AHC Media

Complying With New CMS Nursing Services CoPs

Wednesday, May 27th 2015

Speaker

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- Board Member
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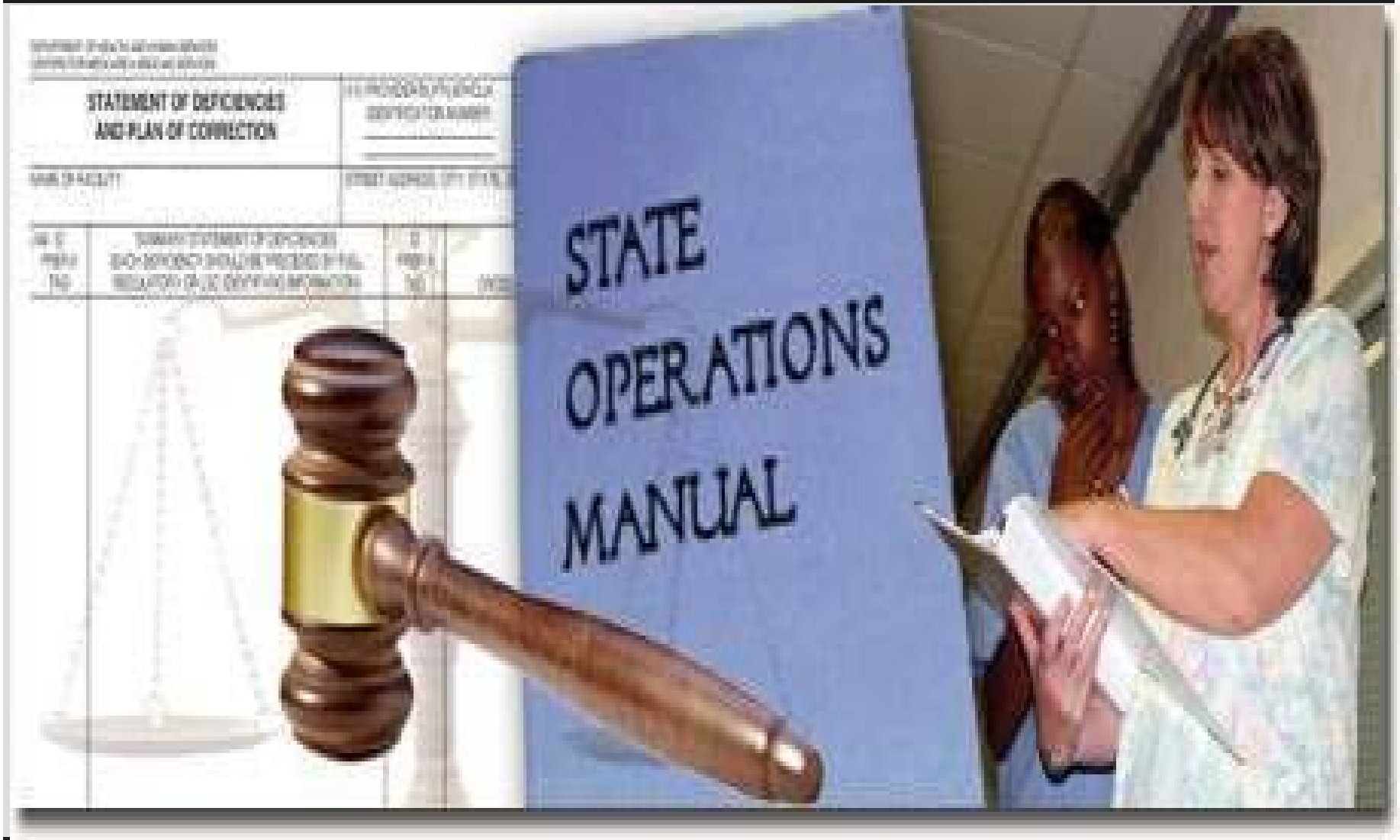
Objectives

- Describe the CMS CoPs all hospital nursing services must follow.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

You Don’t Want One of These



The Conditions of Participation (CoPs)

- Regulations first published in 1986
  - Manual updated April 1, 2015 & 486 pages
  - Many changes since 1986
- 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

- 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

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

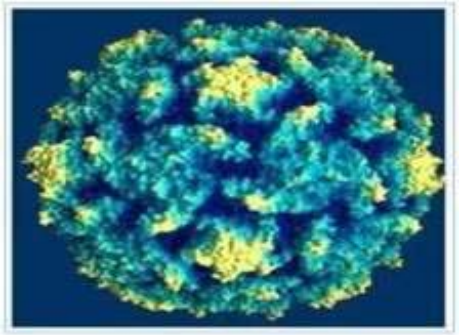
App. No.	Description	PDF File
A	Hospitals	2,185 KB
AA	Psychiatric Hospitals	606 KB

CoP Manual Also Called SOM

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

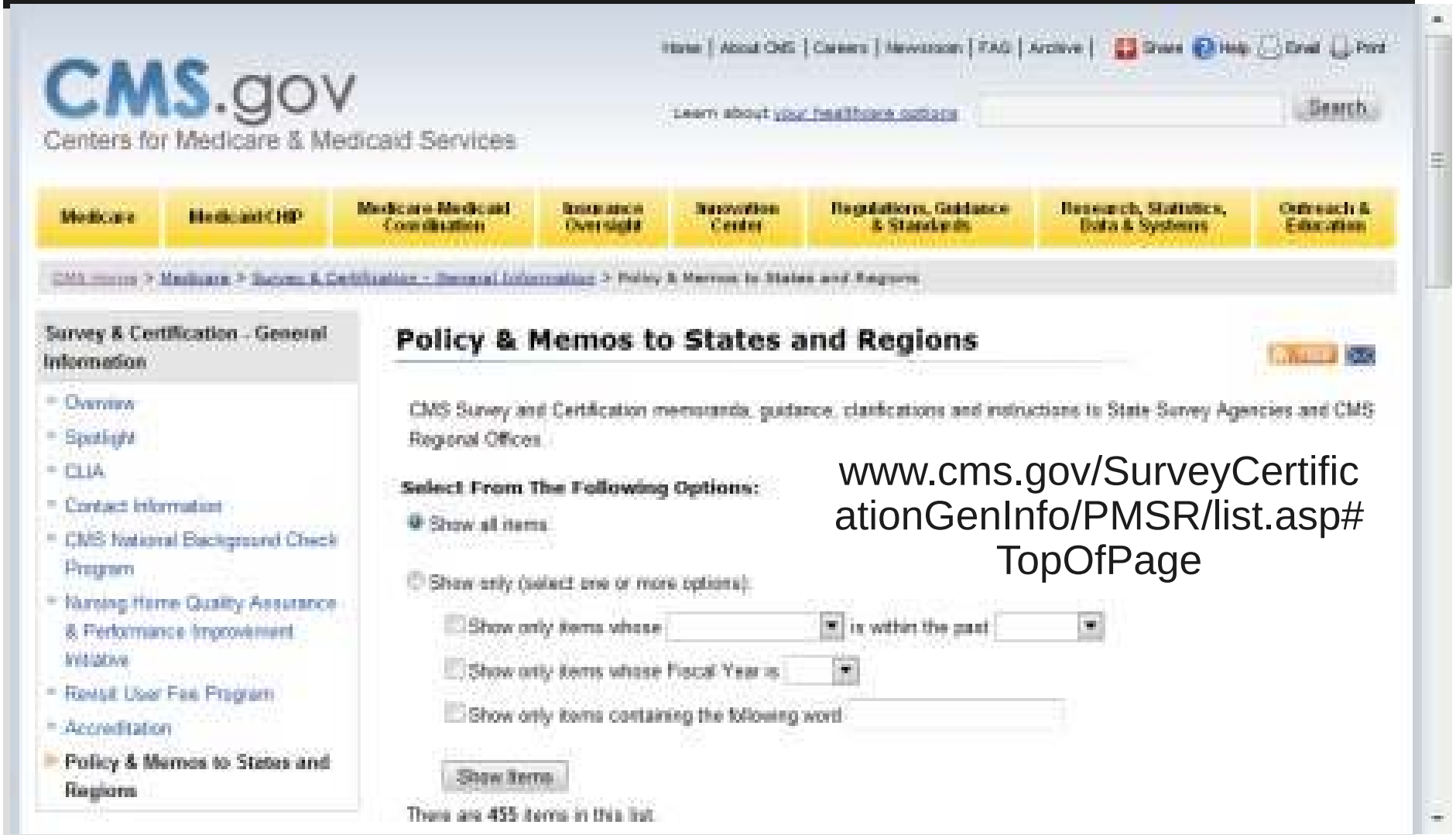
Table of Contents
(Rev. 137, 04-01-15)

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



§482.12 Condition of Participation: Governing Body

CMS Survey and Certification Website



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

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
Public Release of Three Hospital Surveyor Worksheets	15-12-Hospital	2014-11-26	2015
Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Ebola Virus Disease (Ebola)	15-10-Hospitals	2014-11-24	2015
Directions on the Off-Label/Modified Use of Waived Blood Glucose Monitoring Systems (BGMS)	15-11-CLIA	2014-11-24	2015
Rural Health Clinic (RHC) Location Determination Guidance Updated	15-09-RHC	2014-11-14	2015
Information for Clinical Laboratories Concerning Possible Ebola Virus Disease	15-08-CLIA	2014-11-07	2015
Nationwide Expansion of Minimum Data Set (MDS) Focused Survey Background	15-06-NH	2014-10-31	2015
Effect on Microbiology Laboratories Due to the Removal of References to the Clinical Laboratory Standards Institute (CLSI) and to CLSI Documents	15-07-CLIA	2014-10-31	2015
National Background Check Program (NBCP) Grant Award Updates	15-04-ALL	2014-10-24	2015

Example of a CMS Survey 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

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

CAH Memo Makes Many Similar Regulations

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: 15-19-CAH

DATE: **January 16, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised State Operations Manual (SOM) Appendix W, Critical Access Hospitals (CAHs)

Memorandum Summary

The Centers for Medicare & Medicaid Services (CMS) CAH Conditions of Participation (CoPs) Changed in Two Final Rules:

- CMS-3267-F was published on May 12, 2014 and portions related to CAHs became effective July 11, 2014. Among other provisions, this final rule revised the CAH Conditions of Participation (CoP) requirements related to the responsibilities of doctors of medicine (MDs) and doctors of osteopathy (DOs).
- CMS-1599-F was published August 19, 2013 and became effective October 1, 2013. This final rule revised the CAH CoP requirements related to provision of inpatient acute care services.

SOM Appendix W Updated:

- We are updating the pertinent portions of the CAH interpretive guidelines, found in SOM Appendix W, to reflect these rule changes

The Conditions of Participation (CoPs)

- The manual is known as the conditions of participation or the CoPs for short
- The CoP sections are called tag numbers
- They go from Tag 0001 to 1164 and nursing starts at tag **385**
  - All the sections contain a tag number so it is easy to go back and look up that section if you want to read more about it

How to Keep Up with Changes

- First, periodically check to see you have the most current CoP manual[1]
- Once a month go out and check the survey and certification website [2]
- Once a month check the CMS transmittal page [3]
- Have one person in your facility who has this responsibility

- [1] http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf
- 2 http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage
- 3 http://www.cms.gov/Transmittals

Transmittals

www.cms.gov/Transmittals/01_overview.asp

CMS Hospital Worksheets History

- October 14, 2011 CMS issues a 137 page memo in the survey and certification section and it was pilot tested in hospitals in 11 states
- Memo discusses surveyor worksheets for hospitals by CMS during a hospital survey
- Addresses discharge planning, infection control, and QAPI (performance improvement)
  - May 18, 2012 CMS published a second revised edition and pilot tested each of the 3 in every state over summer 2012
  - November 9, 2012 CMS issued the third revised worksheet
  - Final ones issued November 26, 2014

Final 3 Worksheets QAPI

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: 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
- 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

CMS Hospital Worksheets

- Some of the questions asked might not be apparent from a reading of the CoPs
- So the worksheets are a good communication device
- It helps to clearly communicate to hospitals what is going to be asked in these 3 important areas
- Hospitals might want to consider putting together a team to review the 3 worksheets and complete the form in advance as a self assessment
- Hospitals should consider attaching the documentation and P&P to the worksheet

CMS Current Events

- CMS has many recent memos of interest
  - Privacy and confidentiality
  - Luer misconnections, IV and blood and blood products
  - Use of insulin pens issue
  - Single dose vials and safe injection practices
  - Humidity in the OR, infection control 4 breaches
  - Discharge planning
  - Complaint manual and reporting to AO
  - Deficiencies of hospitals, Equipment Maintenance
  - OPO, Medication and Safe Opioid Use

CMS Memo on Insulin Pens

- CMS issues memo on insulin pens on May 18, 2012
- 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

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

Memorandum Summary

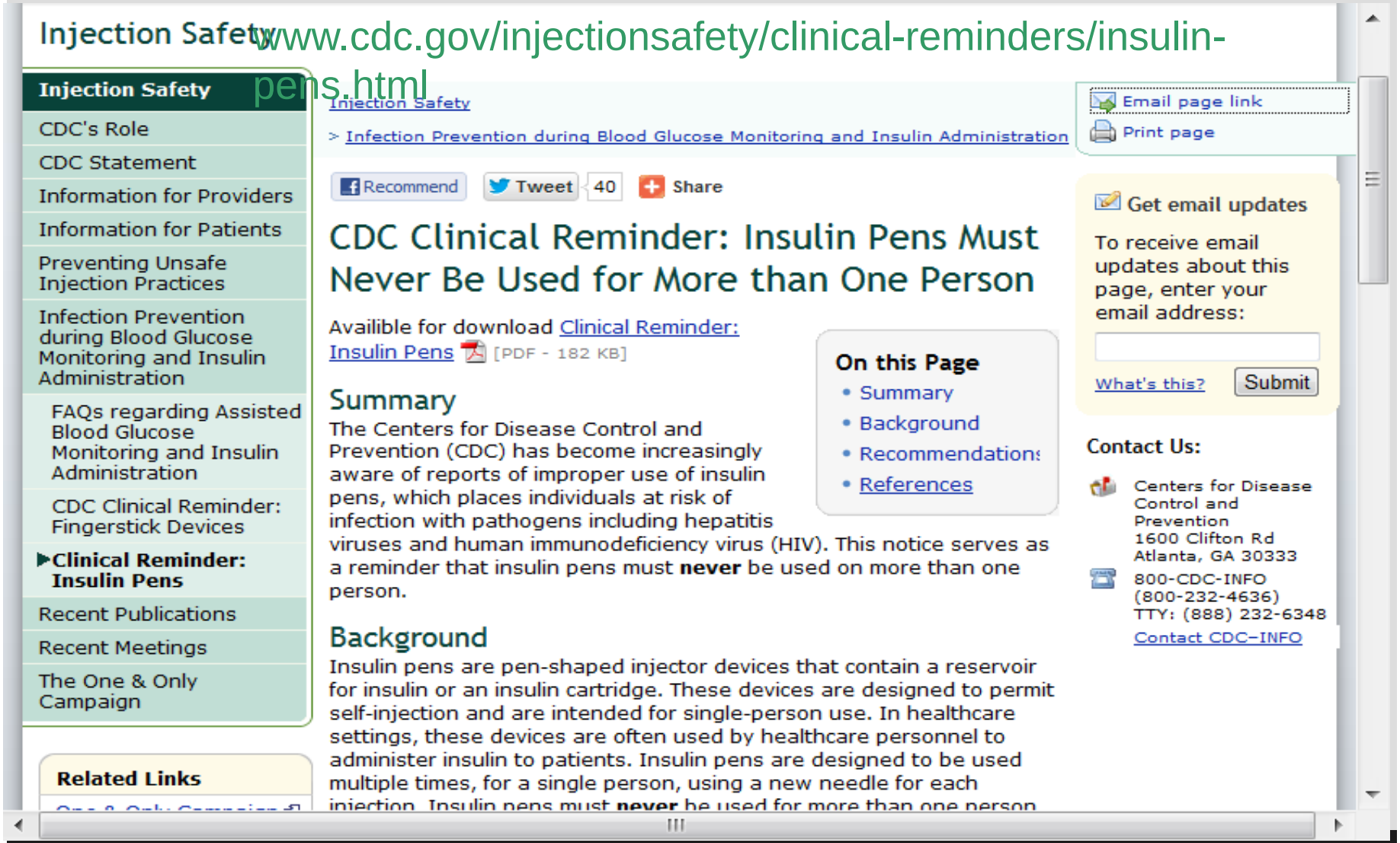
Insulin Pen devices: The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do 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.

