in the Emergency Department

Written by Sue Dill Calloway RN MSN JD

Safe injection practices should be on the radar screen of all urgent care and emergency department physicians, midlevels and nursing staff. There is an increased focus on safe injection practices by regulators such as the Center for Medicare and Medicaid Services (CMS) in the hospital Conditions of Participations (CoPs) and accreditation organizations like the Joint Commission, DNV Healthcare, the Healthcare Facilities Accreditation Program (HFAP), and the Center for Improvement in Healthcare Quality (CIHQ). The recommendations have come from documents that are discussed in this brief and cited at the bottom of the article. It is recommended that this EPIX Patient Safety Brief be shared among physicians, midlevels, nursing staff, infection

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 syringe and needle 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). Backflow into 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, but the contaminated vial is reused. Subsequent patients are now at risk for infection.

Source: www.southernnevadahealthdistrict.org

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 reuse of single-dose vials and misuse of multiple-dose vials. As a result of these incidents, patients have suffered significant harms, including death. CDC and the One & Only Campaign urge healthcare providers to recognize the differences between single-dose and multiple-dose vials and to understand appropriate use of each container type.

This information can literally save a life.

ONEANDONLYCAMPAIGN.ORG

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:

Needles or syringes that have been used for any purpose

Vials with "single-dose vial" printed on the label

Saline bags

Intravenous tubing

ALWAYS follow aseptic technique* when:

Preparing any medication

Disinfecting a vial's septum

Accessing a central line

Injecting any medications

*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) Basic Infection Control and Prevention Plan for Outpatient 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=6D0stMoz80k&feature=youtu.b

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 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

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-36-All

DATE: **May 30, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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 set up referral processes, 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

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

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)

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

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
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-30-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 the need for post-exposure patient notification. 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. **Insulin pens are meant for use by a single patient only.** Each patient/resident must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be cited, consistent with the applicable provider/supplier specific survey guidance, in the same manner as re-use of needles or syringes.

CDC Reminder on Insulin Pens

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 pens must **never** be used for more than one person. Regurgitation 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 and sharing of insulin pens, including an incident in 2011 that required notification of more than 2,000 potentially exposed patients [3]. These events 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

FDA Issues An Alert in 2009

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.wbamc.amedd.army.mil/[1]), and in a smaller number of patients in at least one other hospital. Although the disposable 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.

Insulin Pen Posters and Brochures Available

Insulin Pen Safety – One Insulin Pen, One Person

www.oneandonlycampaign.org/content/insulin-pen-safety

The Safe Injection Practices Coalition created 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:

Specific Materials for Safe Use of Insulin Pens – for Clinicians and Patients

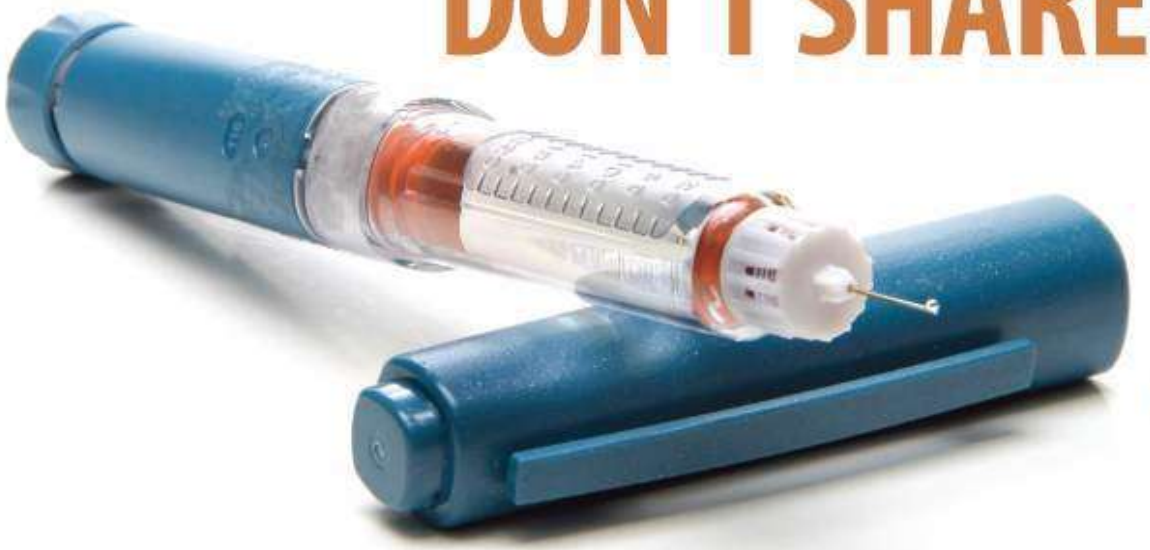
- Poster
- Brochure

Click here to order free copies of these materials from the Centers for Disease Control and Prevention (CDC) (*publication numbers 22-1501 and 22-1503*).

Additional Resources

- VA Patient Safety Alert: Multi-Dose Pen Injectors (Department of Veterans Affairs, January 2013)

BE AWARE
DON'T SHARE



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.

ONE INSULIN PEN, ONLY ONE PERSON

The One & Only Campaign is a public health campaign aimed at raising awareness among the general public and healthcare providers about safe injection practices.

For more information, please visit: www.ONEandONLYcampaign.org

Brochure

DON'T DO IT

Sharing Insulin Pens and Other Injection Equipment Jeopardizes Patients

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single person only and are not to be shared. Unfortunately, there have been continuing reports of persons placed at risk of bloodborne and bacterial pathogen transmission through sharing of insulin pens.

A SIMPLE RULE

Injection equipment (e.g., insulin pens, needles and syringes) should never be used for more than one person.

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

About the Safe Injection Practices Coalition

The Safe Injection Practices Coalition (SIPC) is a partnership of healthcare-related organizations led by the Centers for Disease Control and Prevention that was formed to promote safe injection practices in all U.S. healthcare settings. The SIPC has developed the One & Only Campaign – a public health education and awareness campaign – aimed at both healthcare providers and patients to advance and promote safe injection practices.

For more information, please visit:
www.ONEandONLYcampaign.org

BE AWARE
DON'T SHARE

ONE INSULIN PEN, ONLY ONE PERSON

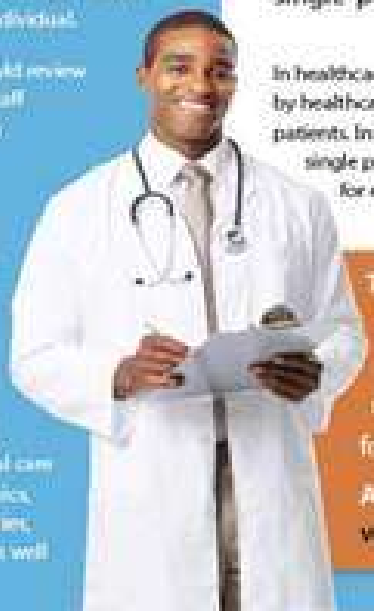
What Every Healthcare Professional Needs To Know

Recommendations for Safe Insulin Pen Use

Protection from infection is a basic expectation anywhere healthcare is delivered. Use of insulin pens and other injection equipment for more than one person poses unacceptable risks and should be considered a "never" event.

- Insulin pens and other injection equipment containing multiple doses of medication are meant for use on a single person only, and should never be used for more than one 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 on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

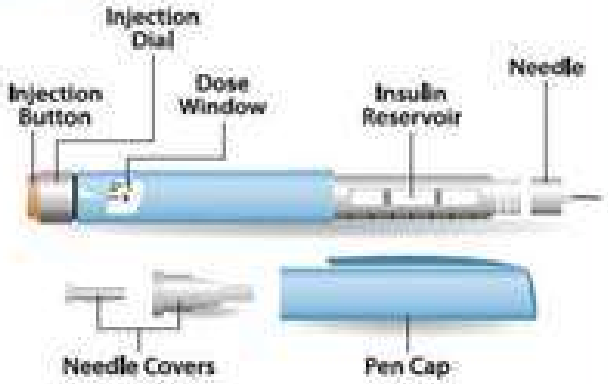
These recommendations apply to any setting where insulin pens and other injection equipment are used, including assisted living or residential care facilities, skilled nursing facilities, clinics, health fairs, shelters, detention facilities, senior centers, schools, and camps as well as licensed healthcare facilities.



