Critical Access Hospitals (CAH)

What every CAH needs to know about the Conditions of Participation (CoPs)
Speaker

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- 614 791-1468 (Call with questions, No emails)
- sdill1@columbus.rr.com
You Don’t Want One of These
Mandatory Compliance

- Hospitals that participate in Medicare or Medicaid must meet the Conditions of Participation (COPs) for all patients in the facilities and not just those who are Medicare or Medicaid patients,

- Hospitals accredited by the Joint Commission (TJC), AOA, CIHQ, or DNV Healthcare have what is called deemed status,
CAH Problematic Standards

- Date and time on all orders and entries
- Verbal orders, Cluttered hallways
- H&Ps, Life safety code issues, EMTALA,
- Informed consent, Cleanliness of dietary
- Plan of care, Privacy and whiteboard,
- Handling, dispensing, storage and administration of medications
- Meeting the nutritional needs of patients
- Healthcare services in accordance with P&P
CAH Problematic Standards

- Medical record documentation must reflect the nursing process, Timing of medications
- Legibility of the medical record, No orders
- Equipment and supplies used in life saving procedure, Hand Hygiene & Gloving
- R&S for PPS hospitals but CAH still need to do something, Failure to Monitor Patient for Safety (Suicide Precautions)
- Infection control issues are big
- What else should we add???
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
  - The ProPublica website for LTC
  - The Association for Health Care Journalist (AHCJ) websites for hospitals
Access to Hospital Complaint Data

DATE: March 22, 2013
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group

Memorandum Summary

- **Survey Findings Posted on [http://www.cms.gov](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 those 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 (POCs):** The posted CMS data do not contain any POC information. State Survey Agencies (SAAs) and CMS Regional Offices (ROs) may see an increase in requests for both the CMS-2567 and any associated POCs.

- **Questions & 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
Hospitals

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

A hospital is an institution primarily engaged in providing, by or under the supervision of physicians, inpatient diagnostic and therapeutic services or rehabilitation services. Critical access hospitals are certified under separate standards. Psychiatric hospitals are subject to additional regulations beyond basic hospital conditions of participation. The State Survey Agency evaluates and certifies each participating hospital as a whole for compliance with the Medicare requirements and certifies it as a single provider institution.

Under the Medicare provider-based rules it is possible for ‘one’ hospital to have multiple inpatient campuses and outpatient locations. It is not permissible to certify only part of a participating hospital. Psychiatric hospitals that participate in Medicare as a Distinct Part Psychiatric hospital are not required to participate in their entirety.

However, the following are not considered parts of the hospital and are not to be included in the evaluation of the hospital’s compliance:

- Components appropriately certified as other kinds of providers or suppliers, i.e., a distinct part Skilled Nursing Facility and/or distinct part Nursing Facility, Home Health Agency, Rural Health Clinic, or Hospice; Excluded residential, custodial, and non-service units not meeting certain definitions in the Social Security Act; and,
- Physician offices located in space owned by the hospital but not functioning as hospital outpatient services departments

Accredited Hospitals - A hospital accredited by a CMS-approved accreditation program may substitute accreditation under that program for survey by the State Survey Agency. Surveyors assess the hospital’s compliance with the Medicare Conditions of Participation (CoP) for all services, areas and locations covered by the hospital’s provider agreement under its CMS Certification Number (CCN).

Although the survey generally occurs during daytime working hours (Monday through Friday), surveyors may conduct
Small or Rural Hospitals

- American Hospital Association has Web site with good information for CAH
- Has recent issues of interest to CAH
- Excellent resources including current list of all CAHs in the US
- Has CAH newsletters
  - go to http://www.aha.org/aha/issues/Rural-Health-Care/update-newsletters.html
AHA CAH Resources

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Home » Issues » Rural Health Care » Resources

ISSUES
Access and Coverage
Affordability
Billings and Collections
Clinical Integration
Eliminating Racial and Ethnic Disparities
Emergency Readiness
Employee Relations
Health Care Reform Moving Forward
Health care for Life

Resources

Small or Rural Update Issues

- Summer 2011
- Fall 2010 Supplement
- August 2010
- Summer 2010

CAH Update Issues

- Summer 2011
- Fall 2010
- Summer 2010

RURAL HEALTH CARE
News
Advocacy
Resources
Contact Us

www.aha.org/aha/issues/Rural-Health-Care/update-newsletters.html
AHA CAH Resources

Update Newsletters

The Section for Small or Rural Hospitals provides its members two electronic newsletters, the Small or Rural Update and the CAH Update, which include the latest information on federal legislative and regulatory activity affecting payment, quality, and access to care.

Small or Rural Update Issues

- Fall 2012
- Summer 2012
- Spring 2012
- Winter 2011
- Summer 2011

www.aha.org/advocacy-issues/rural/update-newsletters.shtml
AHA Critical Access Website

www.aha.org/aha_app/issues/CAH/index.jsp

Critical Access Hospitals

CAHs are rural community hospitals that receive cost-based reimbursement. To be designated a CAH, a rural hospital must meet defined criteria that were outlined in the Conditions of Participation 42CFR485 and subsequent legislative refinements to the program through the BBRA, BIPA, the Medicare Modernization Act, the MIPPA, and the PPACA.

The AHA ensures that the unique needs of its various constituents are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters. Indeed, from its initial creation as part of the Balance Budget Act of 1997, the AHA has been a champion of the development and subsequent improvements and enhancements of the CAH program.

Securing the future of CAHs and the essential role they play in caring for rural America is of paramount importance. The AHA is vigilant in the face of legislative, regulatory and policy proposals that threaten the local delivery of care and rural community health status. The AHA will continue to advocate on behalf of CAHs for fixes to payment and administrative limitations.
CAH Frequently Asked Questions

- What is a Critical Access Hospital?
- How many CAHs are there and where are they located?
- What is the Medicare Rural Hospital Flexibility Program and how is it related to the CAH program?
- What types of facilities are eligible for CAH status?
- What are the location requirements for CAH status?
- Can a CAH add an off-campus provider based entity that does not meet the CAH distance requirements?
- What are the requirements for relocating an existing CAH under the Necessary Provider replacement rules?
- What are the benefits of CAH status?
CMS CAH Website

- CMS has a website for resources
- Includes:
  - State operations manuals
  - Program transmittals
  - Guidance for laws and regulations for CAH
  - Medicare Learning network
  - Other helpful information
  - Email questions to CAHscg@cms.hhs.gov
CMS CAH Website

CMS.gov
Centers for Medicare & Medicaid Services

Home > Provider Type > Critical Access Hospitals Center

Critical Access Hospitals Center

Spotlights

- CMS Will Not Enforce Supervision Requirements for Outpatient Therapeutic Services in Critical Access and Small Rural Hospitals for CY 2010-2011 [PDF, 36KB] (posted 3/16/2011)

- Do you want to find out Medicare Fee-for-Service information quickly? Subscribe to a CMS Electronic Mailing Lists: Keeping Medicare Fee-For-Service Providers Informed [PDF, 410KB] that suits your needs!

Medicare Learning Network (MLN) Spotlights

Go to the Spotlight page for the latest MLN products and announcements! Check it often!
The Conditions of Participation CoPs

- First, published in the Federal Register
  - Federal Register available at no charge at www.gpoaccess.gov/fr/index.html
- Next, CMS publishes Interpretive Guidelines and some include survey procedures,
- Current CoP issued April 7, 2015
- CMS made many changes effective June 7, 2013 and 93 page memo January 16, 2015 which is in current manual
Subscribe to the Federal Register Free

http://listserv.access.gpo.gov/cgi-bin/wa.exe?SUBED1=FEDREGTOC-L&A=1
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.