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 by a single patient/resident, using a new needle for each injection. Insulin pens must never be used for more

CMS Memo on Insulin Pens

- Regurgitation of blood into the insulin cartridge after injection can occur creating a risk if used on more than one patient
- Hospital needs to have a policy and procedure
- Staff should be educated regarding the safe use of insulin pens
- More than 2,000 patients were notified in 2011 because an insulin pen was used on more than one patient
- CDC issues reminder on same and has free flier

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

VA Alert on Insulin Pens

- Pharmacist found several insulin pens not labeled for individual use
- Found used multi-dose pen injectors used on multiple patients instead of one patient use
- New requirement that can only be stored in pharmacy and never ward stocked
- Instituted new education for staff on use
- Part of annual competency of staff
- Instituted new policy of safe use of pen injectors

VA Issues Alert

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL13-04* January 17, 2013

Item: **Multi-Dose Pen Injectors**

Specific Incident: While inspecting inpatient units of a VA facility, the Chief of Pharmacy discovered several insulin pen injectors that were not labeled for individual patients. It was determined that the pen injectors were used to administer insulin to multiple patients by changing the needle between patients. Multi-dose pen injectors are intended for use by one patient only, and the pen injector and cartridges within them should never be shared between patients. The sharing of pen injectors may expose patients to blood-borne pathogens (e.g., HBV, HCV, HIV) through cross contamination in the pen cartridge.

General Information: A similar incident occurred in a VA facility in 2008 involving the use of the same heparin syringe for intravenous line flushes on multiple patients. NCPS published Patient Safety Alert AL08-20 on August 8, 2008 (see references). This alert prohibited the use of the same syringe to administer medications to multiple patients, even if the needle is changed for each patient.

Actions:

1) By close of business (COB) February 04, 2013, the **Facility Director (or designee)**, in consultation with the **Chief of Pharmacy (or designee)**, shall prohibit the use of multi-dose pen injectors (see attachment 1) on all patient care units (i.e., any unit where a staff member is involved in the storage, preparation or administration of a multi-dose pen injector).

   Exceptions to Action 1 include the following:
   - Patients being educated prior to discharge to use a patient-specific multi-dose pen injector.
   - Eligible patients participating in the VA medical center's Self-Medication Program (SMP) as established by VHA Handbook 1108.03 (see references).
   - Patients requiring treatment with a medication delivered in a multi-dose pen injector, and no alternative formulation is available from the manufacturer for

VA Alert on Insulin Pens

- Decided to prohibit multi-dose insulin pen injectors on all patient units except the following:
  - Patients being educated prior to discharge to use a insulin pen injector
  - Eligible patient is self medication program
  - Patient needing treatment and no alternative formulation is available
  - Patients participating in a research protocol requiring an insulin pen
  - Pen injectors dispensed directly to patients as an outpatient prescription

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

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.
Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

About the Campaign | Safe Injection Practices | Healthcare Provider Information | Patient Information | Campaign Resources | News | Contact Us

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.

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

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

ONE INSULIN PEN, ONLY ONE PERSON

Recommendations for Safe Insulin Pen Use

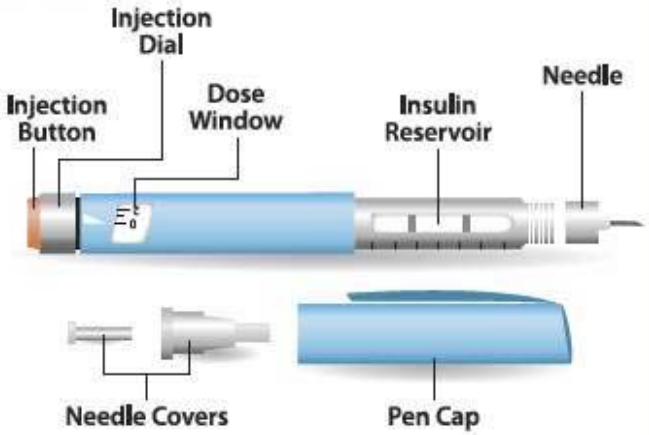
Protection from infection is a basic expectation anywhere healthcare is delivered. Use of insulin pens and other injection equipment for more than one person poses unacceptable risks and should be considered a "never" event.

- 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.

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

CDC Has Flier for Hospitals on Insulin Pens

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Recommendations

Medication and Safe Opioid Use

- CMS issues 32 page memo on medication administration and safe opioid use March 14, 2014 and effective June 6, 2014
  - Risk and patient safety need to review this besides nursing, pharmacy, MEC, and nurse educator
- Concerned about the number of patients with adverse events when taking opioids
- Must have a P&P
- Must train staff and include information that must be in the assessment
- Must document process
  - **Questions to hospitalscg@cms.hhs.gov**

CMS Memo Med & Safe Opioid Use

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: 14-15-Hospital

DATE: **March 14, 2014**

TO: State Survey Agency Directors

FROM: Director
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  - 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

CMS Memo May 30, 2014

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

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

- Memo says Medicare regulations require hospitals that accept M/M to follow their infection control standards
- Some types of infection control breaches, such as ones related to medication administration, pose a risk of bloodborne pathogen transmission that warrant public health authorities to conduct a risk assessment
  - And if necessary to contact the patient
- Outside the scope of CMS but within authority of the SA such as the state department of health

CMS Memo Infection Control Breaches

- If any of the listed breaches are observed, then will take appropriate enforcement action
- And will make the public health authority aware
  - Includes LTC, ASCs, hospice, hospitals, home health agencies, CAH, rural health clinics and dialysis facilities
- CDC is working closely with SA on HAI prevention
- List of breaches to be referred include:
- Using the same needle for more than one individual;

CMS Memo Infection Control Breaches

- 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
- CMS also issued EBOLA and CRE memos

CRE and ERCP's

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-15-32 Hospitals/CAHs/ASCs

DATE: **April 3, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Alert Related to Outbreaks of Carbapenem-Resistant *Enterobacteriaceae* (CRE) during gastrointestinal endoscopy, particularly Endoscopic Retrograde Cholangiopancreatography (ERCP)

Memorandum Summary

- ***Situation:*** Recent newspaper articles, medical publications, and adverse event reports associate multidrug-resistant bacterial infections caused by CRE with patients who have undergone ERCP. Duodenoscopes used to perform ERCP are difficult to clean and disinfect, even when manufacturer reprocessing instructions are followed correctly, and have been implicated in these outbreaks. The U.S. Food and Drug Administration (FDA) has issued a Safety Communication warning, with related updates, that the design of duodenoscopes may impede effective cleaning.

- ***Expectations for Reprocessing Duodenoscopes:*** Hospitals, critical access hospitals (CAHs), and ambulatory surgical centers (ASCs) are expected to meticulously follow the manufacturer's instructions for reprocessing duodenoscopes, as well as adhere to the nationally recognized Multisociety consensus guidelines developed by multiple expert organizations and issued in 2011.

3 EBOLA Memos Issued

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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-24-Hospitals

DATE: **February 13, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Emergency Medical Treatment and Labor Act (EMTALA) and Ebola Virus Disease (EVD) – Questions and Answers (Q+A)

Memorandum Summary

***EMTALA & Ebola Requirements*:**

- On November 21, 2014 the Centers for Medicare & Medicaid Services (CMS) Survey & Certification Group released SC 15-10-Hospitals concerning EMTALA Requirements and Implications Related to the EVD.
- The CMS has received follow-up questions regarding EMTALA and Ebola and has produced a Q+A document in response.

The CMS released S&C 15-10 on November 21, 2014 to provide guidance to hospitals and critical access hospitals (CAHs) regarding meeting EMTALA requirements in the case of individuals potentially exposed to Ebola. The memo is available via the following link:

http://www.cms.gov/Medicare/Provider-Enrollment-and-

CMS Memo on Safe Injection Practices

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

Single Dose Safe Injection Practices

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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.
- ***Administering drugs from one SDV to multiple patients without adhering to USP <797>***

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

CMS Memo on Safe Injection Practices

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

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 which has 10 practices
- 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

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

CMS Memo April 19, 2013

- CMS issues memo related to the relative humidity (RH)
- AORN use to say temperature maintained between 68-73 degrees and humidity between 30-60% in OR, PACU, cath lab, endoscopy rooms and instrument processing areas
- CMS says if no state law can write policy or procedure or process to implement the waiver
- Waiver allows RH between 20-60%
- In anesthetizing locations- see definition in memo

Humidity in Anesthetizing Areas

DEPARTMENT OF HEALTH & HUMAN SERVICES
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Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-25-LSC & ASC

DATE: April 19, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Relative Humidity (RH): Waiver of Life Safety Code (LSC) Anesthetizing Location Requirements; Discussion of Ambulatory Surgical Center (ASC) Operating Room Requirements

Memorandum Summary

- ***RH of ≥20 Percent Permitted in Anesthetizing Locations:*** The Centers for Medicare & Medicaid Services (CMS) is issuing a categorical LSC waiver permitting new and existing ventilation systems supplying hospital and critical access hospital (CAH) anesthetizing locations to operate with a RH of ≥20 percent, instead of ≥35 percent. We are also recommending that RH not exceed 60 percent in these locations.
- ***This Waiver Does Not Apply:***
  - When more stringent RH control levels are required by State or local laws and regulations; or
  - Where reduction in RH would negatively affect ventilation system performance.
- ***Hospitals & CAHs Must Elect to Use the Categorical Waiver:***
  - Individual waiver applications are not required, but facilities are expected to have written documentation that they have elected to use the waiver.
  - At the entrance conference for any survey assessing LSC compliance, a facility that has elected to use this waiver must notify the survey team.
- ***Ongoing Requirements:***
  - Facilities must monitor RH in anesthetizing locations and take corrective actions when needed to ensure RH remains at or above 20 percent.
- ***ASCs:*** ASCs are not subject to all of the same LSC requirements as hospitals, but are required, consistent with 42 CFR 416.44(a)(1), to maintain RH in operating rooms in accordance with nationally accepted guidelines.
- ***State Operations Manual (SOM) Appendices A, E, L, & W are being updated accordingly.***

Impact of Lowering the Humidity

- Lowering humidity can impact some equipment and supplies
- Can affect shelf life and product integrity of some sterile supplies including EKG electrodes
- Some electro-medical equipment may be affected by electrostatic discharge especially older equipment
  - Can cause erratic behavior of software and premature failure of the equipment
  - It can affect calibration of the equipment
- Follow the manufacturers instructions for use that explains any RH requirements

CMS Memo on Low Relative Humidity

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Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 15-27-Hospital, CAH & ASC

DATE: **February 20, 2015**

TO: State Survey Agency Directors

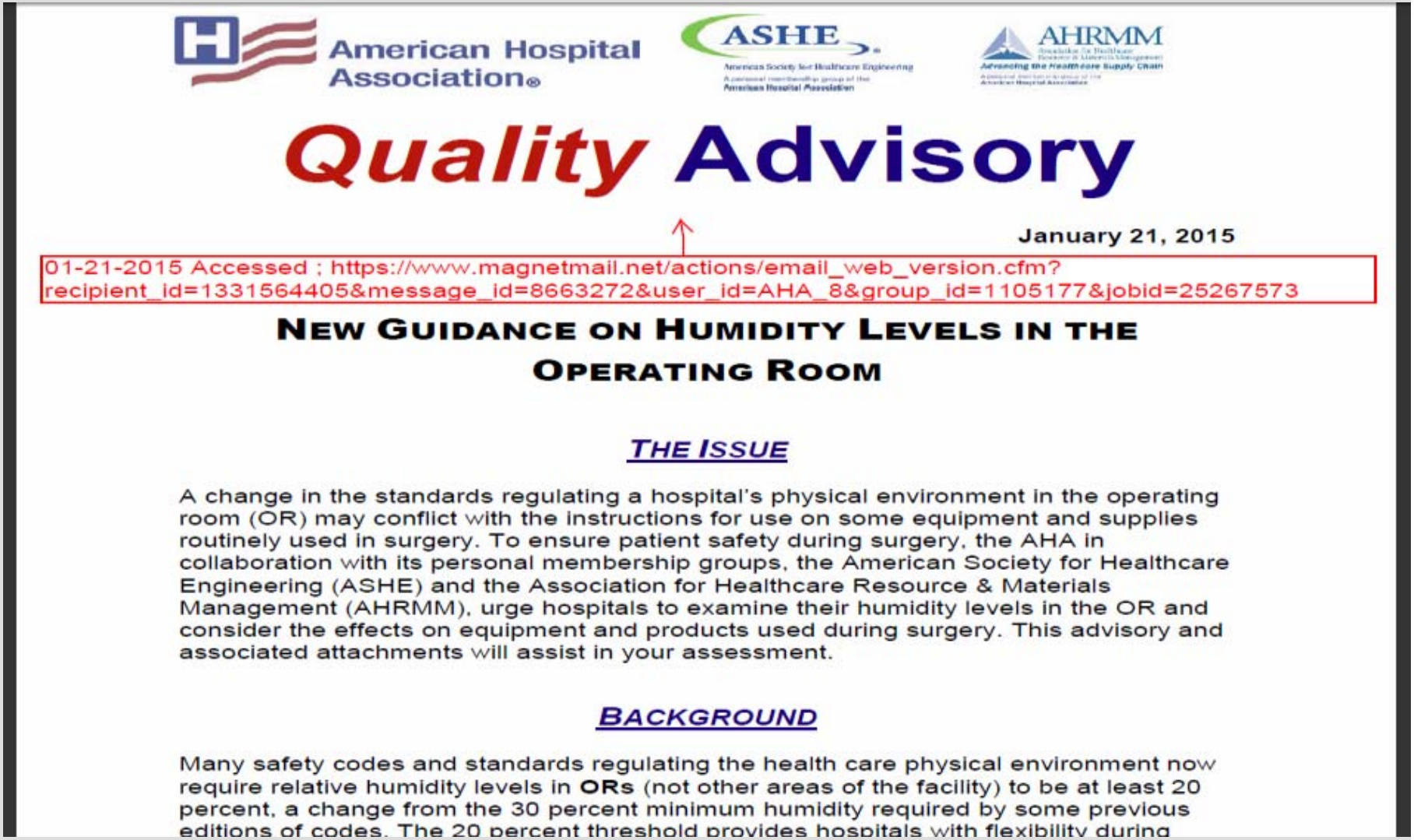
FROM: Director
Survey and Certification Group

SUBJECT: Potential Adverse Impact of Lower Relative Humidity (RH) in Operating Rooms (ORs)

Memorandum Summary

- ***Information on OR RH*** is provided for Ambulatory Surgical Centers (ASCs) & Supplemental Information for Hospitals & Critical Access Hospitals (CAHs) Using the Categorical Waiver of Life Safety Code (LSC) Anesthetizing Location RH Requirements
  - The Association for the Advancement of Medical Instrumentation (AAMI) coordinated the release on January 5, 2015 of a Joint Communication of multiple healthcare-related organizations on how a RH of <30% in ORs may affect the performance of some sterile supplies and electro-medical equipment.
- ***S&C 13-25-LSC & ASC*** permits hospitals and CAHs to use a LSC categorical waiver to establish an RH level <35% in anesthetizing locations. Before electing or continuing to use this categorical waiver, hospitals and CAHs are expected to ensure that the humidity levels in their ORs are compatible with the manufacturers' instructions for use (IFUs) for the supplies and equipment used in that setting.
- ***ASCs do not require a categorical waiver*** in order to use a lower RH level in their ORs but also need to ensure they comply with the IFUs for their OR supplies and equipment.

Impact of Lowering the Humidity



American Hospital Association®

ASHE
American Society for Healthcare Engineering
A personal membership group of the American Hospital Association

AHRMM
Advancing the Healthcare Supply Chain
A personal membership group of the American Hospital Association

Quality Advisory

January 21, 2015

01-21-2015 Accessed ; https://www.magnetmail.net/actions/email_web_version.cfm?recipient_id=1331564405&message_id=8663272&user_id=AHA_8&group_id=1105177&jobid=25267573

NEW GUIDANCE ON HUMIDITY LEVELS IN THE OPERATING ROOM

THE ISSUE

A change in the standards regulating a hospital's physical environment in the operating room (OR) may conflict with the instructions for use on some equipment and supplies routinely used in surgery. To ensure patient safety during surgery, the AHA in collaboration with its personal membership groups, the American Society for Healthcare Engineering (ASHE) and the Association for Healthcare Resource & Materials Management (AHRMM), urge hospitals to examine their humidity levels in the OR and consider the effects on equipment and products used during surgery. This advisory and associated attachments will assist in your assessment.