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 to patients. Insulin pens are designed to be used for a single person multiple times, using a new needle for each injection.

Back flow of blood into the insulin reservoir can occur during an injection. This creates a risk of bloodborne and bacterial pathogen transmission if the pen is used for more than one person, even when the needle is changed.

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

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

Luer Misconnections Memo

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: 13-14-ALL

DATE: March 8, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Luer Misconnection Adverse Events

Memorandum Summary

- **Luer Misconnections continue to result in adverse events and deaths** – Luer connectors easily link many medical components, accessories, and delivery systems. Clinicians, in any type of provider or supplier setting, can mistakenly connect the wrong devices and deliver substances through the wrong route. Despite numerous alerts and warnings, a patient's blood pressure tubing was recently misconnected to an intravenous (IV) line in an ambulatory surgery center (ASC) resulting in a patient death.
- **Adverse Event Complaint Investigation:** During a complaint investigation for an adverse event involving delivery of an incorrect substance or utilization of an incorrect delivery route, surveyors must be alert to whether the event involved misconnection of a Luer device. If so, surveyors must determine whether the facility has taken actions to ensure systems are in place to prevent recurrence of this type of adverse event.
- **Facility Reporting to Food & Drug Administration (FDA):** Surveyors should encourage health care facilities to report problems with Luer misconnections to the FDA, even if no adverse event occurred.

June 2010 Pa Patient Safety Authority

Tubing Misconnections: Making the Connection to Patient Safety

ABSTRACT

Some patients may have multiple tubing lines connected to them for reasons such as delivery of medication and nutrition therapy. With these multiple lines, the potential for tubing misconnections becomes more prevalent. Tubing misconnections can occur with intravenous catheters, feeding tubes, hemodialysis tubes, and tracheostomy cuffs, among other devices. One of the main reasons for tubing misconnections is that many types of tubing for different types of medical devices incorporate luer connectors. These connectors contribute to misconnections because they allow functionally dissimilar tubes or catheters to be connected together. Between January 2008 and September 2009, 36 events of tubing misconnections were reported to the Pennsylvania Patient Safety Authority involving various types of misconnections. Methods for reducing the likelihood of tubing misconnections include equipment design solutions and administrative controls (policies and work practices). Equipment design solutions either prevent the user from making a misconnection or prompt the user to make the correct connection. Administrative controls are policies and practices that reduce the risk of misconnections such as tracing lines back to their source. (Pa Patient Saf Advis 2010 Jun;7(2):41-5.)

Introduction

Depending on acuity level, patients may have many tubing lines connecting them to medical devices and/or for delivering medication or nutrition therapy. Medical devices connected to patients may also have tubing lines connecting the devices with other medical devices. Under these circumstances, tubing misconnections can occur with potentially fatal results. Misconnections have been recognized as a serious problem for many years. One of the earliest published reports of misconnections was the inadvertent delivery of bacteria milk via intravenous (IV) administration in 1972.[1] However, misconnections have garnered most attention in recent years, especially in the United States, due in part to the tubing misconnection Sentinel Event Alert issued by the Joint

for IV delivery connected to nasogastric tubes.[2] The Alert offers risk reduction strategies and recommendations, which are included in the overall risk reduction strategies below.