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and is critical access hospital CoP
State Operations Manual
Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

(Rev. 138, 04-07-15)

Transmittals for Appendix W

INDEX

Survey Protocol

Introduction
Regulatory and Policy Reference
Tasks in the Survey Protocol
Survey Team
Task 1 - Off-Site Survey Preparation
Task 2 - Entrance Activities
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: 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.
Memo with Many Changes

- 93 pages long and advance copy and final in current manual effective April 7, 2015
- Changes to pharmacy, infection control, dietary, nursing, and rehab services
- To reflect changes effective July 11, 2014 including responsibilities of physicians
  - MD or DO needs to review non-physician outpatient order only if required by state law or where a co-signature is required
  - Physician does not need to visit at least every two weeks the CAH
  - P&P committee does not need outside person
April 7, 2015 Changes

- Major changes to pharmacy, dietary, infection control, drugs, and nursing standards and adds rehab
- CMS now has an email address that questions can be addressed
  - CAHSCG@cms.hhs.gov
- Amends 31 tag numbers
  - 211, 260, 261, 270-284, 286-299
- Changes are shown in red
CAH Services Direct Services or Contracts

- CMS published more than 2 dozens changes to the hospital CoP in FR on May 16, 2012 and went into effect June 7, 2013
- Several that impact CAHs
- Currently. The CAH CoP requires that certain types of services be provided directly rather than through contracts or under arrangements
  - This included diagnostic and therapeutic services, lab and radiology services, and emergency procedures
  - CMS eliminated this requirement
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, 440, 442, 482, 483, 485, 486, 488, 491, and 493

[CMS-3267-F]

RIN 0938-AR49

Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule reforms Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This final rule also increases the ability of health care professionals to devote resources to improving patient care, by eliminating or reducing requirements that impede quality patient care or that divert resources away from providing high quality patient care. We are issuing this rule to achieve regulatory reforms under Executive Order 13563 on improving regulation and

How to Find Changes

- Have one person in your facility who goes out to this website once a month and checks for updates,
  - www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp,
- You can do a search for time frame and can add words to search,
  - Click on fiscal year to bring up most current memos
- CMS issues transmittal before putting it into the CAH Manual
- Person in charge of CAH at CMS is Kianna Banks, kianna.banks@cms.hhs.gov, 410 786-3498
Subscribe to the Federal Register Free

http://listserv.access.gpo.gov/cgi-bin/wa.exe?SUBED1=FEDREGTOC-L&A=1
Policy & Memos to States and Regions

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

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- Show only [select one or more options]:
  - Show only items whose [ ] is within the past [ ]
  - Show only items whose Fiscal Year is [ ]
  - Show only items containing the following word [ ]

Show Items

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CMS Transmittals

The Centers for Medicare & Medicaid Services uses transmittals to communicate new or changed policies or procedures that we will incorporate into the CMS Online Manual System. The cover or transmittal page summarizes and specifies the changes. The transmittals for 2000 through 2003 have been archived. The archived transmittals can be accessed using the following URLs:

2003 Transmittals


2002 Transmittals


2001 Transmittals


2000 Transmittals

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 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
Safe Injection Practices

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

Office of Clinical Standards and Quality/Survey & Certification Group

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 repack 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 Pharmacopoeia (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.

Ref: S&C: 12-35-ALL

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 has section in IC worksheet on this
- CMS requires hospitals to follow nationally recognized standards of care like the CDC guidelines
- SDV typically lack an antimicrobial preservative
- Once the vial is entered the contents can support the growth of microorganisms
- The vials must have a beyond use date (BUD) and storage conditions on the label
CMS Memo on Safe Injection Practices

- Make sure pharmacist has a copy of this memo
- If medication is repackaged under an arrangement with an off site vendor or compounding facility ask for evidence they have adhered to 797 standards
- ASHP Foundation has a tool for assessing contractors who provide sterile products

Go to
www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx

Click on starting using sterile products outsourcing tool now
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.

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

ONEANDONLYCAMPAIGN.ORG
Safe Injection Practices www.empsf.org

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
Unsafe Injection Practices and Disease Transmission

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

1. A clean syringe and needle are used to draw the sedative from a new vial.
2. It is then administered to a patient who has been previously infected with hepatitis C virus (HCV). Backflow into the syringe contaminates the syringe with HCV.
3. The needle is replaced, but the syringe is reused to draw additional sedative from the same vial for the same patient, contaminating the vial with HCV.
4. A clean needle and syringe are used for a second patient, but the contaminated vial is reused. Subsequent patients are now at risk for infection.

Source: www.southernnevadahealthdistrict.org
CDC One and Only Campaign

http://oneandonlycampaign.org
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.
Infection Control Breaches

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

Center for Clinical Standards and Quality/Survey & Certification Group

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

Ref: S&C: 14-36-All

Memorandum Summary

- **Infection Control Breaches Warranting Referral to Public Health Authorities:** If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they should refer them to appropriate State authorities for public health assessment and management.

- **Identification of Public Health Contact:** SAs should consult with their State’s Healthcare Associated Infections (HAI) Prevention Coordinator or State Epidemiologist on the preferred referral process. Since AOs operate in multiple States, they do not have to confer with State public health officials to set up referral processes, but are expected to refer identified breaches to the appropriate State public health contact identified at: http://www.cdc.gov/HAI/state-based/index.html
CMS Memo Infection Control Breaches

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

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-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.
CMS Memo on Insulin Pens

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


CDC Clinical Reminder: Insulin Pens Must Never Be Used for More than One Person

Available for download Clinical Reminder: Insulin Pens [PDF - 182 KB]

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.
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
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 an 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
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.wbamic.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 Posts and Brochures Available

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

Insulin Pen Safety – One Insulin Pen, One Person

BE AWARE
DON’T SHARE

ONE INSULIN PEN,
ONLY ONE PERSON

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)
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
Pt Safety Briefs Free at www.empsf.org

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

The Centers for Disease Control and Prevention (CDC) says there are 1.7 million healthcare-associated infections in the US every year. Of these, it is estimated that about 90,000 do the cause death. Infection prevention
CMS Issues 3\textsuperscript{rd} Ebola Memo

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

Center for Clinical Standards and Quality/Survey & Certification Group

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:
Luer Misconnections Memo

- CMS issues memo March 8, 2013
- This has been a patient safety issue 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
Center for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-2116
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality / Survey & Certification Group

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 mismatched to an intravenous (IV) line in an ambulatory surgery center (ASC) resulting in 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.
### Table. Tubing Misconnections Reported to the Pennsylvania Patient Safety Authority, January 2008 to September 2009