BACKGROUND

Many safety codes and standards regulating the health care physical environment now require relative humidity levels in **ORs** (not other areas of the facility) to be at least 20 percent, a change from the 30 percent minimum humidity required by some previous editions of codes. The 20 percent threshold provides hospitals with flexibility during

Lowering Humidity Can Have Other Effects

RELATIVE HUMIDITY LEVELS IN THE OPERATING ROOM
JOINT COMMUNICATION TO HEALTHCARE DELIVERY ORGANIZATIONS
January 2015

This is an important communication to the multiple stakeholders in healthcare whose work touches sterile supplies and electro-medical equipment used in delivering care to patients. The subject is about how relative humidity (RH) levels lower than 30% can impact the integrity and functionality of some of these products, with a special emphasis on RH levels in the operating room (OR). The following professional organizations have collaborated in the development of this communication: Ambulatory Surgery Center Association (ASCA), American College of Clinical Engineering (ACCE), American Hospital Association (AHA), American Society for Healthcare Engineering (ASHE), American Society of Anesthesiologists (ASA), American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE), Association for Healthcare Resource & Materials Management (AHRMM), Association for the Advancement of Medical Instrumentation (AAMI), Association of periOperative Registered Nurses (AORN), Association of Surgical Technologists (AST), Health Industry Distributors Association (HIDA), and the International Association of Healthcare Central Service Materials Management (IAHCSMM).[1]

Complaint Manual Update

- CMS issues memo on April 19, 2013
- CMS updates the Complaint Manual
- Hospital found to be in immediate jeopardy could have a full validation survey if the RO requests it
  - Regional office has discretion
- GAO emphasized need to share complaint information and SA survey finding with the applicable accreditation agency and CMS agrees
  - TJC, DNV,AOA, or CIHQ

Complaint Manual Update

DEPARTMENT OF HEALTH & HUMAN SERVICES
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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-27-Deemed Providers/Suppliers & Hospitals

DATE: **April 19, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Update of State Operations Manual (SOM) Chapter 5, Complaint Investigation

Memorandum Summary

Post-Complaint Survey Procedure - Deemed Providers/Suppliers:

- A full survey of a deemed provider/supplier after a complaint survey with condition-level findings will be made on a selective rather than an automatic basis.
- All survey reports and related correspondence must be shared promptly with a deemed provider/supplier's accrediting organization (AO).

Hospital Restraint/Seclusion Death Reporting: This section is being moved, to reflect the fact that the procedures therein apply to all hospitals, not just deemed hospitals. We are also streamlining the procedure for making disclosures to State Protection and Advocacy (P&A) agencies, to reduce burden.

A. Full Survey After Complaint for Deemed Providers/Suppliers

Luer Misconnections Memo

- CMS issues memo March 8, 2013
- 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
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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.

PA Patient Safety Authority Article

Table. Tubing Misconnections Reported to the Pennsylvania Patient Safety Authority, January 2008 to September 2009

MISCONNECTION	NUMBER OF REPORTS
Secondary intravenous (IV) infusion connected to lower "Y" port of primary IV tubing set	8
Hemodialysis arterial and venous tubing lines reversed	5
G-tube and J-tube lines reversed	3
Incorrect tubing connection (no further explanation provided in reports)	3
Epidural and patient-controlled analgesia (PCA) tubing sets reversed	2
Nonhemodialysis arterial and venous tubing lines reversed	2
Cell saver tubing connected to cell saver reservoir	1
Feeding tube set connected to Broviac®	1
Feeding tube set connected to peripherally inserted central catheter (PICC) line	1
Feeding tube set connected to suction port	1
Imaging contrast tubing set connected to tracheostomy cuff	1
IV tubing set connected to dialysis catheter	1
IV tubing set connected to PICC line	1
IV tubing set connected to tracheostomy cuff	1
Knee irrigation connected to peripheral IV tubing	1
Miscommunication (arterial line noted in medical record as peripheral IV)	1
Oral medication delivered through peripheral IV line	1
Suction line connected to water seal	1
Suction and feeding tubing sets reversed	1
Total	**36**

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 coils, 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, 38 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 only 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.[1] Misconnections have been recognized as a serious problem for many years. One of the earliest published reports of misconnections was the inadvertent delivery of breast milk via intravenous (IV) administration in 1972.[2] However, misconnections have garnered more attention in recent years, especially in the United States, due in part to the safety misconnection Sentinel Event Alert issued by the Joint Commission in April 2006.[3]

for IV delivery connected to nasogastric tubes.[4] 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 misconnections that can result in gas introduced into patients' blood vessels or liquid entering patients' respiratory tracts.[1]

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.[5] The luer connection system consists of male and female counterparts that are joined together either by push (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.[1]

Misconnections in Pennsylvania

Between January 2008 and September 2009, 38 tubing misconnection events were reported to the Authority: 35 liquid-to-liquid events and 3 liquid-to-gas events. (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-month-old infant admitted . . . to determine need for surgery. The physician ordered a 22 ml bolus of 50% dextrose saline[1]. A . . . nurse connected the bag of NS to the patient's lower "Y" on

ISMP Tubing Misconnections www.ismp.org

ISMP MedicationSafetyAlert!® Acute Care

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 gastrointestin 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. *A J Health-Syst Pharm*. 2010;67:734-36). The patient, a 17-month-old child, had a central venous catheter (CVC) in place f 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 syringe 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 administratio sets and syringes. So, even if a liquid medication is prepared in an oral syringe, the medication must be transferred to a 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 whic 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
- IV administration set spiked into enteral nutrition container, resulting in enteral nutrition administered IV.

FDA July 9, 2010 Enteral Feeding

www.fda.gov

To: Manufacturers of Enteral Feeding Tubes

Healthcare Professionals

Hospital Purchasing Departments

Dear Respected Colleague,

FDA is aware that standard luer lock connectors are found on a variety of tubing sets, solution bags and other medical products. The ease of connection between these luer lock connectors have led to misconnections that have inadvertently linked unrelated systems, and at times, have resulted in serious adverse events. Luer lock misconnections are often under-recognized; therefore, adverse events resulting from such misconnections are likely to be under-reported.

These misconnections can be dangerous and result in injuries. Luer connectors easily interconnect many medical components, accessories, and delivery systems across multiple medical applications. Because of the nature of the connector design, human factors, and the clinical environment, healthcare professionals may mistakenly connect the wrong devices and deliver substances through the wrong route.

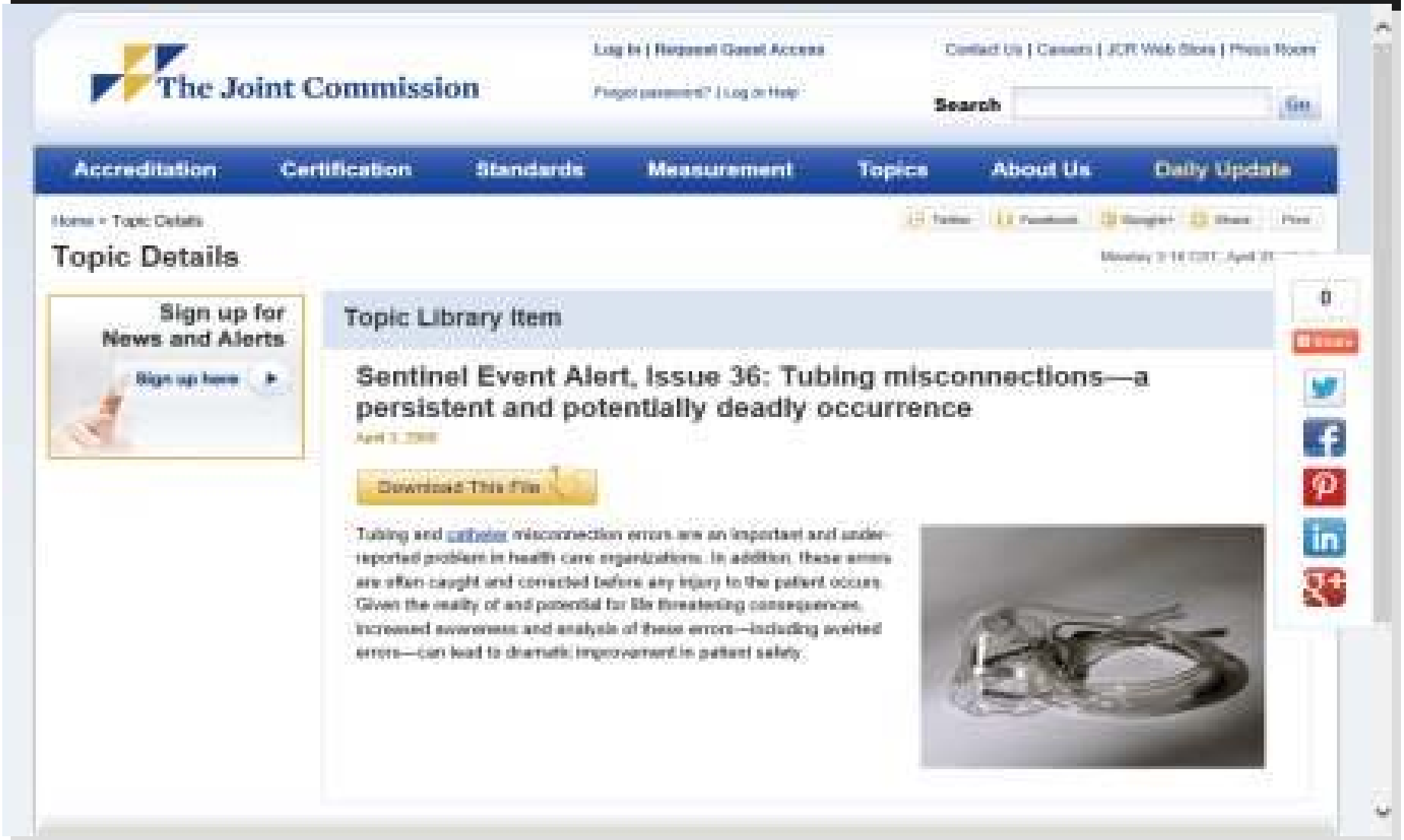
Examples of misconnections include:

- Intravenous infusions connected to epidural lines, and epidural solutions (intended for epidural administration) connected to peripheral or central IV catheters.
- Bladder irrigation solutions using primary intravenous tubing connected as secondary infusions to peripheral or central IV catheters.
- Infusions intended for IV administration connected to an indwelling bladder (foley) catheter.
- Infusions intended for IV administration connected to nasogastric (NG) tubes.
- Intravenous solutions administered with blood administration sets, and blood products transfused with primary intravenous tubing.
- Primary intravenous solutions administered through various other functionally dissimilar catheters, such as external dialysis catheters, a ventriculostomy drain, an amnio-infusion catheter, and the distal port of a pulmonary artery catheter.[1]

In particular, misconnections with enteral feeding tubes and solutions have been

TJC Sentinel Event Alert #36

www,jointcommission.org



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

Misconnections & How to Prepare

Sentinel Event Alert, Issue 53
Page 2

There are various types of misconnections posing dangers, including the following:[3,9]

Types of misconnections		
Enteral feeding tube	connected to	IV (such as *The New York Times* example)[6,10,11]
Limb cuff inflation device	connected to	IV (For example, a 71-year-old woman died post-operatively after a blood pressure cuff was accidentally connected to her IV line, causing an air embolism.)[7]
Epidural solution (intended for epidural administration)	connected to	Peripheral or central IV catheter[10]
Epidural line	connected to	IV infusion[10,11]
Bladder irrigation solution using primary IV tubing (connected as secondary infusion)	connected to	Peripheral or central IV catheter[10,11]
IV infusion (intended for IV administration)	connected to	Indwelling bladder (foley) catheter[10,11]
IV infusion (intended for IV administration)	connected to	Nasogastric (NG) tube[10,11]
Primary IV tube	connected to	Blood product (intended for transfusion)[10,11]
Enteral feeding (gastric or nasal)	connected to	Tracheostomy tube[3]
IV solution	administered via	Blood administration set[10,11]
Primary IV solution	administered via	Various functionally dissimilar catheters (such as external dialysis catheter, ventriculostomy port, amnio-infusion catheter, distal port of pulmonary artery catheter)[10,11]

New Standards Prevent Tubing Misconnections

- New and unique international standards being developed in 2014 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

New standards to prevent tubing misconnections will have unprecedented impact on supply chain and patient safety

What if you could no longer connect any of the equipment that you have in stock to give enteral feedings (e.g., feeding sets, tubes, oral syringes). That is the likely scenario - once new standards to prevent tubing misconnections are released - without a carefully crafted implementation plan across all settings where care is delivered.

The very simple and universal design of most *connectors* in all of health care creates a serious risk that tubes from totally unrelated systems can be inadvertently connected leading to patient death or serious injury. This means that an enteral feeding tube could be accidentally connected to an IV line, delivering formula into a vein with fatal consequences. An international group of stakeholders are working together to solve this problem by developing unique design standards for every delivery system so that unrelated systems can never be mistakenly connected together.

What do these new standards mean for healthcare

New and unique international standards are being developed for connectors for each gas and liquid delivery system in healthcare to make it virtually impossible to connect unrelated systems[1]. These new connector standards will include new designs for connectors of enteral, respiratory, limb cuff inflation, neuraxial, and intravascular systems. It is anticipated that the standards for enteral connectors will be the first to be released in 2014. There will be a phase-in period for product development, market release and implementation guided by the FDA, existing state legislation, suppliers, and national organizations working together.

www.premierinc.com/tubingmisconnections/

Hospital CoPs for QI

- CMS issued new hospital COPs for QA and Performance Improvement
- CMS issues Memo March 15, 2013 on AHRQ Common Formats
  - Hospitals are required to track adverse events for PI
- Starts with tag number 0263
- Short section because the hospital compare program is not part of the CMS CoP
  - Hospital compare is the indicators that must be sent to CMS to receive full reimbursement rates

Report Adverse Events to PI

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: 13-19-HOSPITALS

DATE: **March 15, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: AHRQ Common Formats - Information for Hospitals and State Survey Agencies (SAs) - Comprehensive Patient Safety Reporting Using AHRQ Common Formats

Memorandum Summary

Hospitals are Required to Track Adverse Events: The Condition of Participation (CoP) for Quality Assessment and Performance Improvement (QAPI) at 42 CFR 482.21(a)(2) requires hospitals to track adverse patient events. However, several recent reports completed by the Department of Health and Human Services Office of the Inspector General (OIG) indicated that hospitals fail to identify most adverse events.

Use of the Common Formats May Help Hospitals Improve Tracking. The OIG suggested staff failure to understand what events need to be reported to the hospital's QAPI program contributes to the problems with internal tracking systems. The OIG recommended that the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS) could help hospitals improve their ability to track adverse patient safety events by disseminating information on AHRQ's Common Formats. The Common Formats define a systematic process for reporting adverse events, near misses, and unsafe conditions, and allow a hospital to report harm from all causes. Hospital use of the AHRQ Common Formats is voluntary, but a hospital that uses them and is adept at the analysis that they permit will be in a better position

Adverse Event Reporting

- Hospitals are required to track AE
- Several reports show that nurses and others were not reporting adverse events and not getting into the PI system
- OIG recommends using the AHRQ common formats to help with the tracking
- States could help hospitals improve the reporting process
- Encouraged all surveyors to develop an understanding of this tool


PSO Privacy
Protection Center
Sign In
How do I get an account?
Support:
Help
Contact Us
Search
Welcome to the PSO Privacy Protection Center
Home
About the PSOPPC
Data Submission
AHRQ Common Formats
Technical Assistance Resources
Questions and Answers
News and Alerts
The Patient Safety Organization Privacy Protection Center (PSOPPC) was created by the Agency for Healthcare Research and Quality (AHRQ) to support the implementation of the Patient Safety and Quality Improvement Act (PL-109-41), passed by the United States Congress in July, 2005. The PPC provides technical assistance to PSOs by ensuring patient safety event data is nonidentifiable for data submission and reporting to the NPSD, and provides technical assistance on use of Common Formats. Read more about the PPC
hwww.psoppc.org/web/patientsafety
Common Formats
General Information
Active for Reporting
Hospital Common Formats - v1.2
Hospital Common Formats - v1.1
Open for Public Review/Comment
Readmissions Common Format - v0.1 Beta
Skilled Nursing Facility Common Formats - v0.1 Beta
PSOPPC Services
Services Available to PSOs
Common Formats Support
Submitting Data
Spotlight
To provide feedback on the Common Formats, go to the:

Hospital Common Formats

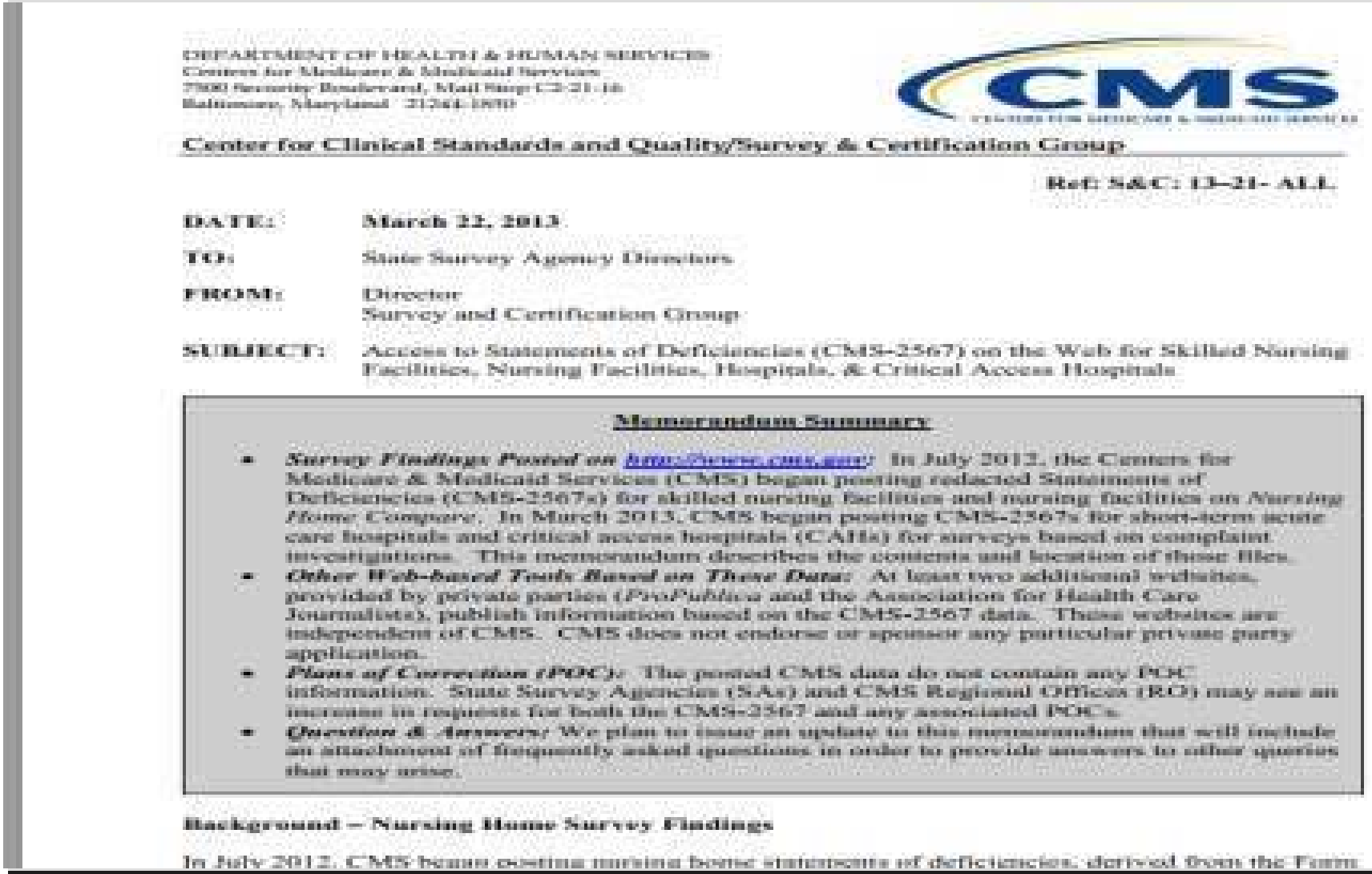
Access to Hospital Complaint Data

- CMS issued Survey and Certification memo on March 22, 2013 regarding access to hospital complaint data
- 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
- Updating quarterly
  - Available under downloads on the hospital website at www.cms.gov

Access to Hospital Complaint Data

- There is a list that includes the hospital's name and the different tag numbers that were found to be out of compliance
  - Many on restraints and seclusion, EMTALA, infection control, patient rights including consent, advance directives and grievances
- Two websites by private entities also publish the CMS nursing home survey data and hospitals
- The ProPublica website
- The Association for Health Care Journalist (AHCJ) websites

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

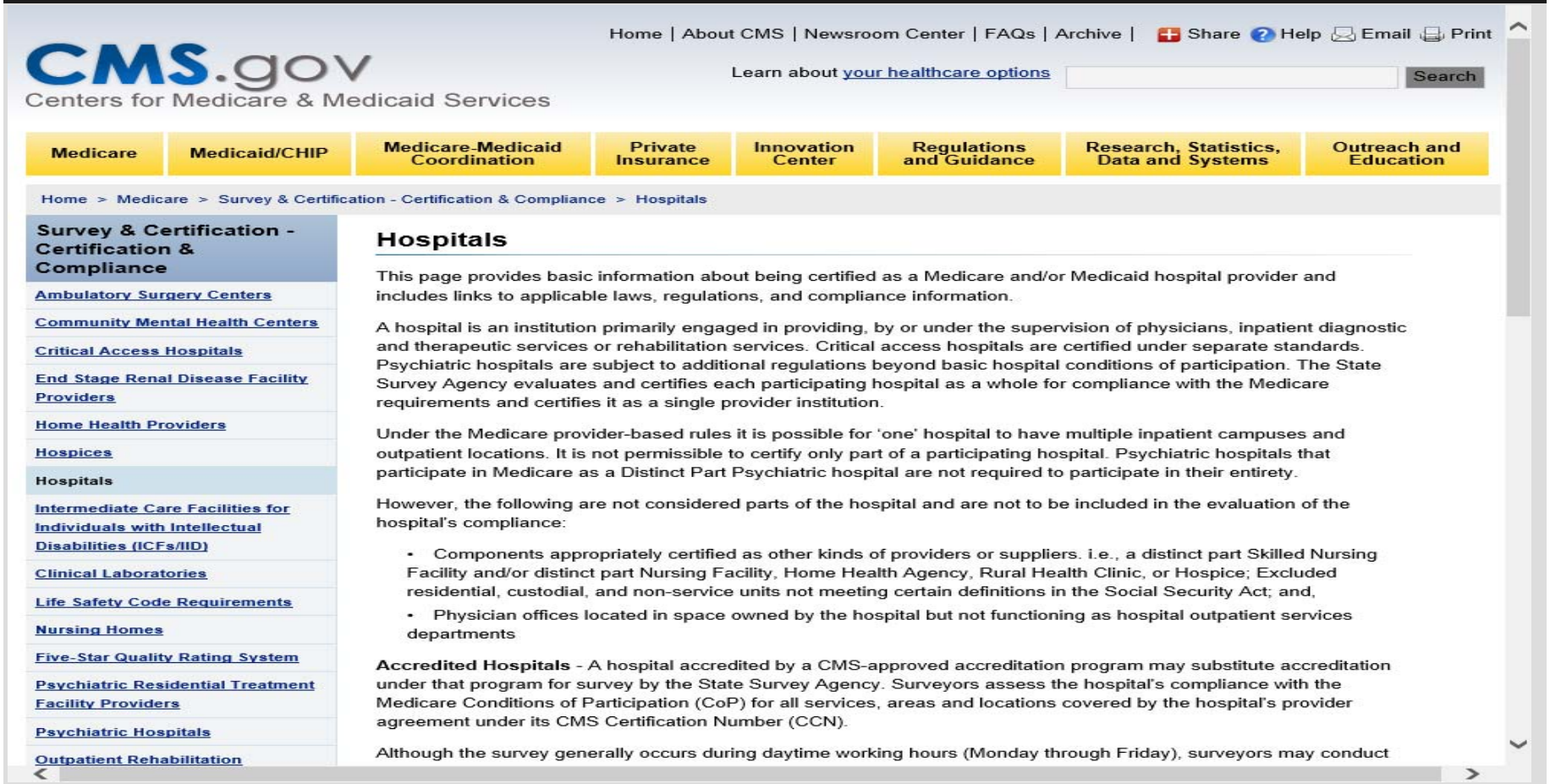
Memorandum Summary

- ***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

TJC Revised Requirements

- TJC has published many changes over the past two years
  - Many of the changes reflected in their standards is to be in compliance with the CMS CoP
  - Standards are for hospitals that use them to get deemed status to allow payment for M/M patients
  - This means hospitals do not have to have a survey by CMS every 3 years
  - Can still get a complaint or validation survey
  - So now TJC standards crosswalk closer to the CMS CoPs (not called JCAHO any more)

Mandatory Compliance

- Hospitals that participate in Medicare or Medicaid must meet the COPs for all patients in the facilities and not just those patients who are Medicare or Medicaid
- Hospitals accredited by TJC, CIHQ, AOA, or DNV Healthcare have what is called deemed status
  - These are the only ones that CMS has given deemed status to for hospitals
- This means you can get reimbursed without going through a state agency survey
  - States can still institute a survey and be more restrictive

Survey Procedure

- Step one is publication in Federal Register
- Step two is where CMS publishes the interpretive guidelines
- The interpretive guidelines provide instructions to the surveyors on how to survey the CoPs
  - These are called survey procedure
  - Not all the standards have survey procedures
  - Questions such as “Ask patients to tell you if the hospital told them about their rights”

Nursing Services 0385

- Standard: Must have an organized nursing service that provides 24 hour nursing services
  - Must have at least one RN furnishing or supervising 24 hours
  - SSA at 1861 (b) states you must have a RN on duty at all times
- Survey procedures determine nursing services is integrated into hospital PI
- Make sure there is adequate staffing

Survey Procedure 385

- Surveyor is suppose to interview the chief nursing officer (CNO) which CMS calls the DON or Director of Nursing
- Surveyor is to request a copy of the organizational chart
- Will look at job descriptions including the CNO
- Surveyor to select at least one patient from every inpatient nursing unit
  - Suppose to observe nursing care
  - To make sure there is adequate staffing
  - Will also look at patient medical records and care plans to make sure up to date, incident reports and P&P and talk to patients

Director of Nursing Service 0386

- Standard; Hospital must have a well organized service of administrative authority and delineations of responsibilities for patient care
- CNO must be a current licensed RN
- CNO is responsible for operating the nursing department
- CNO is responsible for determining types and numbers of nursing personnel and staff
  - Includes nurses, supervisors, assistant director, unit clerks, orderlies, nurse aides etc.

Nursing Service 386

- Must be one nursing service hospital wide
- Operation of nursing services includes the quality of care provided by nursing
- Survey Procedure
  - To verify CNO approves patient care P&P's
  - Verify CNO develops the nursing service staffing P&P
  - Will review the organization chart and look at lines of authority in the nursing department
  - Will read the job description for the CNO to make sure it specified duties and responsibilities of nursing services

Nurse Staffing 392

- Standard; Nursing service must have adequate number of nurses and personnel to care for patients
- Must have a qualified nursing supervisory personnel
- Every department or unit must have a RN present
  - Not available if working on two units at same time
  - Must ensure RN for the bedside care of any patient
  - Must revise as needed for nursing staff absenteeism

Survey Procedure 392

- Surveyor to look at staffing schedules that correlate number and acuity of patients
- Surveyor to take into account the number of patient, intensity of illness and nursing needs
- Surveyor to take into consideration the training and experience of the personnel
- Also to consider the physical layout and size of the hospital
- Surveyor is to review the medical records of the patients to makes sure care is provided as ordered

Nurse Staffing 392

- There are 3 recent evidenced based studies that show the importance of having adequate staffing which results in better outcomes
- Study said patients who want to survive their new hospital visit should look for low nurse-patient ratio
- First evidenced based study on impact of nursing staff on patient outcomes
- Nurse Staffing and Quality of Patient Care, AHRQ, Evidence Report/Technology Report Number 151, March 2007, AHRQ Publication No. 07-E005[1]

[1]http://www.ahrq.gov/downloads/pub/ evidence/pdf/nursestaff/nursestaff.pdf

AHRQ Nurse Staffing and Quality

Evidence Report/Technology Assessment
Number 151

Nurse Staffing and Quality of Patient Care

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Contract No. 290-02-0009

Prepared by:
Minnesota Evidence-based Practice Center, Minneapolis, Minnesota

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www.ahrq.gov/downloads/pub/evidence/pdf/nursestaff/nursestaff.pdf
www.ahrq.gov/downloads/pub/evidence/pdf/nursestaff/nursestaff.pdf

Nursing Linked to Safety

- IOM study also linked adequate staffing levels to patient outcomes
- Limits to number of hours worked to prevent fatigue
- Suggests no mandatory overtime for nurses
- Never work a nurse over 12 hours or 60 hours in one week
  - Or will have 38% or 3 times the error rate

Nursing Linked to Safety

- Also showed medication error rate, falls, pressure ulcers, UTI, surgery site infections, gastric ulcers, codes, readmission rate, LOS (length of stay), etc. are linked to staffing
- Redesigning the work force
- See Keeping Patients Safe: Transforming the Work Environment of Nurses 2004[1]

[1]www.nap.edu/openbook/0309090679/html/23/html

Nursing Staffing Linked to Safety

- AHRQ 2008 has published 3 volume, 51 chapter handbook for nurses at no cost
- Great resource that every hospital should have
- Nurse Staffing and Patient Care Quality and Safety
- Again shows that patient safety and quality is affected by short staffing
- Patient Safety and Quality: An Evidence-Based Handbook for Nurses, 2008[1]

[1] http://www.ahrq.gov/qual/nurseshdbk

AHRQ Agency for Healthcare Research and Quality

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You Are Here: AHRQ Home > Quality & Patient Safety > Medical Errors & Patient Safety > Patient Safety and Quality: An Evidence-Based Handbook for Nurses

Patient Safety and Quality

An Evidence-Based Handbook for Nurses

Nurses play a vital role in improving the safety and quality of patient care—not only in the hospital or ambulatory treatment facility, but also of community-based care and the care performed by family members. Nurses need know what proven techniques and interventions they can use to enhance patient outcomes.

To address this need, the Agency for Healthcare Research and Quality (AHRQ), with additional funding from the Robert Wood Johnson Foundation, has prepared this comprehensive, 1,400-page, handbook for nurses on patient safety and quality—*Patient Safety and Quality: An Evidence-Based Handbook for Nurses.* (AHRQ Publication No. 08-0043).

Experts in the field reviewed the literature, and their contributions are grouped into these sections:

Patient Safety and Quality / Evidence-based Practice / Patient-centered Care / Working Conditions—Work Environment / Critical Opportunities for Patient Safety and Quality / Tools

Select to download the Entire Volume as a PDF file (10 MB) or individual chapters (below). All PDF files are accessible. PDF Help.

Select for Ordering Information.

Edited by Ronda G. Hughes, Ph.D., M.H.S., R.N., of AHRQ

Contents

www.ahrq.gov/qual/nurseshdbk

Introduction

RN 24 Hours a Day A-0393

- Standard: Must have 24 hour nursing services provided or supervised by a RN
  - Exception for rural hospitals that have a nursing waiver granted for temporary shortage of nurses
  - Will make sure salary offered is comparable to three nearest hospitals
- Rural hospitals with 50 or fewer beds may be granted a temporary waiver of 24 hour RN requirement by the regional office
- Surveyor is to verify that there is at least one RN on each unit 24 hours a day

Verify Licensure 394

- Standard: Must have procedure to ensure nursing personnel have valid and current license
  - Hospital procedure must ensure all nurses have a current and valid license
  - Must assure that all staff meet standards such as continuing education and certification and training
  - Surveyor will look at license verification P&P
  - Will look at HR records to make sure licensed

Verification of Nursing License

- Most state boards of nursing have online verification process
  - Considered primary source verification
  - Can print out information for employee file
  - Don’t forget to check the OIG list of excluded individuals (LEIE) and document it in the HR file for nurses

LEIE Downloadable Database

RN for Every Patient 395

- Standard; A RN must supervise and evaluate the nursing care for every patient
- RN must do admission assessment
- Must use acceptable standard of care
- Must follow hospital P&P
- Evaluation would include assessing each patient's needs, health status and response to interventions

Nursing Care Plan 396 2013

- Standard: Hospital must ensure that nursing staff develop and keeps a current, nursing care plan for each patient
  - The nurse plan may be part of an interdisciplinary plan
  - It use to be that nursing had to always have a separate plan of care but changed June 7, 2013
- Frequent problematic standard
- Starts upon admission, includes discharge planning, physiological and psychosocial factors
- Assessment considers goals, physiological and psychosocial factors and discharge planning

Tag 396 Amended June 7, 2013

* * *

A-0396

(Rev.)

§482.23(b)(4) - The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. ***The nursing care plan may be part of an interdisciplinary care plan.***

Interpretive Guidelines §482.23(b)(4)

Nursing care planning starts upon admission. It includes planning the patient's care while in the hospital as well as planning for discharge to meet post-hospital needs. A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis). *The assessment considers the patient's treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. The plan* develop*s* appropriate nursing interventions in response to *the identified nursing care* needs. The nursing care plan is kept current by ongoing assessments of the patient's needs and *of* the patient's response to interventions, and updating or revising the patient's nursing care plan in

response to assessments. The nursing care plan is part of the patient's medical record and must comply with the *medical records* requirements *at §482.24*.

Hospitals have the flexibility of developing the nursing care plan as part of a larger, coordinated

Nursing Care Plan 396 2013

- Based on assessing the patient's needs
- The interdisciplinary POC does not eliminate the need for a nursing plan of care
- You have to have one but it can be part of the larger, coordinated interdisciplinary POC
  - Interdisciplinary plan of care serve to promote collaboration between members of the team
- Care plan is part of the patient's medical records and must be initiated soon after admission, revised and implemented
  - Will look at **6-12** care plans

Nursing Services Plan of Care 2013

- As discussed previously, CMS CoPs requires that a separate nursing plan of care be started immediately after admission and kept current and it must be maintained in the medical record
- The final change would not require a separate plan of care done by nursing if they participated in an interdisciplinary care plan
  - Hospitals could still do a separate stand alone nursing care plan if they want
- The nursing care plan can be integrated into the overall hospital interdisciplinary plan
- Might involve respiratory therapy, PT, OT, etc.