There are many types of misconnections, however, this article will focus on liquid-to-liquid and liquid-to-gas misconnections because these misconnections can pose the most serious harm to patients and are the most frequently reported to the Pennsylvania Patient Safety Authority. Liquid lines are typically those that administer medications or nutrition but can also include solution lines such as flush lines. Medical gas lines are typically used for respiratory support or to power pneumatic medical devices. Liquid-to-liquid misconnections can result in a liquid substance entering the wrong body part or the wrong substance entering the patient. Liquid-to-gas misconnections are incorrect connections that can result in gas introduced into patients' blood vessels or liquid entering patients' respiratory tracts.[3]

A common reason for tubing misconnections, whether liquid-to-liquid or liquid-to-gas, is that many types of tubing lines for different medical devices incorporate common luer connectors. The International Organization for Standardization (ISO) characterizes a luer connector as a conical fitting with a 6% (luer) taper for syringes, needles, and other medical equipment.[4] The luer connection system consists of male and female counterparts that are joined together either by pads (luer slip) or screw-in threaded (luer lock) fittings. Luer connectors contribute to misconnections because they easily allow functionally dissimilar tubes or catheters to be connected together.[5]

Misconnections in Pennsylvania

Between January 2008 and September 2009, 36 tubing misconnection events were reported to the Authority: 15 liquid-to-liquid events and 1 liquid-to-gas event. (See the Table for a breakdown of the types of misconnections reported.) Examples of the Serious Events and Incidents involving misconnections reported to the Authority include the following:

> The patient is a 4-year-old infant admitted . . . to determine need for surgery. The physician ordered a 23 ml bolus of 5% hypertonic saline. A . . . [illegible]

June 2010 Pa Patient Safety Authority

Tubing Misconnections: Making the Connection to Patient Safety

ABSTRACT

Introduction

Misconnections in Pennsylvania

ISMP Tubing Misconnections www.ismp.org

MedicationSafetyAlert!

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 fatal event. Over Memorial Day weekend, a 19-month-old child, who was receiving treatment for a chronic gastrointesti disorder, died at a pediatric care center. A suspension of **QUESTRAN** (cholestyramine) was accidentally given via a central line intravenous catheter instead of through an enteral feeding tube.

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 Health-Syst Pharm*. 2010;67:734-36). The patient, a 17-month-old child, had a central venous catheter (CVC) in place antibiotic therapy. As the procedure began, approximately 3 mL of barium sulfate was injected into the CVC, which was mistaken as the child's gastrostomy tube. Fortunately, no respiratory distress developed and the child was discharged days later.

Luer connector systems, common to many healthcare catheters, tubes, administration sets, extension sets, and syring have been at the heart of many catheter/tubing misconnections. 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 administrati sets and syringes. So, even if a liquid medication is prepared in an oral syringe, the medication must be transferred to parenteral syringe for administration via this type of enteral catheter port, risking the accidental administration of the drug via a parenteral line.

Below are examples of the type of reports we have received associated with catheter/tubing misconnections, all of whi we've described in this newsletter since publication began in 1996:

- IV infusions connected to epidural lines, and epidural solutions connected to IV lines
- Syringe containing IV medication given via an intrathecal catheter
- 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 administrati 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

FDA Luer Misconnections

U.S. Food and Drug Administration

Search FDA

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 the term Luer will be used to describe both Luer and other types of small-bore connectors.

Because 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 receive appropriate orientation and training that emphasizes the risk of tubing misconnections. 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.

This website explains how misconnections 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

Luer Lock (left) and Luer Slip (right)

www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm

New Standards Prevent Tubing Misconnections

- New and unique international standards being developed in 2016/2017 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

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

Managing risk during transition to new ISO tubing connector standards

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

Accredited organizations should consider information in a *Sentinel Event Alert* when designing or redesigning processes and consider implementing relevant suggestions contained in the alert or reasonable alternatives.

Tubing misconnections continue to cause severe patient injury and death, since tubes with different functions can easily be connected using luer connectors, or connections can be "rigged" (constructed) 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 consensus process, the standards are being developed, tested 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 begins now. The Joint Commission urges health care organizations 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, small-bore (less than 8.5 mm inner diameter) connectors will be engineered to make it nearly impossible to connect one delivery system to another delivery system that serves a completely different function[1,2,3,4,5] – for example, accidentally connecting a feeding administration set to a tracheostomy tube, or an intravenous (IV) tube to an epidural site.