<table>
<thead>
<tr>
<th>Misconnection</th>
<th>Number of Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary intravenous (IV) infusion connected to lower “Y” port of primary IV tubing set</td>
<td>8</td>
</tr>
<tr>
<td>Hemodialysis arterial and venous tubing lines reversed</td>
<td>5</td>
</tr>
<tr>
<td>G-tube and J-tube lines reversed</td>
<td>3</td>
</tr>
<tr>
<td>Incorrect tubing connection (no further explanation provided in reports)</td>
<td>3</td>
</tr>
<tr>
<td>Epidural and patient-controlled analgesia (PCA) tubing sets reversed</td>
<td>2</td>
</tr>
<tr>
<td>Nonhemodialysis arterial and venous tubing lines reversed</td>
<td>2</td>
</tr>
<tr>
<td>Cell saver tubing connected to cell saver reservoir</td>
<td>1</td>
</tr>
<tr>
<td>Feeding tube set connected to Braviac®</td>
<td>1</td>
</tr>
<tr>
<td>Feeding tube set connected to peripherally inserted central catheter (PICC) line</td>
<td>1</td>
</tr>
<tr>
<td>Feeding tube set connected to suction port</td>
<td>1</td>
</tr>
<tr>
<td>Imaging contrast tubing set connected to tracheostomy cuff</td>
<td>1</td>
</tr>
<tr>
<td>IV tubing set connected to dialysis catheter</td>
<td>1</td>
</tr>
<tr>
<td>IV tubing set connected to PICC line</td>
<td>1</td>
</tr>
<tr>
<td>IV tubing set connected to tracheostomy cuff</td>
<td>1</td>
</tr>
<tr>
<td>Knee irrigation connected to peripheral IV tubing</td>
<td>1</td>
</tr>
<tr>
<td>Miscommunication (arterial line noted in medical record as peripheral IV)</td>
<td>1</td>
</tr>
<tr>
<td>Oral medication delivered through peripheral IV line</td>
<td>1</td>
</tr>
<tr>
<td>Suction line connected to water seal</td>
<td>1</td>
</tr>
<tr>
<td>Suction and feeding tubing sets reversed</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>36</strong></td>
</tr>
</tbody>
</table>
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 intravenous, ventilatory, 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 nasogastric tubes, 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 similar tubes or catheters to be connected together. Between January 2008 and September 2009, 36 events of tubing misconnections were reported to the Pennsylvania Patient Safety Authority involving various types of misconnections. Methods for reducing the likelihood of tubing misconnections include equipment design solutions and administrative controls (policies and work practices). Equipment design solutions either prevent the user from making a misconnection or prompt the user to make the correct connection. Administrative controls are policies and practices that reduce the risk of misconnections such as tracing lines back to their source.  (Pa Patient Saf Advis 2010;6:2:41-5.)

Introduction
Threading an IV at the bedside, patients may have many tubing lines connecting them to medical devices such as IV delivery, feeding tubes, or delivering medications or nutrition therapy. Medical devices connected to patients may also have tubing lines connecting the devices with other medical devices. Under these circumstances, tubing misconnections can occur with potentially fatal results. Misconnections have been recognized as a significant 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. However, misconnections have garnered more attention in recent years, especially in the United States, due in part to tubing misconnection Sentinel Event Alerts issued by the Joint Commission in April 2006.

Misconnections in Pennsylvania
Between January 2008 and September 2009, in tubing misconnection events were reported to the Authority, 35 liquid-liquid events and 3 liquid-gas events. (See the Table for a breakdown of the types of misconnections reported.) Examples of the Sentinel Events and Incidents involving misconnections reported to the Authority include the following:

The patient is a 9-year-old female admitted... an arterial line for surgery. The physician ordered a... patient’s left ‘Y’ site... connected the line of NS to the patient’s left ‘Y’ site...
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 gastrointestinal 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 an upper gastrointestinal study (Soghoian S, Hoffman RS, Nelson L. Unintentional IV injection of barium sulfate in a child. Am J Health-Syst Pharm. 2010; 67: 34-39). The patient, a 17-month-old child, had a central venous catheter (CVC) in place for 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 syringes, 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 administration 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 which 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 administration set
- Oxygen tubing connected to port of IV administration set
- Breast milk intravenously infused into neonates
- Bladder irrigation solutions given IV, or TPN solutions administered via foley catheter port
- IV administration set spiked into enteral nutrition container, resulting in enteral nutrition administered IV.
Sentinel Event Alert, Issue 36: Tubing misconnections—a persistent and potentially deadly occurrence

April 3, 2010

Tubing and catheter misconnection errors are an important and under-reported problem in healthcare organizations. In addition, these errors are often caught and corrected before any injury to the patient occurs. Given the reality of and potential for life threatening consequences, increased awareness and analysis of these errors—including avoided errors—can lead to dramatic improvement in patient safety.
Managing Risk During the Transition

Managing risk during transition to new ISO tubing connector standards

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\textsuperscript{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 connection and disconnection during the introduction phase.

Published for Joint Commission accredited organizations and interested healthcare 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.
There are various types of misconnections posing dangers, including the following:\(^3,^9\)

<table>
<thead>
<tr>
<th>Types of misconnections</th>
<th>Connected to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enteral feeding tube</td>
<td>Connected to IV (such as The New York Times example)(^6,^10,^11)</td>
</tr>
<tr>
<td>Limb cuff inflation device</td>
<td>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)</td>
</tr>
<tr>
<td>Epidural solution (intended for epidural administration)</td>
<td>Connected to Peripheral or central IV catheter(^10)</td>
</tr>
<tr>
<td>Epidural line</td>
<td>Connected to IV infusion(^10,^11)</td>
</tr>
<tr>
<td>Bladder irrigation solution using primary IV tubing (connected as secondary infusion)</td>
<td>Connected to Peripheral or central IV catheter(^10,^11)</td>
</tr>
<tr>
<td>IV infusion (intended for IV administration)</td>
<td>Connected to Indwelling bladder (foley) catheter(^10,^11)</td>
</tr>
<tr>
<td>IV infusion (intended for IV administration)</td>
<td>Connected to Nasogastric (NG) tube(^10,^11)</td>
</tr>
<tr>
<td>Primary IV tube</td>
<td>Connected to Blood product (intended for transfusion)(^10,^11)</td>
</tr>
<tr>
<td>Enteral feeding (gastric or nasal)</td>
<td>Connected to Tracheostomy tube(^3)</td>
</tr>
<tr>
<td>IV solution</td>
<td>Administered via Blood administration set(^10,^11)</td>
</tr>
<tr>
<td>Primary IV solution</td>
<td>Administered via Various functionally dissimilar catheters (such as external dialysis catheter, ventriculostomy port, amnio-infusion catheter, distal port of pulmonary artery catheter)(^10,^11)</td>
</tr>
</tbody>
</table>
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.
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

- Will use whenever a validation survey or certification survey is done at a hospital by CMS for PPS hospitals
- Not currently being used for CAH
- However, highly suggest that every CAH review and be aware of what is in these three forms
- Helps to understand how the guidelines are interpreted
- Especially since infection control standards are very similar
### Section 2 Discharge Planning – Policies and Procedures

<table>
<thead>
<tr>
<th>Elements to be assessed</th>
<th>Manner of Assessment Code (list all that apply) &amp; Surveyor Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 Are discharge planning policies and procedures in effect for all inpatients?</td>
<td></td>
</tr>
<tr>
<td>2.1a <em>Specifically:</em></td>
<td>○ Yes ○ No ○ 1 ○ 2 ○ 3 ○ 4 ○ 5</td>
</tr>
<tr>
<td>2.1b Are staff members responsible for discharge planning activities correctly following the hospital’s discharge planning policies and procedures?</td>
<td>○ Yes ○ No ○ 1 ○ 2 ○ 3 ○ 4 ○ 5</td>
</tr>
</tbody>
</table>

**NOTE:** If no for either 2.1a or 2.1b cite the applicable standard for identification of patients needing discharge planning (42 CFR 482.43(a); discharge planning evaluation (42 CFR 482.43(b); or developing and implementing the discharge plan (42 CFR 482.43(c). (Tags A-0800, A-0806, A-0817)

| 2.2 Does the discharge planning process apply to certain categories of outpatients? | ○ Yes ○ No ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 |
| If yes, check all that apply: | ○ Same day surgery patients ○ Observation patients who are not subsequently admitted ○ ED patients who are not subsequently admitted ○ Other |

| 2.3 Is a discharge plan prepared for each inpatient? | ○ Yes skip to question 2.8 ○ No, go to question 2.4 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 |

**NOTE:** No citation is made related to questions 2.2 and 2.3

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Interview = 1 Observation = 2 Discharge Planning Document Review = 3 Medical Record Review = 4 Other Document Review = 5
CMS Hospital CoPs