RN Assigns Care of Patient 397

- Standard: RN must assign the nursing care of each patient to other nursing staff in accordance with patient needs
  - Based on the qualifications and competence of the staff available
- RN must make all patient care assignments
- CNO will ensure all staff have proper education, experience, competence and qualifications for each patient
- Surveyor will review nursing assignments to make sure staff are qualified

Agency Nurses 398

- Standard: Agency nurses must adhere to P&P's
  - CMS calls them non-employee nurses
- CNO must provide adequate supervision and evaluate (once a year) activities of agency nurses
  - Includes other personnel such as volunteers
  - Must be supervised by RN who is a hospital employee
- CNO must make sure agency nurses know the hospital P&P
- Must include orientation to hospital and to specific unit, emergency procedures, and safety P&P's

Preparation/Admin of Drugs 405 2014

- Standard: Drugs must be prepared and administered according to state and federal law
  - Amended Dec 2011, June 7, 2013 and 2014
- Standard: Need an practitioner's **order**
  - Important issue with CMS to have an order for all medications administered or standing order
  - Make sure order is documented in the medical record
  - Surveyor will observe nurse prepare and pass medications

Drugs & Biologicals 405

- Drugs and biologicals may be administered on orders of other practitioners:
  - Allowed by state law
  - State scope of practice act
  - Hospital P&P and
  - MS bylaws and R/R (Rules and Regulations)
- Must not only be within acceptable standards of practice (SOP) but done under the supervision of nursing
- CMS has blue box advisories which are not to be cited

Pharmacy Should Prepare Piggybacks & IVs

For Information – Not Required/Not to be Cited

Although the regulation addresses both preparation and administration of drugs and biologicals and does not prohibit preparation of drugs by nursing staff, to improve patient safety it is generally preferable for hospitals to avoid nurse preparation of drugs in patient care areas, and instead rely upon pharmacy IV admixture systems and/or commercially available unit dose products.

Preparation/Administration of Drugs 405

- Standard: Medications must be prepared and administered with acceptable national standards of practice and mentions five organizations
  - National Coordinating Council for Medication Error Reporting and Prevention
  - Institute for Healthcare Improvement
  - U.S Pharmacopeia
  - Institute for Safe Medication Practices
  - Infusion Nurses Society
  - CDC at www.cdc.gov
  - Also according to the TJC MM chapter, manufacturer's directions and hospital policy

Timing of Medication Administration Tag 405

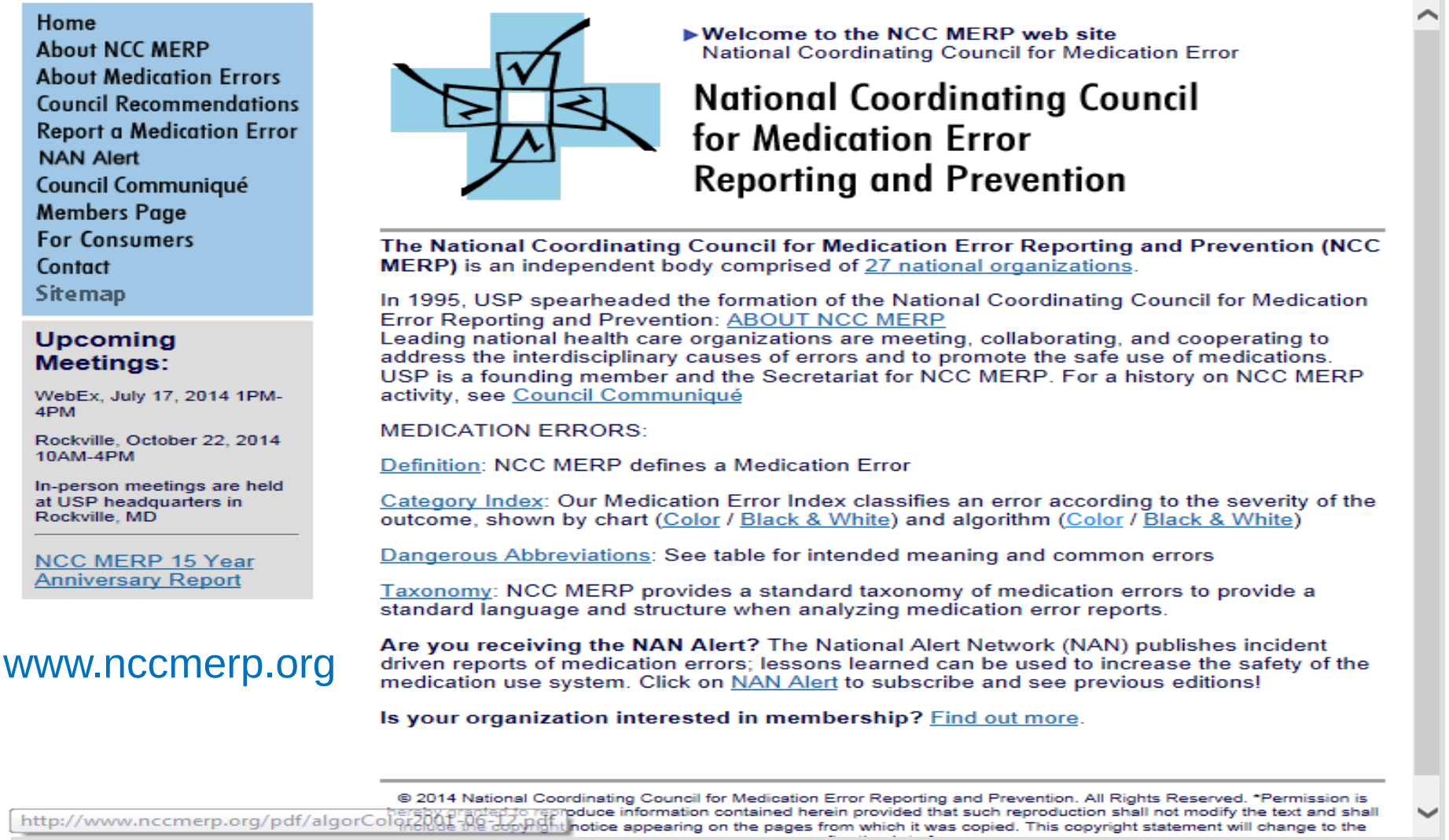
- What are acceptable standards of care?
  - National organizations that are recognized in the field issue written statements and policies that direct patient care
- The hospital's P&Ps must be consistent with SOC
- Standards of care can be set by state pharmacy boards and national organizations like the ones mentioned by CMS
- Others include:
  - ASHP (American Society of Healthcare System Pharmacist), American Nurses Association (ANA), American Pharmacy Association (APA), APIC, etc.

ISMP Institute for Safe Medication Practices

Infusion Nurses Society INS

www.ins1.org

National Coordinating Council



Upcoming Meetings:

WebEx, July 17, 2014 1PM-4PM

Rockville, October 22, 2014 10AM-4PM

In-person meetings are held at USP headquarters in Rockville, MD

NCC MERP 15 Year Anniversary Report

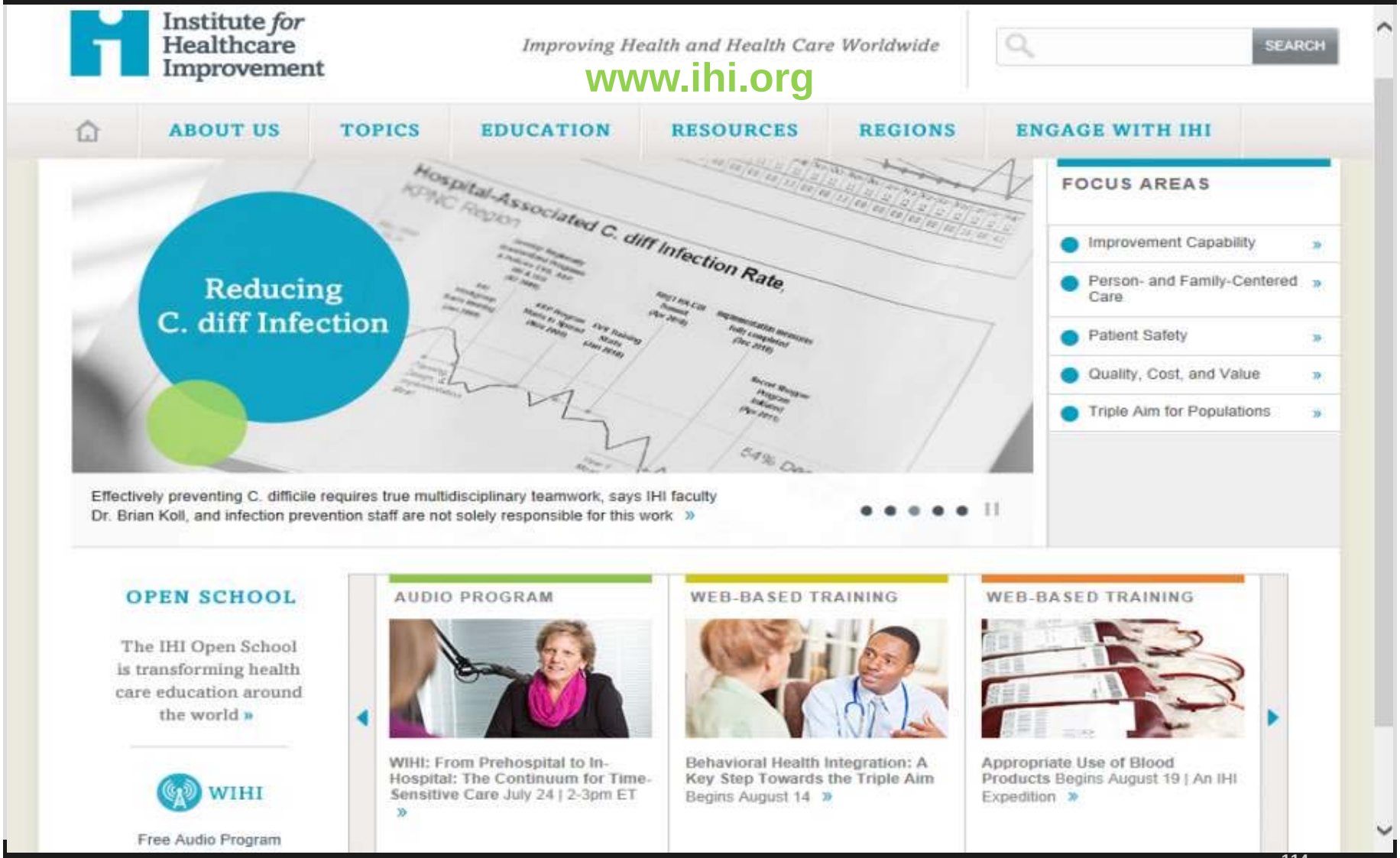
NATIONAL ALERT NETWORK (NAN)

Print

The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP) publish the alerts from the National Medication Errors Reporting Program, operated by ISMP. The alerts are incident driven. The NCC MERP, ISMP and the ASHP encourage the sharing and reporting of medication errors, so that lessons learned can be used to increase the safety of the medication use system.

February 18, 2014	Potential inaccuracy of electronically transmitted medication history information used for **medication reconciliation**
June 10, 2013	Important Change with **Heparin Labels**
April 17, 2013	Confusion regarding the generic name of the HER2-targeted drug **KADCYLA** (**ado-trastuzumab emtansine**)
January 23, 2013	Severe burns and permanent scarring after **glacial acetic acid** (≥ 99.5%) mistakenly applied topically
April 25, 2012	Proper disposal of **fentaNYL patches** is critical to prevent accidental exposure
March 18, 2012	Potential for wrong route errors with Exparel (**bupivacaine liposome injectable suspension**)
Jun 2011	Risk of potentially fatal overdose with **colistimethate**
June 2010	**EPINEPHrine** pre-filled syringe shortage
Apr 2010	Another child is victim of **heparin** error

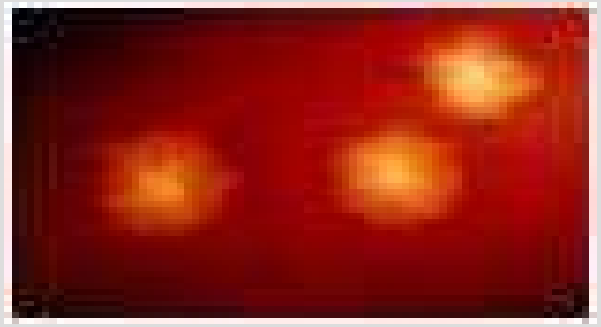
Institute for Healthcare Improvement IHI

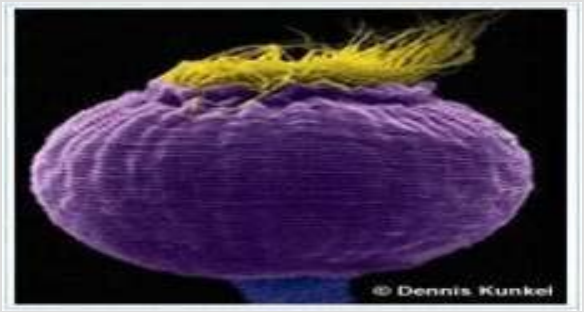


USP U.S. Pharmacopeial

Centers for Disease Control & Prevention CDC

CDC IV Guidelines





- Every hospital should have the 2011 CDC Guidelines for the Prevention of Intravascular Catheter Related Infections
  - How to prep the skin for the peripheral IV
  - How to secure the needle
  - How long to change the dressing
  - How long do you change the IV tubing

www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011

Naomi P. O'Grady, M.D.[1], Mary Alexander, R.N.[2], Lillian A. Burns, M.T., M.P.H., C.I.C.[3], E Patchen Dellinger, M.D.[4], Jeffery Garland, M.D., S.M.[5], Stephen O. Heard, M.D.[6], Pamela A. Lipsett, M.D.[7], Henry Masur, M.D.[1], Leonard A. Mermel, D.O., Sc.M.[8], Michele L. Pearson, M.D.[9], Issam I. Raad, M.D.[10], Adrienne Randolph, M.D., M.Sc.[11], Mark E. Rupp, M.D.[12], Sanjay Saint, M.D., M.P.H.[13] and the Healthcare Infection Control Practices Advisory Committee (HICPAC)[14].

1National Institutes of Health, Bethesda, Maryland
2Infusion Nurses Society, Norwood, Massachusetts
3Greenich Hospital, Greenwich, Connecticut
4University of Washington, Seattle, Washington
5Wheaton Franciscan Healthcare-St Joseph, Milwaukee, Wisconsin
6University of Massachusetts Medical School, Worcester, Massachusetts
7Johns Hopkins University School of Medicine, Baltimore, Maryland
8Warren Alpert Medical School of Brown University and Rhode Island Hospital, Providence, Rhode Island
9Office of Infectious Diseases, CDC, Atlanta, Georgia
10MD Anderson Cancer Center, Houston, Texas
11The Children's Hospital, Boston, Massachusetts
12University of Nebraska Medical Center, Omaha, Nebraska
13Ann Arbor VA Medical Center and University of Michigan, Ann Arbor, Michigan

CDC 10 Recommendations

- The CDC has a page on Injection Safety that contains the excerpts from the Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- Summarizes their 10 recommendations for safe injection practices
- CMS expects hospitals to follow the CDC guidelines
  - Available at http://www.cdc.gov/ncidod/dhqp/injectionSafetyPractices.html

10 CDC Standards Safe Injection Practices

Injection Safety

- **Injection Safety**
- CDC's Role
- CDC Statement
- Information for Providers
- Information for Patients
- Preventing Unsafe Injection Practices
- ▶**Safe Injection Practices**
  - CDC Clinical Reminder: Spinal Injection Procedures
- Infection Prevention during Blood Glucose Monitoring and Insulin Administration
- Recent Publications
- Recent Meetings
- The One & Only Campaign

Related Links

- One & Only Campaign
- HICPAC

Injection Safety > Preventing Unsafe Injection Practices

Email page link
Print page

Recommend 7 Tweet Share

Safe Injection Practices to Prevent Transmission of Infections to Patients

Download the complete 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings [PDF - 3.80 MB]

III.A.1.b. Safe Injection Practices The investigation of four large outbreaks of HBV and HCV among patients in ambulatory care facilities in the United States identified a need to define and reinforce safe injection practices 453. The four outbreaks occurred in a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The primary breaches in infection control practice that contributed to these outbreaks were 1) reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag) and 2) use of a single needle/syringe to administer intravenous medication to multiple patients. In one of these outbreaks, preparation of medications in the same workspace where used needle/syringes were dismantled also may have been a contributing factor. These and other outbreaks of viral hepatitis could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications 453, 454. These include the use of a sterile, single -use, disposable needle and syringe for each injection given and prevention of

Contact Us:

Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333

800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348
Contact CDC–INFO

Medication Errors Tag 405

- CMS talks about the studies that show the large number of medication errors in hospitals
- Institute of Medicine said drug related adverse outcomes in 1.9 million inpatient hospital stays
- This is 4.7% of all patient stays
- There are 838,000 patient who are treated and released for drug related AE
- This is 0.8% of all visits
- Despite CPOE, ePHI, scanning and other technologies

Drugs & Biologicals 405

- CMS would allow them to document and sign the order
- For example, the above practitioners would be permitted as allowed by the state scope of practice such as by the state pharmacy board and if the hospital has granted them privileges
  - A PharmD manages the Anticoagulant Clinic or works with diabetic patients in managing their insulin
  - The MS approved the INR chart for patients on warfarin (coumadin)
  - Pharmacists changes dose and writes and signs off order

Drugs and Biologicals 405

- CMS calls them drugs and biologicals
  - Joint Commission calls them medications
  - Each state law differs on scope of practice on what PA, NP, CRNA, Pharm.D etc. can do so be aware of your state specific law
  - July 11, 2014 regulation where MS can C&P certain non-physician providers
- Drugs and biologicals must be administered by or under the supervision of nursing or other personnel as allowed by law, P&Ps, and MS bylaws and R/Rs

Standing Orders and Outpatient Orders

- Drugs must be administered in response to an order from a practitioner or concerning standing orders
- This includes ordering outpatient services for practitioners who are not privileged but are permitted by hospital & MS P&P to order
- Exception is for flu and pneumovac
  - Need physician approved protocol after assessment of contraindications

CMS Changes to Medication Administration

- CMS issued a survey and certification memo with changes to Tag 405 on December 22, 2011, June 7, 2013 and March 14, 2014 memo effective June 6, 2014
  - Tag 405 use to say that all medications must be given within 30 minutes of the scheduled time
  - Now three blocks of time to give medications
  - Thanks to efforts of the ISMP
  - Included section on standing orders all but one sentence moved to tag 457

Tag 405 Revised June 7, 2013

A-0405

(Rev.)