The first new ISO connector standard (ANSI/AAMI/ISO 80369-1) 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

Pharmacist Must Review- Pharmacy Closed

From: CMS Hospital SCG [mailto:HospitalSCG@cms.hhs.gov]
Sent: Tuesday, June 02, 2015 3:14 PM
To: Sue Dill
Cc: CMS Hospital SCG; Eddinger, David W. (CMS/CCSQ)
Subject: RE: Question on Appendix A

The hospital is required to have a pharmacist available to review the medication orders at all times before the medication is administered (except in the case of emergencies.)

From: Sue Dill [mailto:sdill1@columbus.rr.com]
Sent: Tuesday, June 02, 2015 2:56 PM
To: CMS Hospital SCG; Eddinger, David W. (CMS/CCSQ)
Subject: RE: Question on Appendix A

Next Previous

Thank you for your response but it did not answer my question. There is no pharmacist from midnight to 6 am and the patient needs a medication at 2 am. The nurse supervisor goes to the night cabinet and gets the medication needed and verifies it with the RN who is going to administer it. A pharmacist does not review the medication until 6 am. The hospital has a policy to this effect. I just wanted to make sure there is no deficiency for not having a pharmacist review the medication at 2 am when it is given. That there is no first review by a

Incremental Doses OK Same needle/syringe

From: McCoy, Erin M. (CMS/CCSQ) [mailto:Erin.McCoy@cms.hhs.gov]
Sent: Wednesday, June 11, 2014 4:06 PM
To: sdill1@columbus.rr.com
Cc: CMS Hospital SCG
Subject: re: Question on reuse of a syring

Ms. Dill,

David Eddinger forwarded your email to our hospital team. I have consulted with our Infection Preventionist and we are in agreement that incremental dosing using a needleless system, as you described, is acceptable when completed with aseptic technique. The situation you described would not be considered an infection control breach.

I hope this is helpful.

Erin

Erin McCoy MS, RN, ONC
Nurse Consultant
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7500 Security Boulevard
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410-786-2337

The information provided in this email is only intended to be general summary information to the public. It is not intended to take the place of statute, regulations or official CMS policy.

From: Sue Dill [mailto:sdill1@columbus.rr.com]
Sent: Wednesday, June 04, 2014 12:05 PM
To: Eddinger, David W. (CMS/CCSQ)
Subject: Question on reuse of a syring