- Appendix W, Tag **C-0150 to C 0408**,
  - See visitation memo adding tag 1000-1002 which is after tag 298
  - It is out of order
- Interpretive guidelines updated more frequently now so check monthly for updates
  - Manual includes swing beds in CAHs,
CMS Hospital CoPs

- Consider doing a gap analysis,
- Take each section and on left hand side of page document how you comply with each section,
- Time consuming but will have with compliance,
- Include policies and yellow section that corresponds to the required P&P in the CoP
- Have one person in charge who can keep up with changes and who knows what to do if CMS shows up for validation or complaint survey
Rehab or Behavioral Health Dept CAH

- Remember, CAH can have up to a ten bed **rehab** or **psych** (behavioral health) unit
- If so it is surveyed under the regular hospital CoP program even though CAH has a separate manual
- It is **Appendix A**
- Last updated April 1, 2015 and manuals changing frequently so always check the CMS website
TJC Revised Requirements

- TJC or the Joint Commission (not called JCAHO anymore) has made many changes to bring their standards into closer alignment with CMS
- Having less differences is helpful to hospitals,
- Have some that are for hospitals that use them to get deemed status (DS) or payment for M/M patients,
  - Will specify DS after the standard
Introduction

- Medicare CoPs are found at 42 CFR Part 485 Subpart F.

- Authority to make copies of things is at 42 CFR 489.53,
  - Recommend you have surveyor make you a copy also,
  - Please ask surveyor not to make copy of peer review material-abstract out what is needed,

- Can get all CFR now electronically off Internet free at GPO access at www.gpoaccess.gov
  - Click on Code of Federal Regulations and can do search or click on e-CFR, or http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl,
Resources to Keep Handy

- Appendix W Hospital CoPs ("C")
  - Unless CAH has a separate rehab or behavioral health unit and then you need Appendix A - Hospital CoP also for these departments
- Survey protocol and module,
- Q - Immediate jeopardy.
- V - EMTALA,
- W - Hospital swing beds - if you have these,
- B - Home health
- I - Life safety code
The interpretive guidelines provide instructions to the surveyors on how to survey the CoPs-like questions to the test,

They have **survey procedure** instructions to determine the hospital policy for notifying patients of their rights,

Ask patients to tell you if the hospital told them about their rights,

Deficiency citation show how the entity failed to comply with regulatory requirements and not the guidelines!
First 26 pages list the survey protocol, includes a section on:

- Off-survey preparation,
- Entrance activities,
- Information gathering/investigation,
- Preliminary decision making and analysis of finding,
- Exit conference,
- Post survey activities,
Swing Bed Module

- When patients need brief transitional care at the hospital at the end of their acute care stay,
- If swing beds then do survey under CAH swing-bed requirements found at 42 CFR Part 485.645,
- Reimbursement is for Skilled Nursing care as opposed to Acute Care,
- Term is for reimbursement and has no relationship to geographic location in the hospital,
Swing Bed Module

- May be in acute care status one day and then in swing bed status the next day,
- 3-day qualifying stay for the same spell of illness in any hospital or CAH is required prior to admission to swing-bed status for Medicare patients,
- Actual swing-bed survey requirements are referenced in the Medicare Nursing Homes requirements at 42 CFR Pt 483
Swing Bed Counts

- Surveyor will verify 25 bed rule,
- Will count inpatient beds but not observation beds,
- Does **not** count OR, PACU, L&D, newborn nursery (unless medical treatment) or ED stretchers, sleep lab beds, exam tables, or observation beds (210),
- Do count birthing beds where patients remain after giving birth,
- Do **not** count beds in Medicare certified rehab or psychiatric distinct part units,
- Will conduct open record review on all swing bed patients,
- Swing bed deficiencies are documented on a separate form even though survey done simultaneously,
Regulation/Interpretive Guidelines

- Starts with a tag number, example C-0150,
- C refers to the CAH CoPs,
- Recall first is the section from federal register (CFR)
- Then the section called the “interpretive guidelines”,
- Some have a section called “Survey Procedure” and will explain how it is surveyed or what policies will be reviewed, what questions to ask or documents to look at,
Compliance with Laws  C-150

- Standard: The CAH must be in compliance with all federal, state, and local laws,
- Surveyor may interview CEO or other designated by hospital to determine this,
- May refer non-compliance to proper agency with jurisdiction such as OSHA
  - TB, blood borne pathogen, universal precautions, or EPA (haz mat or waste issues),
Advance Directives  151  2013

- Standard: CAH must be in compliance with federal laws and regulations related to the health and safety of patients
- Inpatients and outpatients have the right to make advance directives
- Staff must comply with their advance directives
- Patients have the right to refuse treatment
- Make have a DPOA or another person such as a support person/patient advocate
May use advance directives to designate a support person for a person of exercising the visitation rights

If patient incapacitated and DPOA then must give this information to make informed decisions and consent for the patient

CAH must also seek the consent of the patient’s representative when informed consent is required for a care decision

- Surrogate decision makers step into shoe of patient when incompetent
Advance Directives  

- Must provide advance directive information to the competent patient when admitted
  - Must also give to the outpatient if in the ED, observation, or same day surgery patient
  - Must document you gave it in the medical record
- If incapacitated then to the family or surrogate
- Has conscience objector clause but must still allow DPOA or support person to make decision if incapacitated
Advance Directives 151

- Can not require one
- Document in the medical record
- Must make sure staff is educated on the P&P
- This includes the right to make a psychiatric advance directive or mental health declaration
  - Should still give consideration even if not a state specific law
- Must provide community education
Physician Ownership Disclosures

- Must disclose if physician owned hospital
  - This includes ownership by immediate family member and must be in writing
  - If none of physician owner refer then the hospital must sign attestation to this effect
- Physicians must also disclose to patients who they refer
  - This must be as a condition for getting MS privileges
- Disclose in writing if physician not on premise 24 hours a day for emergencies
  - Sign acknowledgement if patient admitted
Compliance with Laws/Licensure

- Standard: Patient care services must be provided with in accordance with laws (152),
- Ensure delegation as allowed by law,
- Ensure practicing according to scope of practice, such as NP, CNS, PA,
- Standard: Hospital must be licensed (153)
- Personnel must be licensed or certified if required by state (Tag 154: doctors, nurses, PT, PA, OT, x-ray tech. et. al.),
- Review sample of personnel files and make sure credentials and licensure is up to date,
If CAH moves then status and location must be reassessed

- Harder to relocate now, See tag 166 on relocation

Many changes to relocation and allows for grandfathering (see SOM Manual 2)

Criteria for determining mountainous terrain, revised definitions of primary and secondary roads, documentation needed to relocate CAH and 75% rule,
CAH must meet the location requirements at the time of the initial survey (160)

Compliance is reconfirmed at the time of every subsequent full survey

Tag 162 discusses information regarding if the CAH has been classified as an urban hospital

Discusses CAH located outside any area that is a metropolitan statistical area

CAH must be in a rural area
Q&A

**Question:** Can a CAH add an off-campus provider based entity that does not meet the CAH distance requirements?

**Answer:** As of January 1, 2008, all CAHs, including necessary provider CAHs, that create or acquire an off-campus provider-based facility such as a clinic, or a psychiatric or rehabilitation distinct part unit, must meet the CAH distance requirement of a 35-mile drive to the nearest hospital or CAH (or 15 miles in the case of mountainous terrain). This provision excludes Rural Health Clinics, as defined under 405.2401(b), from the list of provider-based facilities that must comply with this requirement. Details about this requirement are available in a Final Rule published in the November 27, 2007 issue of the *Federal Register* as part of the Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates. See Section XVIII. Changes Affecting Critical Access Hospitals (CAHs) and Hospital Conditions of Participation (CoPs), starting on page 66877.