§482.23(c) Standard: Preparation and Administration of Drugs

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(1) **Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.**

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations….

(2) **All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.**

Interpretive Guidelines §§482.23(c)*(1), (c)(1)(i)* and (c)(*2*)

According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people each year.[1] *It has been estimated that drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital*

Transmittal Medication Admin Dec 22, 2011

CMS Manual System
Pub. 100-07 State Operations
Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 77	(Advance Copy)	Date: December 22, 2011

SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for 42 CFR 482.23(c), concerning medication administration.

REVISED MATERIAL - EFFECTIVE DATE*: December 22, 2011
IMPLEMENTATION DATE: December 22, 2011

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/§482.23(c) Standard: Preparation and Administration of Drugs/A-0405

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

A-0405

(Rev.77, Issued: 12-22-11, Effective/Implementation: 12-22-11)

www.cms.gov/Transmittals/01_overview.asp

CMS Memo Med & Safe Opioid Use

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: 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

Final Transmittal Issued June 6, 2014

CMS Manual System
Pub. 100-07State Operations Provider Certification

Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)

Transmittal 116 | **Date: June 6, 2014**

SUBJECT: Revised State Operations Manual (SOM), Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for various provisions of 42 CFR 482.23(c), concerning medication administration, and 42 CFR 482.51(b)(4), concerning post-operative patient care.

NEW/REVISED MATERIAL - EFFECTIVE DATE: June 6, 2014
IMPLEMENTATION DATE: June 6, 2014

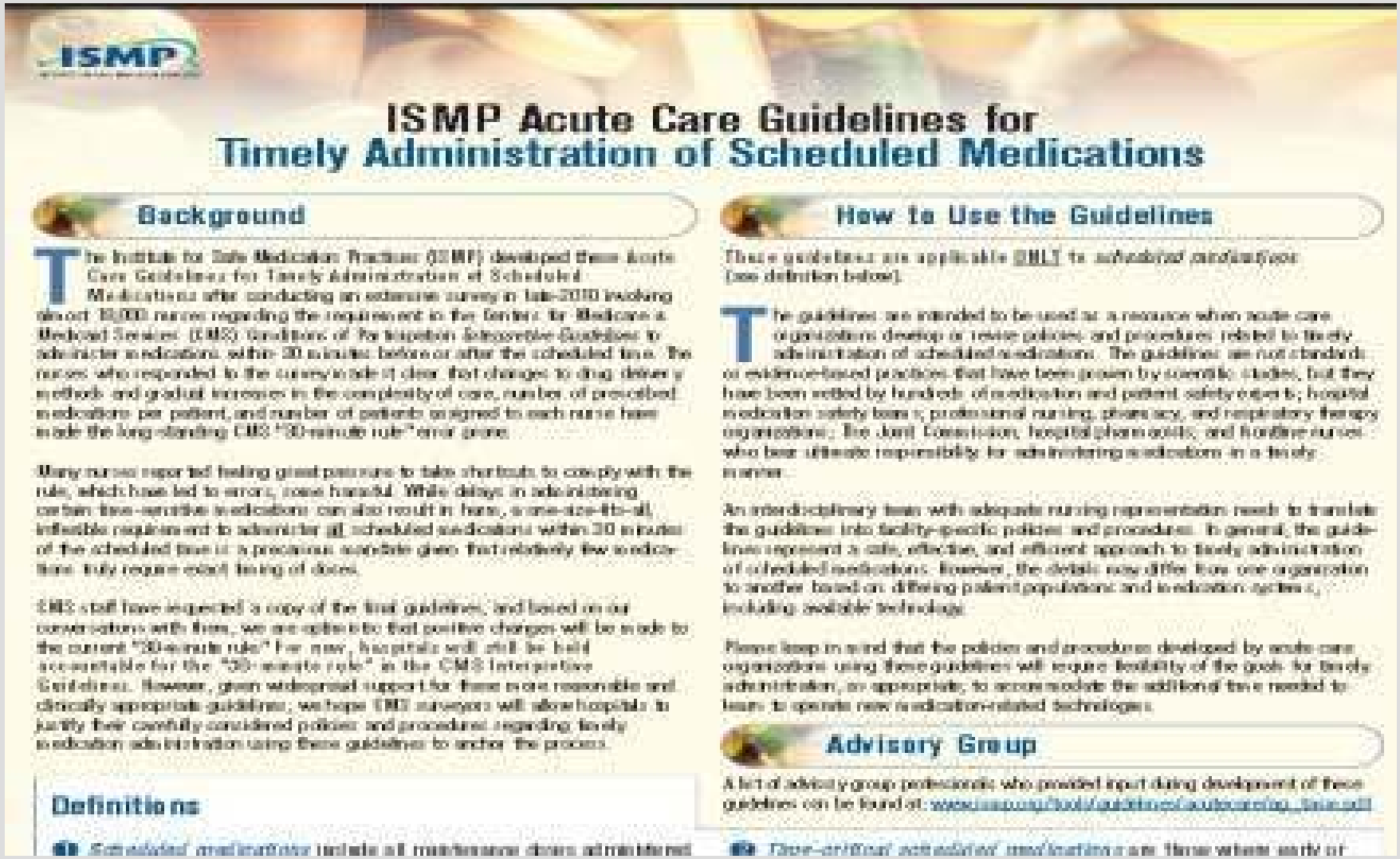
The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0405/§482.23(c)Standard: Preparation and Administration of Drugs
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0409/§482.23(c)(4)/Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/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.
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0957/§482.51(b)(4)/There must be adequate provisions for immediate post-operative care.

www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R116SOMA.pdf

ISMP New Guideline www.ismp.org



ISMP

ISMP Acute Care Guidelines for Timely Administration of Scheduled Medications

Background

The Institute for Safe Medication Practices (ISMP) developed these Acute Care Guidelines for Timely Administration of Scheduled Medications after conducting an extensive survey in late-2010 involving about 10,000 nurses regarding the requirement in the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation *Interpretive Guidelines* to administer medications within 30 minutes before or after the scheduled time. The nurses who responded to the survey made it clear that changes to drug delivery methods and gradual increases in the complexity of care, number of prescribed medications per patient, and number of patients assigned to each nurse have made the long-standing CMS "30-minute rule" error prone.

Many nurses reported feeling great pressure to take shortcuts to comply with the rule, which have led to errors, some harmful. While delays in administering certain time-sensitive medications can also result in harm, a one-size-fits-all, inflexible requirement to administer all scheduled medications within 30 minutes of the scheduled time is a precarious yardstick given that relatively few medications truly require exact timing of doses.

CMS staff have requested a copy of the final guidelines, and based on our conversations with them, we are optimistic that positive changes will be made to the current "30-minute rule." For now, hospitals will still be held accountable for the "30-minute rule" in the CMS Interpretive Guidelines. However, given widespread support for these more reasonable and clinically appropriate guidelines, we hope CMS surveyors will allow hospitals to justify their carefully considered policies and procedures regarding timely medication administration using these guidelines to anchor the process.

Definitions

Scheduled medications include all maintenance drugs administered

How to Use the Guidelines

These guidelines are applicable ONLY to *scheduled medications* (see definition below).

The guidelines are intended to be used as a resource when acute care organizations develop or revise policies and procedures related to timely administration of scheduled medications. The guidelines are not standards or evidence-based practices that have been proven by scientific studies, but they have been vetted by hundreds of medication and patient safety experts; hospital medication safety teams; professional nursing, pharmacy, and respiratory therapy organizations; the Joint Commission; hospital pharmacists; and frontline nurses who bear ultimate responsibility for administering medications in a timely manner.

An interdisciplinary team with adequate nursing representation needs to translate the guidelines into facility-specific policies and procedures. In general, the guidelines represent a safe, effective, and efficient approach to timely administration of scheduled medications. However, the details may differ from one organization to another based on differing patient populations and medication systems, including available technology.

Please keep in mind that the policies and procedures developed by acute care organizations using these guidelines will require flexibility of the goals for timely administration, as appropriate, to accommodate the additional time needed to learn to operate new medication-related technologies.

Advisory Group

A list of advisory group professionals who provided input during development of these guidelines can be found at: www.ismp.org/tools/guidelines/acutecare/ag_team.pdf

Time-critical scheduled medications are those where early or

Practitioner Order Requirements 2014

- Name of the patient
- Age and weight of the patients to facilitate dose calculation requirements
  - Must have P&P to address for children and use only Kg or Grams for newborns
  - Other circumstances like as weight on elderly patient with history of renal failure and is being prescribed antibiotics
  - Hospitals must specify a unified approach
- Date and time of the order

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

Practitioner Order Requirements 2014

- Drug name
- Dose, frequency, and route
- Dose calculation requirements
- Exact strength or concentration, when applicable
- Quantity and/or duration, when applicable
- Specific instructions for use, when applicable and
- Name of the prescriber

Medical Staff Approved P&P 2014

- MS must approve the P&P for medication administration
  - Should be part of PI process
  - Should be done in consultation with nurses and pharmacists
  - Drugs must be administered under supervision of nursing or other personnel
- CMS has many specifics which must be included in this MS approved P&P
- Needs to be consistent with state law and the scope of practice

P&P Requirements

- Must identify the categories of licensed personnel who can prepare and administer
  - For example, Ohio allows RNs and LPNs who have passed a pharmacy course to prepare and administer
- Must include the types of medications they are allowed to prepare and administration
  - For example, the Ohio Board of Nursing does not allow a LPN to hang blood or give certain IV medications
- Must address education or training requirements and CMS has some recommendations

Education Recommendation

- CMS recommend training in orientation and as part of continuing education
- Training **may** include the following;
  - Safe handling and preparation of authorized medications
  - Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications
  - Equipment, devices, special procedures, and/or techniques required for medication administration (IV pumps, PCA, tubing, etc.)

P&P Requirements

- What must be included in the training during orientation or CNE to demonstrate competence
- Training content and documentation of **competence**
- P&P must include basic safe practices for medication administration such as the following required elements
  - Patient's identity
    - To make sure it is the right patient and identifiers might include name, MR number, id number, DOB
    - Confirmed by wrist band, patient identification card, patient statement or other things included in the hospital policy

P&P Requirements 2014

- There must be agreement between the patient's MAR (medication administration record) and the medication's label
- Need to have culture of safety in which staff feel comfortable to ask questions
- Confirm before medication is given the following on the five rights:
  - Right medication, right patient, right dose
  - Right route (IM, PO, IV, IO, intrathecally, etc)
  - Right time to adhere to the prescribed frequency and time of administration

Medication Process 405 2014

- Medication process has five stages
  - Ordering/prescribing
  - Transcribing and verifying
  - Dispensing and delivering
  - Administering
  - And monitoring/reporting
- CMS also mentions the recent literature mentions the nine rights of medication administration

9 Rights of Medication Administration

For Information – Not Required/Not to be Cited

Recent literature identifies up to nine "rights" of medication administration including:*

- *Right patient*
- *Right drug*
- *Right route*
- *Right time*
- *Right dose*
- *Right documentation*
- *Right action (appropriate reason)*
- *Right form*
- *Right response*

However, other sources refer to 8 or 10 "rights, and some of these topics, such as right action, appear to involve prescribing and/or dispensing. Accordingly, there does not (yet) appear to be consensus about expanding beyond the 5 "rights."

**Reference: Elliott, M. and Lis, Y. (2010). The Nine Rights of Medication Administration: An Overview. British Journal of Nursing, Vol. 19, 5, 300-305.*

Timing of Medication 405

- P&P needs to include the timing of medication based on the nature of the medication and the clinical application to include:
  - Medications or categories of medications **not eligible** for scheduled dosing times
    - These are ones that require exact time based on diagnosis type, treatment requirements or therapeutic goals
    - Include definition in your P&P
    - Also looks at patient risk factors
    - Such as stat drugs, loading dose, one time dose for scheduled procedure, doses timed for serum drug level, PRN, or investigational drugs

3 Time Frames for Administering Medication

Time Critical Medicine

1 hour before or after

2 hours before or after

Timing of Medication P&P

- Medications that are **eligible** for scheduled dosing times
  - These are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc.
  - Goal is to achieve a therapeutic blood level
  - BID meds might be given at 9am/9 pm or 8am/8pm
  - Policy has the standardized times so pharmacy knows when to send to unit and nurse can assess VS if needed (such as pulse rate if dig) or review blood work (like a serum K level, INR, or dig level)

Timing of Medication P&P

- Medications that are **eligible** for scheduled dosing times (continued)
  - P&P on first dose of medication, using judgment regarding next dose, retiming of missed or omitted doses
- Medications that can be given outside of their scheduled dosing time
- Evaluation of the medication timing policy and including adherence rate
  - Must track medication errors related to timing of medications and include in the PI process

Timing of Medication P&P

- Time-critical scheduled medications (30 minute or 1 hour total window)
  - These are ones in which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect
  - P&P must include whether these drugs are always time critical
  - Examples include: Antibiotics, Anticoagulants, Insulin, Anticonvulsants, Immunosuppressive agents, Non-IV Pain medication, medication more frequently than every 4 hours, and administered within a specified period of time in the order

Timing of Medication P&P

- Non-time-critical scheduled medications
  - These are medications for which a longer or shorter interval of time since the prior dose does not significantly change the medication's therapeutic effect or otherwise cause harm
  - Greater flexibility is given
  - Medications given once daily, weekly, or monthly
  - May be given within **2 hours** before or after but can not exceed a total window of 4 hours (such as Allegra once a day)
  - Med scheduled more frequently than daily but less than every 4 hours (such as bid or tid) can be given **1 hour** before or after for window not to exceed 2 hours

Timing of Medication P&P

- Missed or late administration of medications
  - Policy must include what action to take if missed or not given in permitted window of time
  - Missed dose may be due from patient who is out of the department, patient refusal, problems related to medication being available or other reasons
  - Policy needs to include parameters of when nursing staff are allowed to use their own judgment on the rescheduling of late or missed dosed
  - Missed or late doses must be reported to the attending physician

Assessment & Monitoring of Patients 2014

- Patients on medications needed to be carefully monitored (all new section)
  - May need clinical and lab data to evaluate medication
  - Monitor respiratory status, pulse ox, BP, end tidal CO2 with patients on **opioids**
  - Evaluate clinical signs such as confusion, agitation, unsteady gait, itching etc.
  - Know **high risk medications** policy and safe practices
  - Know risk factors for ADE such as patient has liver or kidney failure, history of sleep apnea, obesity, smoking, drug-drug interaction and first time medication use

Assessment/Monitoring of Patients Receiving Medications

Observing the effects medications have on the patient is part of the multi-faceted medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse effects and timely initiation of appropriate corrective action. Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- *Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;*

- *Physical signs and clinical symptoms relevant to the patient's medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.*

Certain types of medications are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients. (See also the discussion of high-risk medications (typically referred to as "high-alert" medications) in the guidance for §482.25(b))

For Information – Not Required/Not to be Cited

The Institute for Safe Medication Practices (ISMP) makes available a list of high alert medications, which it defines as those medications that bear a heightened risk of causing significant patient harm when they are used in error. The current list may be found at:
http://www.ismp.org/Tools/highAlertMedicationLists.asp

ISMP List of High Alert Medication

ISMP's List of *High-Alert* Medications

Printer friendly version

High-alert medications are drugs that bear a heightened risk of causing 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)	epoprostenol (Flolan), IV
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)	magnesium sulfate injection
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)	methotrexate, oral, non-oncologic use
antiarrhythmics, IV (e.g., lidocaine, amiodarone)	opium tincture
antithrombotic agents, including: ■ anticoagulants (e.g., warfarin, low-molecular-weight heparin, IV unfractionated heparin) ■ Factor Xa inhibitors (e.g., fondaparinux) ■ direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran etexilate, lepirudin)	oxytocin, IV nitroprusside sodium for injection potassium chloride for injection concentrate potassium phosphates injection promethazine, IV vasopressin, IV or intraosseous

High Alert How to Guide IHI

v03
10/01/2008

PROTECTING 5 Million lives FROM HARM IHI.org

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

So What's In Your Policy?