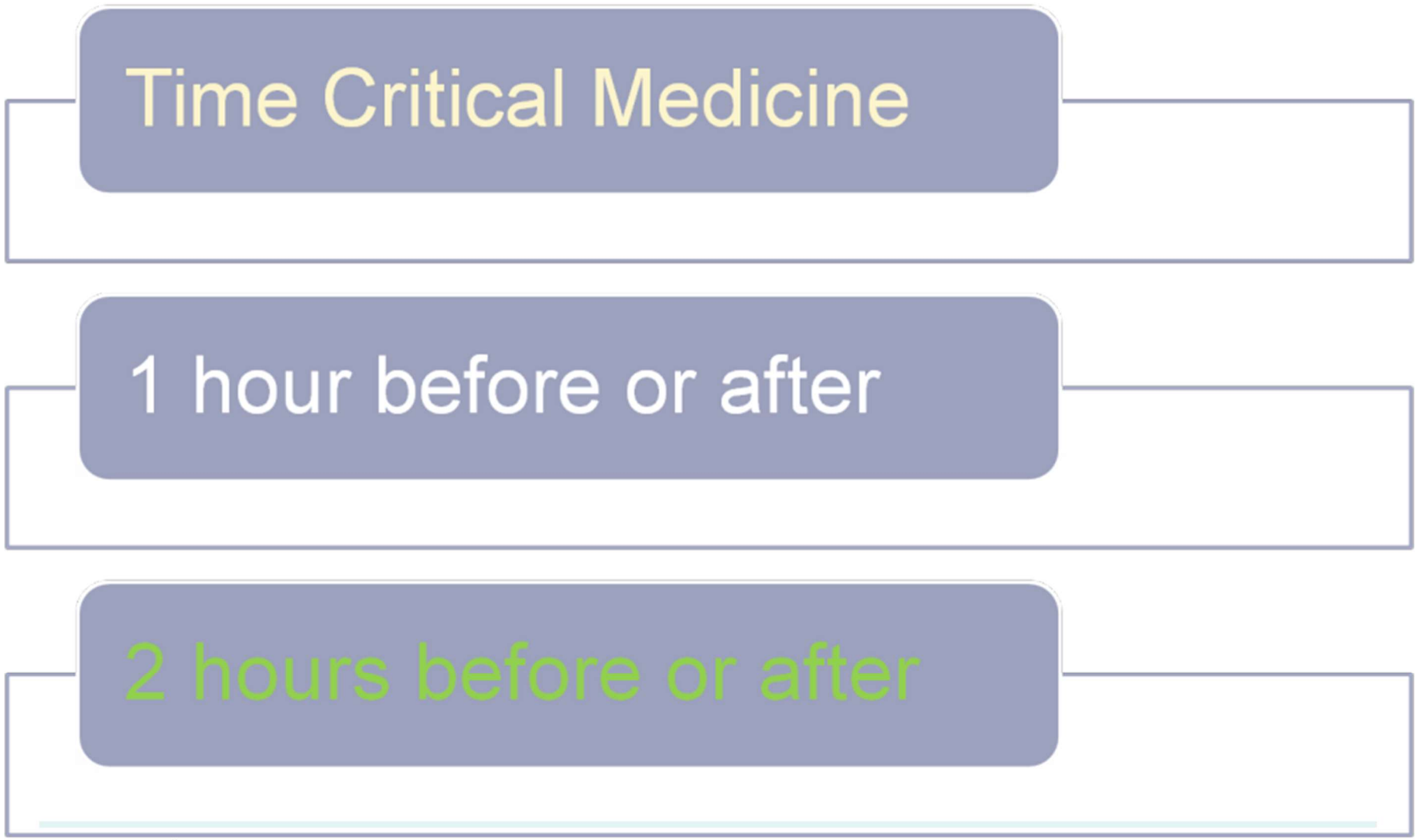
David, I have a question that I thought you might be able to answer for me. It was asked by someone at one of our Ohio Hospitals during an education program yesterday on Safe Injection Practices. A PACU nurse is using a needleless system to give a patient pain medication. She administers a dose and then disconnects the needleless syringe. She now wants to give the patient another dose. Is it permissible to use the same needleless syringe. For example, the nurse has a one mg syringe of HydroMORPHONE (Dilaudid) and the order is to administer 0.2 mg every ten minutes. She pushes 0.2 mg IV and returns to administer more in ten minutes.

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
  - Some medications are critical or time senstive 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, or every 6 hours so 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



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

Safe Use of Opioids

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-15-Hospital

DATE: **March 14, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-Operative Care of Patients Receiving IV Opioids

Memorandum Summary

- ***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 under the pharmaceutical services and quality assessment/performance 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 medication administration, particularly for post-operative patients receiving IV opioid medications, in order to prevent adverse events.
- ***Immediate Post-operative Care:*** Clarification is also being made to the guidance for the surgical services CoP requirement for hospitals to have adequate provisions for immediate post-operative care, to emphasize the need for post-operative monitoring of patients

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

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 that 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

Compounding 2016

- Must label it unless your 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

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

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 in considered as a self administered medication

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.