**Question:** What are the requirements for relocating an existing CAH under the Necessary Provider replacement rules?

**Answer:** CAHs that have been granted Necessary Provider status and want to rebuild in a new location that does not meet the distance requirements of the 35-mile rule will be treated in the same manner as if they were building a replacement facility at the previous location. The new CAH facility will have to continue to meet the same criteria that led to its original state designation, serve at least 75% of the same service area, offer 75% of the same services, and utilize at least 75% of the same staff in its new location. See the September 7, 2007 letter from CMS to State Survey Agency Directors titled *Critical Access Hospitals (CAHs): Distance from Other Providers and Relocation of CAHs with a Necessary Provider Designation* for more detailed information.
Location in a Rural Area  8-30-13

§485.610(b) Standard: Location in a Rural Area or Treatment as Rural

The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section or the requirements of either (b)(3) or (b)(4) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(a) of this chapter and is not among a group of hospitals have been redesignated to an adjacent urban area under §412.252 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103 of this chapter.

(3) Effective for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on June 3, 2003.

(4) Effective for October 1, 2009 through September 30, 2011, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2009, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2010, was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on November 20, 2008.

Interpretive Guidelines §485.610(b)

Rural Location

Among other requirements, pursuant to 42 CFR 485.610(b), all CAHs must either be located in a rural area or treated as rural in accordance with 42 CFR 412.103 in order to be eligible for CAH designation. (The temporal provisions at 42 CFR 485.610(b)(4)
Agreement with Network Hospitals

- Standard: CAH that is a member of a rural network must have agreement with at least one hospital that is a member of the network.

- A CAH must develop agreements with an acute care hospital related to patient referral and transfer, communication, emergency and non-emergency patient transportation.

- Will ask how CAH communicates with other hospitals—do you keep a communication log?
Working with the Other Hospital

- What P&P related to communication system?
- Will review any written agreements with local EMS
- Need to provide for transport between the two facilities
- Do the two hospitals have electronic sharing of patient data, telemetry and medical records? (193)
Credentialing and QA Agreement 195

- Standard: The CAH has to have an agreement with a hospital that is a member of the network or QIO for quality improvement and credentialing
  - State networking requirements vary
- Agreement for QA need to include a medical record review as part of quality and to establish medical necessity of care at CAH,
- Surveyor will review P&P to determine how information is obtained, used and how confidentiality is maintained,
Telemedicine Agreements C&P 196

- Standard: Agreements for C&P Telemedicine Physicians
- Board must make sure agreement with distant-site hospital (DSH) or distant-site telemedicine entity (DSTE)
- Decide what category of practitioners are eligible for appointment to the MS
- Board appoints with recommendation of the MS
- Board approves the MS bylaws and other MS rules and regulations
State Operations Manual
Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

(Rev.)

[* * *]

C-0196

[§485.616 Condition of Participation: Agreements]

(c) Standard: Agreements for credentialing and privileging of telemedicine physicians and practitioners.

(i) The governing body of the CAH must ensure that, when telemedicine services are furnished to the CAH’s patients through an agreement with a distant-site hospital, the agreement is written and specifies that it is the responsibility of the governing body of the distant-site hospital to meet the following requirements with regard to its physicians or practitioners providing telemedicine services:

   (i) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

   (ii) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.
Agreements for C&P  196

- Make sure MS is accountable to the board for quality of care provided to the patients
- Must have and follow criteria for selection of MS that is based on individual character, competence, training, experience, and judgment
- Make sure under no circumstance is privileges based solely on certification, fellowship, or membership in a special body or society
[(c) Standard: Agreements for credentialing and privileging of telemedicine physicians and practitioners.]

(3) The governing body of the CAH must ensure that when telemedicine services are furnished to the CAH’s patients through an agreement with a distant-site telemedicine entity, the agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to the CAH and as such, in accordance with §485.635(c)(4)(ii), furnishes the contracted services in a manner that enables the CAH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in this section with regard to its physicians and practitioners providing telemedicine services.

(4) When telemedicine services are furnished to the CAH’s patients through an agreement with a distant-site telemedicine entity, the CAH’s governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site telemedicine entity regarding individual distant-site physicians or practitioners. The CAH’s governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that the following provisions are met:

(i) The distant-site telemedicine entity’s medical staff credentialing and privileging process and standards at least meet the standards at (c)(1)(i) through (c)(1)(vii).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides a current list to the CAH of the distant-site physician’s or practitioner’s privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or renewed by the State in which the CAH whose patients are receiving the telemedicine services.
Emergency Services  200

- Standard: Must provide emergency care necessary to meet the needs of its inpatients and outpatients,
- The ED cannot be a provider-based off-site location,
- Must comply with acceptable standards of practice,
- Including those established by national professional organizations such as ACEP, ENA, ACS, ANA, AMA, American Association for Respiratory Care,
Emergency Services

- Need qualified medical director,
- MS must have P&P regarding the care provided in the ED,
- Policies current and revised based on QA activities,
- MS must establish qualifications to get privileges to provide ED care,
- ED must be adequately staffed,
- Must have adequate equipment,
Emergency Services 200

- Must determine the categories and numbers of staff needed in the ED
  - MD/DO, RN, ward clerks, PA, NP, EMTs,

- The scope of diagnostic and/or therapeutic respiratory services offered by the CAH should be defined in writing, and approved by the medical staff
  - CT scans, venous Doppler's, ultrasound et. al.,
14 ED Written Policies

- P&P must be developed approved by MS,
- And mid-level practitioners who work in the ED,
- Need triage procedures,
- Each type of service provided,
- Qualifications, education, training, of personnel authorized to perform respiratory care services and if supervision is needed,
ED Written Policies

• Equipment assembly and operation;
• Safety practices, including infection control measures;
• Handling, storage, and dispensing of therapeutic gases;
• Cardiopulmonary resuscitation;
• Procedures to follow in the advent of adverse reactions to treatments or interventions;
• Pulmonary function testing;
ED Written Policies

- Therapeutic percussion and vibration;
- Bronchopulmonary drainage;
- Mechanical ventilatory and oxygenation support;
- Aerosol, humidification, and therapeutic gas administration;
- Administration of medications; and
- Procedures for obtaining and analyzing ABGs.
ED Staff Training

Surveyor will interview ED staff to make sure knowledgeable including (so include in education of ED staff):

1. Parenteral administration of electrolytes, fluids, blood and blood components;
2. Care and management of injuries to extremities and central nervous system;
3. Prevention of contamination and cross infection; and
4. Provision of emergency respiratory services.
EMTALA and ED 24 hours

- Must still meet EMTALA (anti-dumping) requirements,
- Revised July 16, 2010 into 68 pages,
- Must have 24 hour ED services available,
- A CAH without inpatients is not required to have emergency staff on site 24 hours a day (If no patients, CAH may close),
- Can have NP, PA, or MD on site within 30 minutes,
CMS welcomes the use of telemedicine by CAH

CAH not required to have a doctor to appear when patient comes to the ED

PA, NP, CNS, or physician with emergency care experience must show up within 30 minutes

If MD/DO does not show up must be immediately available by phone or radio contact 24 hours a day
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  

DATE:  June 7, 2013

TO:  State Survey Agency Directors

FROM:  Director  
Survey and Certification Group

SUBJECT:  Critical Access Hospital (CAH) Emergency Services and Telemedicine:  
Implications for Emergency Services Condition of Participation (CoPs) and  
Emergency Medical Treatment and Labor Act (EMTALA) On-Call Compliance

Memorandum Summary

• The Center for Medicare & Medicaid Services (CMS) Welcomes use of Telemedicine by  
CAHs:  Telemedicine has great potential to expand availability of specialty care services,  
including emergency medicine services, to rural populations.  However, misconceptions  
about CAH CoP and EMTALA requirements may cause unnecessary concerns about, or  
create barriers to, using telemedicine.