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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.[i]

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.

Assessment & Monitoring of Patients

- ADE, such as anaphylaxis or opioid-induced respiratory depression may require timely and appropriate
- Post-medication monitoring in case of a high alert medication may include regular assessment of VS, pulse ox, and sedation levels of post surgery patient on PCA
- Such as Richmond agitation sedation scale (RASS) or the Pasero Opioid-Induced sedation scale (POSS), Inova Sedation Scale (ISS), Ramsey scale, Aldrete Scoring system

Pasero Opioid-induced Sedation Scale POSS

Pasero Opioid-induced Sedation Scale (POSS)

https://secure.tha.com/surveys/files/pasero-opioid-induced-sedation-scale-poss.pdf

S = Sleep, easy to arouse
Acceptable; no action necessary; may increase opioid dose if needed

1. Awake and alert
Acceptable; no action necessary; may increase opioid dose if needed

2. Slightly drowsy, easily aroused
Acceptable; no action necessary; may increase opioid dose if needed

3. Frequently drowsy, arousable, drifts off to sleep during conversation
Unacceptable; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory; decrease opioid dose 25% to 50% or notify prescriber or anesthesiologist for orders; consider administering a non-sedating, opioid-sparing nonopioid, such as acetaminophen or an NSAID, if not contraindicated.

4. Somnolent, minimal or no response to verbal or physical stimulation
Unacceptable; stop opioid; consider administering naloxone; notify prescriber or anesthesiologist; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory.

Richmond Agitation Sedation Scale RASS

Richmond Agitation Sedation Scale (RASS) *

www.icudelirium.org/docs/RASS.pdf

Score	Term	Description	
+4	Combative	Overtly combative, violent, immediate danger to staff	
+3	Very agitated	Pulls or removes tube(s) or catheter(s); aggressive	
+2	Agitated	Frequent non-purposeful movement, fights ventilator	
+1	Restless	Anxious but movements not aggressive vigorous	
0	Alert and calm		
-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact) to *voice* (≥10 seconds)	Verbal Stimulation
-2	Light sedation	Briefly awakens with eye contact to *voice* (<10 seconds)	
-3	Moderate sedation	Movement or eye opening to *voice* **(but no eye contact)**	
-4	Deep sedation	No response to voice, but movement or eye opening to *physical* stimulation	Physical Stimulation
-5	Unarousable	No response to *voice or physical* stimulation	

Procedure for RASS Assessment

1. Observe patient
   a. Patient is alert, restless, or agitated. **(score 0 to +4)**
2. If not alert, state patient's name and *say* to open eyes and look at speaker.
   b. Patient awakens with sustained eye opening and eye contact. **(score –1)**
   c. Patient awakens with eye opening and eye contact, but not sustained. **(score –2)**
   d. Patient has any movement in response to voice but no eye contact. **(score –3)**
3. When no response to verbal stimulation, physically stimulate patient by shaking shoulder and/or rubbing sternum.

Comparison of Sedation Scales Medscape

Pain Management Nursing

Comparsion of Selected Sedation Scales for Reporting Opioid–Induced Sedation Assessment

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Pain Manag Nurs. 2009;10(3):154-164.

Comment Print

Study Aims and Methods

The present research study was designed to report measures of reliability and validity of three sedation scales currently used to measure sedation as an outcome of opioid administration for pain management in non-critical care settings: the Inova Health System Acute Care Sedation Scale (ISS), the RASS, and the POSS. Reliability and validity had not been previously established for any of these scales in the non-critical care setting. The following research questions were addressed by the study:

Research question 1: Is there a significant difference in validity or reliability between three commonly used sedation scales when used by non-critical care nurses for the measurement of postopioid sedation?

Research question 2: Is there a significant difference in means observed between scales in the total correct score obtained by the nurses (sedation score and nursing actions chosen)?

Research question 3: Is there a significant difference in means observed between scales in the nurses' total combined rating of each scale's performance regarding ease of use, information provided to inform clinical decision making, and confidence (in

score obtained and actions chosen)?

The study aims had immediate organizational Significance, because the scale (the ISS) used to assess opioid-induced sedation at the facility in which the research was conducted had not previously been tested for

EDITORS' RECOMMENDATIONS

Vital Signs: Overdoses of Prescription Opioid Pain Relievers and Other Drugs Among Women

Deaths and Severe Adverse Events Associated With Anesthesia-Assisted Rapid Opioid Detoxification

Chronic Pain Treatment With Opioid Analgesics

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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

Surveyor Procedure Tag 405

- Surveyor to verify the established time requirements do not exceed the following:
  - 1 hour for time-critical scheduled medications
  - 2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours and
  - 4 hours for medications prescribed for daily or longer administration intervals

Survey Procedures

- Surveyor to verify nurses are administering medications within their scope of practice
- That the MS has approved the P&P which include the timing of medications
- Verify the hospital has P&P that identify which medications are:
  - Not eligible for scheduled dosing times
  - Eligible for scheduled dosing times and are time-critical and
  - Eligible for scheduled dosing times and are not time-critical.

Survey Procedures

- Surveyor to watch a nurse pass meds and make sure patient is identified
- Make sure nurse follows policy when administering medications
- Surveyor to interview nurses and make sure they understand the hospital policy and timing of medications
- Can the nurses identify time-critical and non-time critical medications?
- Will look at standing orders to make sure they comply with these requirements

Survey Procedures 2014

- Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?
- Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?
- Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?

Physician Order 406 2013

- Standard: Drugs and biologicals can be prepared and administered on the orders contained in pre-printed and electronic standing orders, order sets, and protocols
  - If meets tag 457 requirements which is a new tag number where standing order section was moved to
- An exception is flu and pneumovax which can be given by protocol approved by the MS after assessment of contraindications
  - Order does not need to be authenticated

Drugs Tag 406 Revised 2013

A-0406

(Rev.)

§482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).

§482.23(c)(*3*) - With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and and who is responsible for the care of the patient as specified under §482.12(c)…

§482.23(c)(3)(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordanc with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Physician Order 406 2013

- Orders for drugs must be documented and signed by practitioners allowed to write them
  - Or signed by practitioners as allowed by state law, state scope of practice, hospital P&P and MS bylaws and R/Rs
- Doctors can write orders and if allowed NP and PAs
- Removed section about use of rubber stamps which is in the medical record chapter anyway
- Adds a section that talks about standing orders

Standing Orders 406

- Nurses or others authorized by hospital P&P and state law may
  - Administer drugs and biologicals in accordance with pre-printed and electronic standing orders, order sets, and protocols
  - CMS collectively just refers to these as standing orders
- Need to address well defined clinical scenarios involving medication administration
- Refers to tag **457** for requirements on standing order P&Ps

Examples of Standing Orders 2013

- Practitioner must still sign off, date, and time
- Chest pain protocol or asthma protocol with Albuterol and Atrovent are an example of initiation of orders
- Code teams gives ACLS drugs in an arrest
- Timing of orders should not be a barrier to effective emergency response
- Preprinted order
  - Should send memo so doctors and providers are aware of the standing order guidelines in tag 457

Verbal Orders 407 2013

- Standard; Verbal orders, if used, are be used infrequently
- Verbal orders are a patient safety issue
- Have lead to many errors
- Joint Commission has standard and NPSG, CMS has standard in CMS hospital CoPs, QIO 7th scope of work, National Coordinating Council recommendations
- Rewrite your P&P and Medical staff by-laws to be consistent with these standards
- Repeated VO section in MR starting with tag 454 and reiterated area of verbal orders offer too much room for error

Revised June 7, 2013

A-0407

(Rev.)

§482.23(c)(*3*)(i) - If verbal orders are used, they are to be used infrequently.

Interpretive Guidelines §482.23(c)(*3*)(i)

Verbal orders, if used, must be used infrequently. This means that the use of verbal orders must not be a common practice. Verbal orders pose an increased risk of miscommunication that could contribute to a medication or other error, resulting in a patient adverse event. Verbal orders should be used only to meet the care needs of the patient when it is impossible or impractical for the ordering practitioner to write the order or enter it into an electronic prescribing system without delaying treatment. Verbal orders are not to be used for the convenience of the ordering practitioner. (71 FR 68679)

Hospitals are expected to develop appropriate policies and procedures that govern the use of verbal orders and minimize their use, such as *policies which*:

- Describe *situations in which verbal orders may be used as well as* limitations or prohibitions on the*ir* use;
- Provide a mechanism to *establish the identity and authority of* the practitioner issuing a verbal order;
- List the elements required for inclusion in the verbal order process;

CMS Verbal Orders

- Emphasizes to be used infrequently and never for convenience of the physicians
- This means that physician should not give verbal orders in nursing station if he or she can write them
- Can be used in emergency or if surgeon is scrubbed in during surgery
- Regulation broadens category of practitioners who can sign orders off
- CMS suggests four things in hospital P&P on verbal orders

Verbal Orders P&P Should Include

- Limitations on VO such as not for chemotherapy
  - Include situations in which they may be used
- List the elements for a complete VO
  - Such as patient name, drug, dose, frequency, name of person giving and taking order, etc
- Provide guidelines for clear and effective communications
- Establish identity and authority of practitioner issuing VO

Verbal Orders 408 2013

- Standard: When verbal orders are used must be accepted by persons authorized in hospital P&P
- Verbal order for drugs and biologicals may be accepted by individual permitted by state and federal law and hospital P&P to accept
  - For example, hospital allows pharmacists to accept drug orders
  - Hospital will not accept order for Vancomycin IV from an medical assistant in the physicians office
  - It must be from the physician or office nurse
  - Must document order in the chart

Signing Off Verbal Orders 2013

- Physician must sign off a verbal order, **date,** and **time** it when signed off
- Any physician or practitioner on the case can sign off any VO of another
  - CMS permanently renewed
- This practice must be addressed in the hospital's P&P
- Now a NP or PA may sign off a verbal order, if within their scope (where they had authority to write order) and allowed by state law, hospital policy and delegated to this by the physician

Verbal Orders Changes in 2013

- The 2 main changes were placed in tag 454 in the MR chapter and not in the nursing section
  - Regulation states that verbal orders should be authenticated based on state law
  - Some states require order to be signed off in 24 hours or 48 hour
- If no state law use to say you had to do this within 48 hours
  - No longer say if no state law follow your P&P but sign off asap such as next time the physician sees the patient
  - Need hospital P&P to reflect these guidelines
  - Write it down and repeat it back

Joint Commission Verbal Orders

- RC.02.03.03 (IM 6.50) requires that qualified staff receive and record VO
- Define in writing who can receive and record VO
- Date and document identity of who gave, received, and implemented the order
- Authenticated within time frame law/regulation
- Write it down and read back the completed order or test result

Blood Transfusions and IVs 409 2013 & 2014

- Standard: Blood transfusions and IV medications must be administered with state law and MS P&P
  - CMS previously issued a memo on May 13, 2011 and updates in 2014 Medication Memo effective 6-6-2014
- Use to require special training for this and there was a long list of things that nurses had to be trained on
- CMS eliminated the regulations mandating training for non-physicians who administer IV medication and blood and blood products
  - CMS says because this training is already standard practice but must still be **competent** in those areas
  - Must follow your P&P and state scope of practice

Blood and IV Medication Training

- Must still follow **state law requirements**
  - In some states an LPN can not hang blood
  - Or the LPN can not push certain IV medications in some states
  - Must show they are competent
- Must still have approved **Medical Staff Policies** and Procedures in place
- Staff must follow these which have most of the things that were previously required

Blood Transfusions and IVs 2014

- Hospital P&P for blood and IV medication must be based on state law and MS P&P and must address the following: (all new section)
  - Vascular access route such as central line, peripheral or implanted port and what medications can be given IV and via what type of access devices
  - Basic safety practices for medication administration
    - Tracing line and tubes prior to administration to be sure proper route
    - Verify proper programming of infusion devices

A-0409
(Rev.)

§482.23(c)(4) - Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

Interpretative Guidelines §482.23(c)(4)

Intravenous (IV) medications and blood transfusions must be administered in accordance with State law and approved medical staff policies and procedures. Further, many of the medications included in the high-alert categories are administered intravenously. (See also the discussion of high-risk/high-alert medications in the guidance for §482.25(b).) Hospital policies and procedures for blood transfusions and IV medications must be based on accepted standards of practice, and must address at least the following:

Vascular Access Route

Patients may require a form of vascular access to deliver blood or medications, either venous or arterial, based on the desired treatment plan. Safe administration of blood transfusions and IV medications includes the correct choice of vascular access. IV medications, such as fluids, antibiotics, and chemotherapy, may require specific types of access, such as peripheral or central catheters versus implanted port devices, based on the medication's chemical properties or safety concerns. Hospital policies and procedures must address which medications can be given intravenously via what type of access.

Blood Transfusions and IVs 2014

- Patient Monitoring
  - Monitor for the effects of the medication since IV medications have a more rapid effect
  - Monitoring to include assessment of risk factors that would influence type and frequency of monitoring
  - Such as patient with renal failure on Vancomycin and dose is based on lab test
- P&P expected to address
  - Monitoring for fluid and electrolyte balance
  - Monitor patients on high alert meds including **opioids** and evaluate for over-sedation and respiratory depression

Blood Transfusions and IVs 2014

- Risk factors for patients receiving opioids include
  - Snoring or history of sleep apnea
  - No recent opioid use or first-time use of IV opioids
  - Increased opioid dose requirement or opioid habituation
  - Longer length of time receiving general anesthesia during surgery
  - Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other CNS depressants
  - Preexisting pulmonary or cardiac disease
  - Thoracic or other surgical incisions that may impair breathing

Blood Transfusions and IVs 409 2014

- Hospital P&P is expected to address:
  - Monitoring for fluid and electrolyte balance
  - Monitoring patients for high alert medications including IV opioids
  - Expected to address monitoring for over-sedation and respiratory depression for safe opioid use
    - Can erroneous assume patient is asleep when they are having progressive symptoms of respiratory compromise
    - Factors that put patients at high risk include snoring, history of sleep apnea, first time use of IV opioids, increased opioid dose, longer length of time receiving general anesthesia, pulmonary or cardiac disease or thoracic or surgical incisions

Assess and Monitor Patients 2014

- Need to assess and monitor the effects of the medications
- To allow for early identification of adverse effects
- Some may need to use clinical and lab data to evaluate efficacy of medication therapy
  - For **opioids** may need to monitor respiratory status, vital signs such BP, O_2 sat, pain level, sedation scale, and carbon dioxide levels
- Evaluate symptoms such as confusion, agitation, unsteady gait, pruritus, somnolence etc.
- Be aware of high alert medications

Blood Transfusions and IVs

- P&P must include who can conduct the assessments
- The frequency and duration of the assessments
- Under what circumstances practitioners prescribing IV opioids are allowed to establish protocols that differ from hospital P&P
- Assessment includes VS (TPR and BP), pain level, respiratory status, sedation level and ETCO2
- Also mentions APSF monitoring of opioids including ETCO2

ISMP Use a Standard Sedation Scale

For Information – Not Required/Not to be Cited

In addition to assessing risk for respiratory depression, the Institute for Safe Medication Practices recommends hospitals use a standard sedation scale when assessing patients receiving PCA. Scales such as the Richmond Agitation Sedation Scale, Pasero, Ramsey, or Glasgow Coma Scale are useful in assessing sedation.