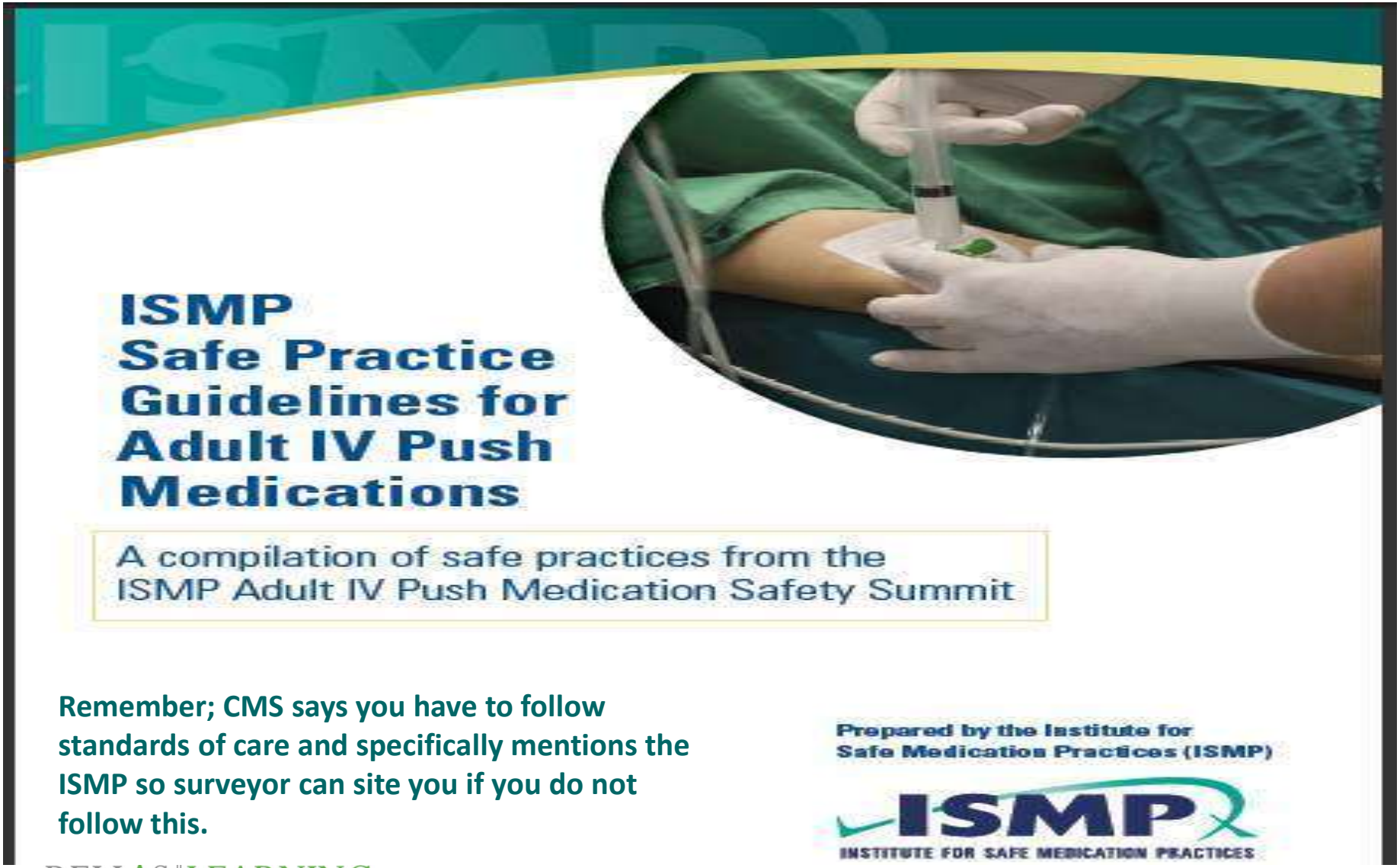
(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

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 at www.ismp.org
- The document is organized into factors that increase the risk of IV push medications in adults,
  - Current practices with IV injectible 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

IV Push Medicine Guidelines



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.

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

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 dry
- Medication from a glass ampule 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

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
  - This are to flush an IV line and are not approved to use to dilute medication

3.6 Do NOT dilute or reconstitute IV push medications by drawing up the contents into a commercially-available, prefilled flush syringe of 0.9% sodium chloride.

Discussion: Commercially available prefilled syringes of saline and heparin are regulated by the US Food and Drug Administration as *devices*, not as medications. These devices have been approved for the flushing of vascular access devices, but have NOT been approved for the reconstitution, dilution, and/or subsequent administration of IV push medications. Such use would be considered "off label" and not how manufacturers intended these products to be used, nor have prefilled flush syringes been tested for product safety when used in this manner.