• The CAH Emergency Services CoP does not Require a Physician to Appear On-site  
Whenever an Individual Comes to the Emergency Department (ED):  
  • Under 42 CFR 485.618(d), a doctor of medicine (MD), a doctor of osteopathy (DO), a  
  physician assistant (PA), a nurse practitioner (NP), or a clinical nurse specialist (CNS),  
  with training or experience in emergency care, must be immediately available by  
  telephone or radio, and available on-site within 30 minutes (60 minutes for CAHs in  
  frontier areas that meet certain conditions).  Under the CAH CoPs an MD or DO is not  
  required to be available in addition to a non-physician practitioner.  
  • Under the CoP at §485.618(e), an MD or DO must be immediately available by  
  telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide  
  information on treatment of emergency patients, and refer patients.  This requirement  
  can be met by the use of a telemedicine MD/DO as well as by an MD/DO who practices  
  on-site at the CAH.

• EMTALA is Not a Barrier to Using Telemedicine to Extend CAH Emergency Services:  
  • If using telemedicine for emergency and other services, a CAH is not required to  
  include the telemedicine physicians on its physician on-call list mandated under the
Availabilty of Drugs 201

- CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment,
- Required by state and local law and in accordance with accepted standards of practice,
- Surveyor will ask how you make sure equipment, supplies, and medications are always available,
Emergency Drugs  203

Drugs used in life-saving procedures, includes:

- Analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensive, diuretics, and electrolytes and replacement solutions.

- Know how you maintain your inventory and how drugs are replaced,
Emergency Equipment 204

Equipment and supplies commonly used in life-saving procedures, includes;

- Airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.
Make sure staff know where the equipment is located,

Know how supplies are replaced and who is responsible for doing this,

Will examine sterilized equipment for expiration dates,

Will check for equipment maintenance schedule (defibrillator),
Blood and Blood Products 205

- Need services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis,
- No requirement to store blood on site,
- Can provide in emergency directly or through arrangement,
- Some cases more practical to transport patient to where the blood is,
Blood and Blood Products

- If CAH does tests on blood will be surveyed under CLIA if tests are done,
- If collecting blood you must register with the FDA,
- If only storing blood for transfusion and refers all tests to outside lab then not performing test as defined by CLIA,
- Need agreement in writing regarding the provision of blood between CAH and testing lab,
Blood and Blood Products

- Blood must be appropriately stored to prevent deterioration,
- If types and cross matches must have necessary equipment
- Or can keep 4 units O Neg on hand at all times,
- Release to give, signed by doctor, is needed if not cross matched when indicated in an emergency
Blood Storage 206

- Blood storage must be under the control and supervision of a pathologist or other qualified doctor,
- If blood banking done under arrangement, the arrangement has to be approved by MS and administration,
- Will look for an agreement,
Staffing Personnel 207

- Must have practitioner (physician, PA, NP) with training in emergency care on call and immediately available within 30 minutes,
- 60 minutes if CAH in frontier area (with less than 6 residents per sq. mile and area meets criteria for remote by the state and CMS) and state determines longer time than 30 minutes needed is only way to provide care,
- Will review call schedules,
- Will ask staff if they know who is on call,
Staffing Personnel 207

- Will review documentation that PA, NP, or MD was on site within this time frame,
- RN will satisfy this if for temporary period and CAH has less than 10 beds and is in frontier area (state governor has to sent letter to CMS as part of rural health plan),
- CAH must submit this letter to surveyor and demonstrate shortage and unable to provide,
- Also if state law has more stringent staffing requirements, like MD on duty 24 hours, must follow,
  - See CMS Memo
Coordination with EMS  209

- Must coordinate with EMS,
- Have a procedure where available by phone or radio on 24 hour basis to receive calls,
- Should have policies and procedure in place to ensure MD/DO is available by phone or radio contact,
- And when emergency instructions are needed,
CAH maintains no more than 25 acute care inpatient beds at any one time

- Doesn’t include observation beds, sleep studies or ED

Any of the inpatient 25 beds can be used to provide acute or long term care (swing beds) dependent on patient need

Does not count if CAH has up to 10 bed rehab unit or behavioral health unit

Average basis of 96 hours per patient,
Observations/LOS 211  2015

- Previously, could not operate distinct units,
- Observations stay is usually not more than 48 hours, unless more strict state limit of 24 hours,
- Rewrite your policy on observation beds to meet this section and the 2 midnight rule,
- They do not count observation beds in 25 bed count now or in calculating average LOS,
  - Make sure you are using appropriately,
- See the CMS memo on the two midnight rule and 2015 changes
  - Place in an outpatient observation bed
  - Admit as an inpatient to telemetry
January 30, 2014

Hospital Inpatient Admission Order and Certification

As a condition of payment for hospital inpatient services under Medicare Part A, section 1814(a) of the Social Security Act requires physician certification of the medical necessity that such services be provided on an inpatient basis. The order to admit as an inpatient ("practitioner order") is a critical element of the physician certification, and is therefore also required for hospital inpatient coverage and payment under Part A. The physician certification, which includes the practitioner order, is considered along with other documentation in the medical record as evidence that hospital inpatient service(s) were reasonable and necessary. When a physician signs the certification, they are certifying that inpatient hospital services were reasonable and necessary.

The following guidance applies to all inpatient hospital and critical access hospital (CAH) services unless otherwise specified. For the remainder of this guidance, when we refer to hospitals, we are also referring to CAHs. The complete requirements for the physician certification are found in 42 CFR Part 424 subpart B and 42 CFR 412.3. An electronic version of the CFR is available online at: http://www.ecfr.gov/cgi-bin/text-idx?sid=0ccf28130d181e0b9118119c2b4d40ed&c=ecfr&tpl=/ecfrbrowse/Title42/42tab_02.tpl.

A. Physician Certification. For physician certification of inpatient services of hospitals other than inpatient psychiatric facilities:

1. Content: The physician certification includes the following information:
   a. Authentication of the practitioner order: The physician certifies that the inpatient services were ordered in accordance with the Medicare regulations governing the order. This includes certification that hospital inpatient services are reasonable and necessary and in the case of services not specified as inpatient-only under 42 CFR 419.22(n), that they are
Two Midnight Rule

- Need an order and need to document medical necessity (on hold right now)

- For inpatient CAH services only, the physician must certify that the beneficiary may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH.