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

For Information – Not Required/Not to be Cited

Institute for Safe Medication Practices Guidelines for PCA Monitoring

Assessment of Opioid Tolerance	*Vital Signs*	*Pain*	*Sedation*	*Respiratory*		
				Rate	*Quality*	*SPO_2* &/or $ETCO_2$***
Baseline Assessment before PCA	*X*	*X*	*X*	*X*	*X*	*X*
PCA Initiation or Change in Drug/Syringe *Q 15 minutes x 1 hour* *Q 1 hour x 4 hours* *Then Q 2 hours*	*X*	*X*	*X*	*X*	*X*	*X*
PCA Dose Change or Bolus *Q 1 hour x 4 hours* *Then Q 2 hours*	*X*	*X*	*X*	*X*	*X*	*X*
Adverse Event or Patient Deterioration (e.g., adverse change in sedation score) *Q 15 minutes x 1 hour* *Q 1 hour x 4 hours* *Then Q 2 hours*	*X*	*X*	*X*	*X*	*X*	*X*
Hand-offs/Shift Change	*X*	*X*	*X*	*X*	*X*	*X*

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013 ISMP adapted these recommendations from the San Diego Patient Safety Council

* *SPO_2: Saturation of peripheral oxygen via pulse oximetry*

Safe Opioid Use & Safe Medication Use

- Patients at great risk for adverse events include age, liver or kidney failure, history of sleep apnea, history of smoking, drug-drug interaction, first time medication use and weight
  - Obesity could increase apnea and smaller patients could more sensitive to dose levels of medications
- Risk factors need to be considered in determining how often to monitor and what type of monitoring
- Must communicate important information in hand-offs such as change of shift

Safe Opioid Use & Safe Medication Use

- ADR, such as opioid-induced respiratory depression require timely intervention as per established hospital protocols
- Must also report to physician or LIP immediately
- High alert medications would want to check VS, O_2 sat, $ETCO_2$, and sedation levels to prevent respiratory depression and arrest
- **Staff are expected to include patient's reports of his experience of the medication's effects**
- **Educate the patient and family about notifying staff if difficulty breathing**

Safe Opioid Use & Safe Medication Use

- Hospital policy is expected to address the manner and frequency of monitoring
- Hospital P&P is expected to include information to be communicated at shift change
- It is important to document order, medication record, lab reports, vital signs etc.
- Document after actual administration of medication and no documentation in advance
- Surveyor will make sure staff is knowledgeable about intervention protocol if ADE occurs

Anesthesia Patient Safety Foundation

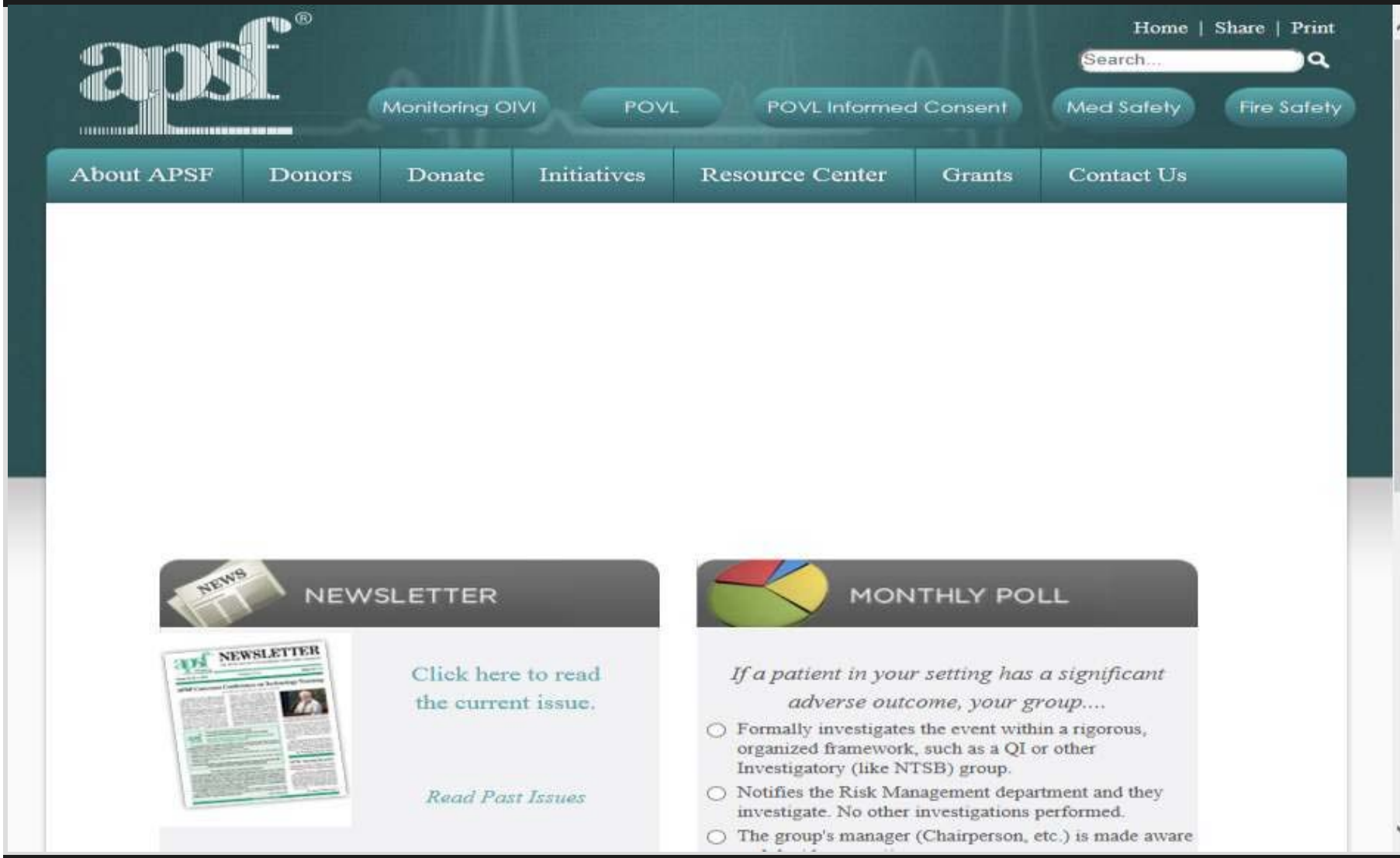
Anesthesia Patient Safety Foundation

- *APSF calls for every patient receiving postoperative opioid analgesics to be managed based on the following clinical considerations*:*
  - *Individualize the dose and infusion rate of opioid while considering the unique aspects of each patient's history and physical status.*
  - *Make continuous monitoring of oxygenation (pulse oximetry) the routine rather than the exception.*
  - *Assess the need for supplemental oxygen, especially if pulse oximetry or intermittent nurse assessment are the only methods of identifying progressive hypoventilation.*
  - *When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.*

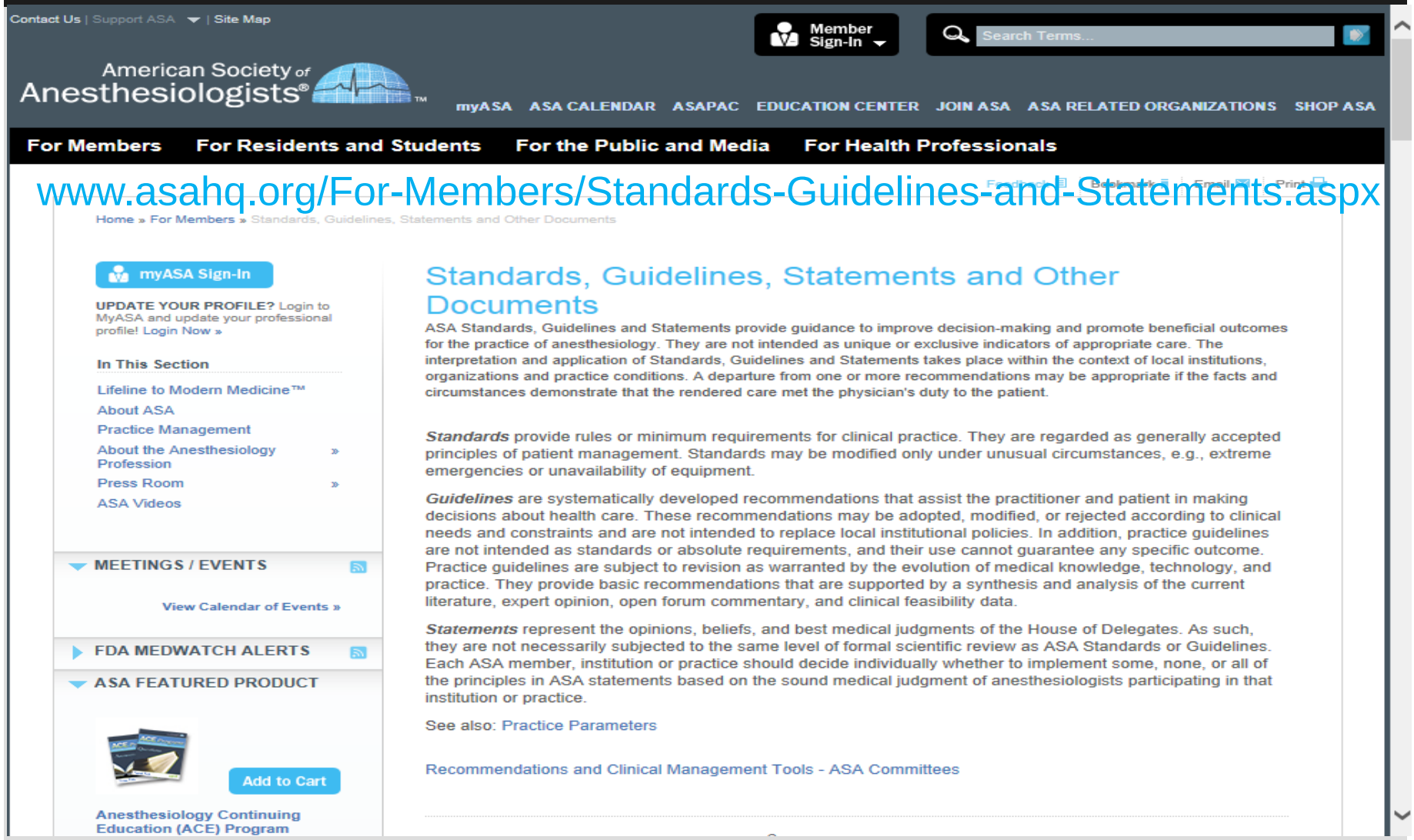
When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.

APSF also has issued a video on opioid induced ventilatory impairment: http://apsf.org/resources_video4.php

APSF Website www.apsf.org



ASA Standards and Guidelines



Blood Transfusions 2014

- Confirm correct patient
- Verify correct blood product
- Standard calls for two qualified persons, one who is administering the transfusion
  - TJC NPSG allows one person hanging blood if use bar coding
- Document monitoring
- P&P include how frequent you monitor the patient and do vital signs
- How to identify and treat and report any adverse transfusion reaction

Blood Components and Blood Administration Procedures

According to the U.S. Department of Health and Human Services, 13,785,000 units of whole blood and red blood cells were transfused in the United States in 2011[5]. The collection, testing, preparation, and storage of blood and blood components are regulated by the Food and Drug Administration. However, administration of blood products via transfusion is governed by §482.23(c)(4). Blood transfusions can be life-saving. However, like IV medications, blood transfusions are not without risk of harm to patients. Transfusion reactions and/or errors can be fatal.

In addition to the safe practices and other safety considerations that apply to all IV medication administration, policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to:

- *Confirming the following prior to each blood transfusion:*
  - *the patient's identity*
  - *verification of the right blood product for the right patient*

  The standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation.

- *Requirements for patient monitoring, including frequency and documentation of monitoring*

Blood Transfusions 2014

- Staff must be **competent** in venipuncture
- Competent in using vascular access devices
- Trained in early detection and intervention for opioid over-sedation
- Must document competency
- So make sure nursing education is aware and staff trained in orientation periodically
- Make sure staff educated on P&P

Survey Procedure 2014

- Interview nursing staff on different units who administer IV medications and blood transfusions. Are staff knowledgeable with respect to:
  - Venipuncture techniques
  - Safe medication administration practices, including general practices applying to all types of medications and practices concerning IV tubing and infusion pumps
  - Maintaining fluid and electrolyte balance
  - Patient assessment for risk related to IV medications and appropriate monitoring
  - Early detection and intervention

Survey Procedure 2014

- Will look to see if any blood transfusions
- To review staff files for evidence of competency in administering IV medication and blood products
- Surveyor encouraged to watch staff hang blood or observe IV medication given
  - Were safe injection practices followed
  - Was appropriate access for IV medication
  - Are patients monitored for adverse reactions
  - Were transfused patients correctly identified and correct blood administered?

Incident Reports A-410 2013

- Standard: There must be procedure for reporting transfusion reactions, adverse drug reactions (ADRs) and errors in administration of drugs
- See tag 508 which was amended 5-13-2011 in the pharmacy section which affects nursing
- Survey procedure
  - Request procedure for reporting
  - They may review the incident reports or other documentation through QAPI program

A-0410

(Rev.)

§482.23(c)(5) - There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Interpretive Guidelines §482.23(c)(5)

Adverse drug reactions and drug administration errors

There is a similar but more detailed and prescriptive requirement concerning internal hospital reporting of adverse drug reactions, drug administration errors and incompatibilities under the Pharmaceutical Services CoP at §482.25(b)(6). Therefore, it is not necessary for hospitals to establish a different procedure in the case of adverse drug reactions and drug administration errors for such events when nurses administer drugs or transfusions. Consult the guidance for §482.25(b)(6) to see what must be reported, to whom, and in what timeframe. Failure to make required reports concerning adverse drug reactions and errors in administration of drugs should be cited under §482.23(c)(5) when the drug was administered by a nurse, as well as under §482.25(b)(6).

Transfusion reactions

Transfusion reactions can occur during or after a blood transfusion. A patient's immune system recognizes the foreign blood product and attempts to destroy the transfused cells. Incompatible blood products are typically the cause of transfusion reactions. Symptoms may include back pain, bloody urine, hives, chills, fainting, dizziness, fever, flank pain, and skin flushing. More serious complications may include acute kidney failure, anemia, respiratory distress, shock and even death.

Transfusion reactions are serious and can be life-threatening. The hospital must have policies and procedures in place for the internal reporting of transfusion reactions. The policies must

Transfusion Reactions, ADEs, Drug Errors

- Establish a procedure in the case of ADEs and drug errors when nurses administer drugs or transfusions
- Refers back to tag 508 regarding reporting these into the PI system
  - Often done on an incident report
- Transfusion reactions can be serious and life threatening
  - Discussed the symptoms of a transfusion reaction: chills, hives, back pain, bloody urine, dizziness, fever, flank pain, skin flushing, kidney failure, anemia, shock, respiratory failure or death

Transfusion Reactions

- Must have P&P to ensure transfusion reactions are reported
- Must be reported immediately to practitioner
- Must be documented in the chart
- Must be reported to the PI program
- Surveyor is suppose to look at the hospital P&P and internal reports of transfusion reactions
- Will ask to see any incident reports

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 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
- CMS only made one change in 409 in June 6, 2014 and that is to include PCA as a self administered medication

Only Change in Tag 409 in 2014

- PCA pumps allow for the self-administration of intravenous (IV) medications to patients
- References the section in Tag 409 just discussed concerning assessment and monitoring requirements for post-surgical patients receiving IV opioids
- Including via patient-controlled analgesia (PCA) pumps, in and out of the post-anesthesia care (PACU) and intensive care units (ICU)

CMS Adds New 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.

Self-Administer Medications 2013 & 2014

- CMS added new tag numbers 412 and 413
- Previously, the only section on self administered medications was in the pharmacy standard under tag 502
- Standard: The hospital may allow a patient or caregiver/support person to self administer medications in accordance with hospital P&P
  - This includes hospital issued medication and patient's own medication brought in
- These are very long sections so need to read

Self-Administer P&P Must Include

- Self administer P&P **must** include:
  - Need an order
  - Make sure assess capacity and document
    - Is the patient competent and not confused
  - Instruct the person on how to give safely
  - Address the security of the medication
  - Document when given in the medical record
  - Assess if receiving opioids including PCA

Self-Administer Medications

- Not required to do
  - Could be beneficial to some patients
- Generally applies to inpatients but may find appropriate situations for outpatients
  - Hospital does for observation patients on Medicare since does not pay for oral medications
  - Asthma patient has inhaler at bedside or patient has hemorrhoid cream or patient learns to give subq Heparin
- Teaching patient to use their medications could avoid readmissions or returns to the ED

Self-Administer Medications

- Some cases nurse may need to supervise
- May want to include in the P&P when supervision by the nurse is needed
- May exclude certain medications from self administration
- Medical staff, nursing and pharmacy departments must collaborate in developing P&P
- Surveyor will assess carefully to ensure these standards and policy requirements are met

Self Administer Medications 413

- New tag number in 2013
- Standard: The hospital may allow a patient or caregiver to self administer own medication or hospital issued medications as defined by P&P
- Must have policies to include:
  - Need an order which is consistent with P&P
  - Assess capacity of the patient and document
  - Evaluate the medicine for integrity
  - Address security of the medication
  - Document each medicine given

Other Sections That Impact Nursing

- There are many other sections that impact nursing that are located outside the nursing standards section;
  - Provide copy of patient rights to patient including visitation rights (Tag 95)
  - Review of contracted services (Tag 85)
  - Provision of emergency services in the ED (91)
  - Interpreters for patients with limited English proficiency (116)
  - Grievance process (118)

Other Sections That Impact Nursing

- Informed consent (131)
- Advance directives (132)
- Right to privacy (143)
- Freedom from abuse and neglect (145)
- Confidentiality (146)
- Restraint and seclusion (154)
- PI (274)
- H&P (358)

Other Sections That Impact Nursing

- Autopsies (364)
- Medical records (466)
- Discharge summary (468)
- Pharmacy and medications (490)
- Radiology orders (529)
- Lab services (578)
- Blood and blood components (592)
- Look back program (592)

Other Sections That Impact Nursing

- Dietary policies and assessment (618)
- Utilization review (652)
- Infection control (747)
- Discharge planning (800)
- Organ donation (884)
- Surgery and anesthesia (940,1000)
- Outpatient (1079 and amended 7-16-2012)
- Rehab and respiratory therapy (1123 and 1151)

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The End! Questions????

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