Warnings intended to limit the use of prefilled syringes for medication preparation and administration appear on some syringe barrels, clearly stating "IV flush only." Some manufacturers have also limited or removed the gradation markings on the prefilled flush syringes in order to prevent measurement of a secondary medication in the flush syringe. When prefilled syringes are used in an off-label manner, the practitioner and employer bear the legal liability for any adverse events occurring from this practice.[31]

The mislabeling that occurs when medications are added to a prefilled syringe and a secondary label is not applied creates significant risk for errors. In many cases, the manufacturer's label is permanently affixed to the syringe barrel and contains product codes and a barcode as well as specific information about the fluid and its volume. When another medication is added to this syringe, there is no adequate method to amend the manufacturer's label, without covering the current information.[31] Thus, the syringe frequently remains labeled as 0.9% sodium chloride, when it also contains the diluted or reconstituted medication.

Although this unsafe practice is widespread, and many who use it mistakenly believe the risk of an error is insignificant—a belief clearly reinforced during public comment regarding this guidance statement—summit participants arrived at a consensus that the practice must be eliminated.

3.7 When necessary to prepare more than one medication in a single syringe for IV push administration

IV Push Medications Guidelines

- Combination of more than one medication is a single syringe is seldom necessary and could result in unwanted changes in the medication
- Never use IV solution or mini bags as a common source to flush an IV as to dilute for more than one patient
- Label syringes of IVP medication unless prepared and immediately given with no break
- Administer IV push medication at rate recommended by manufacturer or supported by evidenced based practices and often given too fast

CMS Infection Control Worksheet

Safe Injection Practices and Antimicrobial Stewardship

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

Final 3 Worksheets

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

REF: S&C: 15-12-Hospital

DATE: November 26, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Public Release of Three Hospital Surveyor Worksheets

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

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 Performance Improvement (QAPI), 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.

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

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

Elements to be assessed		Su
1.C.1 The hospital has policies and procedures to minimize the risk of development and transmission of multidrug-resistant organisms (MDROs) within the hospital (applicable to all persons in the hospital).	◯ Yes ◯ 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.	◯ Yes ◯ 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.	◯ Yes ◯ No	
If no to any part of 1.C.1 through 1.C.3, cite at 42 CFR 482.42(a) (Tag A-0749)		
1.C.4 The hospital can provide a list of target MDROs. 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 for criteria that may be used to define epidemiology important organisms: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf	◯ Yes ◯ No	
1.C.5 The hospital can demonstrate the criteria used to determine epidemiologically important MDROs on their list.	◯ Yes ◯ 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.	◯ Yes ◯ No	

Safe Injection Practices and Sharps Safety

Section 2.B. Injection Practices and Sharps Safety (Medications and Infusates)

Elements to be assessed		Surveyor Notes		Surveyor Notes
Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection a communicable disease including the following:				
Note: If possible, questions in this section should be assessed through observation in two separate patient care areas or settings of the hospital.			○ Second observation not available (If selec questions 2.B.1 – 2.B.15 RIGHT column will b blocked)	
2.B.1 Injections are prepared using aseptic technique in an area that has been cleaned and is free of contamination (e.g., visible blood, or body fluids).	○ Yes ○ No ○ Unable to observe		○ Yes ○ No ○ Unable to observe	
2.B.2 Needles are used for only one patient.	○ Yes ○ No ○ Unable to observe		○ Yes ○ No ○ Unable to observe	
2.B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes).	○ Yes ○ No ○ Unable to observe		○ Yes ○ No ○ Unable to observe	
2.B.4 Insulin pens are used for only one patient.	○ Yes ○ No ○ Unable to observe		○ Yes ○ No ○ Unable to observe	
2.B.5 The rubber septum on all medication vials, whether unopened or previously accessed, is disinfected with alcohol	○ Yes		○ Yes	

The End! Questions????

Sue Dill Calloway RN, Esq.
CPHRM, CCMSCP
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(no email question, call)

THANK YOU

RELIAS | LEARNING