- Time as an outpatient at the CAH does not count towards the 96 hours requirement.
  - The clock for the 96 hours only begins once the individual is admitted to the CAH as an inpatient.
  - Time in a CAH swing-bed also does not count towards the 96 hour inpatient limit.
Observations 211

- Have specific criteria for placing patient in and discharging from observation
- Inappropriate use of observation beds subjects Medicare beneficiary to increased coinsurance liability
  - 20% of CAH customary charges then if properly admitted as inpatient,
- Observation is not appropriate for:
  - Substitute for inpatient admission
  - For continuous monitoring
  - Medically stable patients who need diagnostic testing or outpatient procedure (blood chemo, dialysis)
Observation Not Appropriate

- Patients awaiting nursing home placement
- For convenience to the patient or family
- For routine prep or recovery prior to or after diagnostic or surgical services
- As a routine stop between the ED and inpatient admission
- No prescheduled observations services
- Observation services begin and end with the order of the physician
Observation 211

- Must provide documentation to show that observation bed is not an inpatient bed
- Need specific criteria for observation services
- Must be different than inpatient criteria
- 10 bed observation unit might be disproportionately large
- Surveyor might determine observation is actually inpatient overflow unit
Don’t Count in 25 Bed Count 211

- Exam or procedure tables
- Stretchers
- OR tables and PACU bed
- Newborn bassinets and isolettes for well baby boarders unless baby held for treatment
- OB beds if active labor but do count birthing rooms where patient stays after giving birth
- ED carts
- 10 bed distinct unit rehab or behavioral health
Observation starts and ends with order
  - No standing orders for observation

Hospice beds can be dedicated are also counted as part of the 25 beds,
  - Except 96 hour average LOS rule does not apply,

Medicare does not reimburse the CAH for hospice patients only the Hospice,

So the CAH has to negotiate payment from the hospice through an agreement,
Length of Stay 212

- That does not exceed, on an annual average basis, **96 hours per patient**, 
- State Fiscal Intermediary (FI) will determine compliance with this CoP, 
- Calculate the CAH’S length of stay based on patient census data, 
- If CAH exceeds the length of stay limit, the FI will send a report to the CMS-RO as well as a copy of the report to the SA, 
- CAH will have to do plan of correction,
Standard: CAH is constructed, arranged, and maintained to ensure access to and safety of patients.

Additionally, it must provide adequate space to provide care to patients.

Must be constructed in accordance with state and federal law.

Will look to see if maintained in a manner to ensure safety of patients.

- Conditions of ceilings, walls, and floors
Must have housekeeping and preventative maintenance programs,

All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition

These means facilities, supplies and **equipment** must be maintained,

How do you ensure your equipment is maintained properly

- Boilers, elevators, air compressors, ventilators, X-ray equipment, IV pumps, stretchers, IV equipment, air compressors, elevators, maintenance log,
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland  21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group
Ref: S&C: 14-07-Hospital

DATE:       December 20, 2013
TO:         State Survey Agency Directors
FROM:       Director
            Survey and Certification Group
SUBJECT:    Hospital Equipment Maintenance Requirements

Memorandum Summary

- **S&C 12-07-Hospital Superceded:** We are updating previously provided guidance to clarify:
  - Hospital facilities, supplies and equipment must be maintained to ensure an acceptable level of safety and quality.
  - A hospital may adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment from what is recommended by the manufacturer, based on a risk-based assessment by qualified personnel, unless:
    - Other Federal or state law; or hospital Conditions of Participation (CoPs) require adherence to manufacturer’s recommendations and/or set specific requirements. For example, all imaging/radiologic equipment must be maintained per manufacturer’s recommendations; or
    - The equipment is a medical laser device; or
    - New equipment without a sufficient amount of maintenance history has been
Memorandum Summary

- In accordance with 42 CFR 485.623(b)(1), CAHs are required to maintain all essential mechanical, electrical, and patient-care equipment in safe operating condition.
  - A CAH may adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment from what is recommended by the manufacturer, based on a risk-based assessment, unless:
    - Other Federal or state law, or CAH Conditions of Participation (CoPs) require adherence to manufacturer’s recommendations and/or set specific requirements. For example, the National Fire Protection Association (NFPA) Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 485.623(d) have some provisions pertinent to equipment maintenance, and compliance with these requirements is assessed on Federal surveys; or
    - The equipment is imaging/radiologic equipment or a medical laser device; or
    - New equipment without a sufficient amount of maintenance history has been acquired.
  - CAHs electing to adjust facility or medical equipment maintenance must develop policies and procedures and maintain documentation supporting their Alternate Equipment Maintenance Plan.
Make sure maintenance is aware of 15 page equipment memo which became effective Nov 2014

Discusses preventive maintenance and inspection of equipment
  - As recommended by the manufacturer or based on a risk-based assessment unless federal or state law of CoP specifies otherwise

Discusses alternative equipment maintenance (AEM) program

Must demonstrate that qualified personnel are performing risk based assessments, PM, or establishing the AEM program
To comply consider the following:

- Maintain a written inventory of all medical equipment or written inventory of selected equipment categorized by risk assessment
  - Such as life support equipment
- Identify high risk medical equipment on the inventory for which there is a risk of serious injury or death should it fail such as life support equipment
- Staff must be qualified to perform
- Identify in writing how to maintain, inspect, and test the medical equipment on the inventory
Equipment Memo

- Make sure the frequency is in accordance with manufacturers recommendation or with strategies of an alternate equipment maintenance (AEM) program
  - An example for medical equipment is the American National Standards Institute for the Advancement of Medical Equipment Handbook

- The frequency in testing, inspecting, and maintaining must be in accordance with manufacturers recommendation for the following: medical device lasers, new medical equipment with insufficient maintenance history to support use of AEM, imaging and diagnostic equipment, etc.
Disposal of Trash

- Standard: There is proper routine storage and prompt disposal of trash,
- Includes biohazardous waste,
- Must be disposed of in accordance with standards (EPA, OSHA, CDC, environmental and safety),
- Includes radioactive materials,
- Will look for policies for proper storage and disposal,
Storage of Drugs  224

- Standard: Drugs and biologicals must be appropriately stored,
- Must be properly locked in the storage area,
  - Make sure medication carts in C-section rooms are locked
  - Make sure drugs are not left out in open in tube system or on dumb waiter ledge
- Surveyor will ask what standards, guidelines, or law you using to make sure they are stored,
Physical Environment 225

- **Standard:** Premises clean and orderly
- **Means** uncluttered with equipment not stored in corridors,
- Area is neat and well kept
- Spills not left unattended,
- No peeling paint or floor obstructions,
- No visible water leaks or plumbing problems
Standard; There must be proper ventilation, lighting, and temperature controls,

In pharmaceutical, patient care and food preparations

Proper ventilation in areas with nitrous oxide, glutaraldehyde, xylene, pentamidine, or other potentially hazardous substances,

Isolation rooms comply with laws such as CDC 2007 Isolation Guidelines, OSHA, NIH, et al,
Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection,

Including anesthetizing locations where inhalation anesthesia agents are used

Excessive humidity in the operating room is conducive to bacterial growth and compromises the integrity of wrapped sterile instruments and supplies,

- RH at 35% or greater unless waiver is used of 20% or greater

Acceptable standards such as from AORN or the Facilities Guideline Institute or FGI) should be incorporated into CAH policy.
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

Center for Clinical Standards and Quality / Survey & Certification Group

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
  - When 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, L, L, & W**: Are being updated accordingly.

Ref: S&C: 13-25-LSC & ASC
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
Center for Clinical Standards and Quality/Survey & Certification Group

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

Quality Advisory

January 21, 2015

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

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).
Proper Ventilation & Lighting 1-31-14

C-0226
(Rev. 99 Issued: 01-31-14, Effective: 01-31-14, Implementation: 01-31-14)

§485.623(b)(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

Interpretive Guidelines §485.623(b)(5)

There must be proper ventilation in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);
- Pharmaceutical preparation areas (hoods, cabinets, etc.);
- Laboratory locations; and
- Anesthetizing locations. According to NFPA 99, anesthetizing locations are “Any area of a facility that has been designated to be used for the administration of nonflammable inhalation anesthetic agents in the course of examination or treatment, including the use of such agents for relative analgesia.” NFPA 99 defines relative analgesia as “A state of sedation and partial block of pain...
Must have adequate number of refrigerators to make sure foods and meds are stored,

Surveyor will verify these areas are well lit,

Surveyor will verify compliance with ventilation in patients with TB or other airborne diseases,

Surveyor will verify food products are stored under appropriate conditions (time, temperature, packaging) based on national sources like USDA and FDA,
Emergency Procedures 227

- Standard: Assure safety of patients in non-medical emergencies,
- Staff trained in handling emergencies such as reporting and extinguishing of fires, evacuations, et al.,
- Report all fires to the state officials,
- Will interview staff to make sure they know what to do in case of a fire,
How do you ensure all personnel are trained to manage non medical emergencies?

Ask staff what to do in case of a tornado, hurricane, earthquake, or blizzard,

Review staff training documents and in-service records to confirm training,
Physical Environment 228

- Standard: Provide for emergency power and lighting in ED and for battery lamps or flashlights in other areas,
- Must comply with the applicable provisions of the Life Safety Code,
- National Fire Protection Amendments (NFPA) 101, 2000 Edition and applicable references such as NFPA-99: Health Care Facilities, for emergency lighting and emergency power,
Emergency Fuel and Water  229

- **Standard:** Provide for emergency fuel and water supply (snow bound or flooding),
- Must have system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care,
- Includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas,
- Source of information on water is FEMA,
- Have a plan for prioritizing their use until adequate supplies are available,
Emergency Preparedness Plan  230

- Develop a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations,

- Coordinate with Federal, State, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.)

- Develop appropriate responses that will ensure the safety and well being of patients.
CMS Revised Checklist Memo

- CMS issues 8 page memo on Feb 28, 2014
- Regarding checklist for emergency preparedness (EP)
- Update provides information about patient tracking, supplies and collaboration
- Discusses Oct 24, 2007 memo on EP
- This updated checklist can be found at S&C Emergency Preparedness Website http://www.cms.hhs.gov/SurveyCertEmergPrep
CMS Revised Checklist

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

DATE:  February 28, 2014
TO:  State Survey Agency Directors
FROM:  Director
Survey and Certification Group

Memorandum Summary

Revised Emergency Preparedness Checklist: The Centers for Medicare & Medicaid Services (CMS) is alerting healthcare facilities that we have revised current emergency preparedness checklist information for health care facility planning. These updates provide more detailed guidance about patient/resident tracking, supplies and collaboration.

The CMS has previously provided information to facilities concerning emergency preparedness in Survey and Certification letter S&C-08-01, issued on October 24, 2007. That memo provided a frequently ask questions (FAQ) document to provide direction on allowable deviations from provider survey and certification requirements during a declared public health emergency. It
# EMERGENCY PREPAREDNESS CHECKLIST

## RECOMMENDED TOOL FOR EFFECTIVE HEALTH CARE FACILITY PLANNING

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Not Started</th>
<th>In Progress</th>
<th>Completed</th>
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| **Develop Emergency Plan:** Gather all available relevant information when developing the emergency plan. This information includes, but is not limited to:  
- Copies of any state and local emergency planning regulations or requirements  
- Facility personnel names and contact information  
- Contact information of local and state emergency managers  
- A facility organization chart  
- Building construction and Life Safety systems information  
- Specific information about the characteristics and needs of the individuals for whom care is provided |             |             |           |
| **All Hazards Continuity of Operations (COOP) Plan:** Develop a continuity of operations business plan using an all-hazards approach (e.g., hurricanes, floods, tornadoes, fire, bioterrorism, pandemic, etc.) that could potentially affect the facility directly and indirectly within the particular area of location. Indirect hazards could affect the community but not the facility and as a result interrupt necessary utilities, supplies or staffing. Determine all essential functions and critical personnel. |             |             |           |
| **Collaborate with Local Emergency Management Agency:** Collaborate with local emergency management agencies to ensure the development of an effective emergency plan. |             |             |           |
| **Analyze Each Hazard:** Analyze the specific vulnerabilities of the facility and determine the following actions for each identified hazard:  
- Specific actions to be taken for the hazard  
- Identified key staff responsible for executing plan  
- Staffing requirements and defined staff responsibilities  
- Identification and maintenance of sufficient supplies and equipment to sustain operations and deliver care and services for 3-10 days, based on each facility’s assessment of their hazard vulnerabilities. |             |             |           |
Proposed Changes EP Requirements

- CMS publishes proposed rule in the Federal Register on December 27, 2013
- Requires hospitals that accepts Medicare or Medicaid to adequately plan for disasters
- Whether natural or man made
- Would have to coordinate with federal, state, and local emergency preparedness systems
- To enhance patient safety during an emergency
Proposed Changes EP Requirements

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

DATE: January 3, 2014

TO: State Survey Agency Directors

FROM: Director  Survey and Certification Group

SUBJECT: Publication of NPRM for Emergency Preparedness – Informational Only

Memorandum Summary

Publication of NPRM for Emergency Preparedness: This proposed rule would establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It would also ensure that these providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations.

The publication can be viewed at: https://federalregister.gov/a/2013-30724 and provides details on how to submit comments. Comments are invited within 60 days of publication.

Effective Date: Immediately.
Emergency Preparedness Plan

The following issues should be considered when developing the comprehensive emergency plans:

- Differences needed for each location where the certified CAH operates;
- Special needs of patient populations treated at the CAH (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);
- Security of patients and walk-in patients;
- Security of supplies from misappropriation;
Emergency Preparedness Plan

- Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;
- Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);
- Communication among staff within the CAH itself;
Emergency Preparedness Plan

- Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;
- Identification, availability and notification of personnel that are needed to implement and carry out the CAH’S emergency plans;
- Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;
Emergency Preparedness Plan

- Provisions for gas, water, electricity supply if access is shut off to the community;
- Transfer or discharge of patients to home or other healthcare settings,
- Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.
FIRE Inspections 231-233

- Must meet LSC of National Fire Protection Association such as NFPA-99 (231)
- CMS can allow state surveyor to apply state’s fire and safety code if CMS finds that it adequately protects patients
- CMS can waive specific provisions of the LSC if it would result in unreasonable hardship
  - But only if the waiver does not put patients at risk
Maintains written evidence of regular inspection and approval by State or local fire control agencies,

Surveyor will examine copies of inspection and approval reports from State and local fire control agencies,
Governing Body  241

- Standard; CAH has a governing body or individual that assumes legal responsibility for implementing and monitoring P&Ps,
- Must have 1 governing body or responsible person,
- Board must determine what categories of practitioners are eligible for appointment and reappoint to MS (NP, PA, dentist, CRNA) and there is written criteria for staff appointments,
- Done with advice of MS,
Governing Body  241

- Must be consistent with state and federal law requirements,
- Board approves MS bylaws and any revisions
  - Surveyor will look for this,
- Board responsible for conduct of CAH and for quality of care to patients,
- All patients must be under the care of a member of the MS
  - Or under care of member of MS under their supervision
Governing Body

- Criteria for MS is based on individual character, competence, training, experience and judgment,
- Surveyor will look to see Board or written documentation of person responsible for CAH,
- Will look to verify that Board has categories of practitioners for appointment to MS,
- Confirm that Board appoints all members to the MS,
Disclosure

- CAH discloses the names and addresses of its owners or those with controlling interest,
- Either directly or indirectly has 5% or more ownership,
- Surveyor will look for policy on reporting changes of ownership,
- Need policy on how to reporting changes for person responsible for operation of hospital (CEO) to state agency and also for reporting changes in medical director (243,244),
Staffing 250

- Standard: CAH has professional staff that includes one or more physicians, and may include PA, NP, or CNS,
- Need to have organizational chart which shows names of all MD/DO and mid-level providers
  - PA, NP, or CNS
- Surveyor will review work schedules,
Staffing  252

- Standard: All ancillary staff must be supervised by professional staff,
- Have sufficient staff to take care of patients
  - Emergency services, nursing services, Tag 253,
- Will review staffing schedules and daily census records,
  - Make sure answer call lights promptly
  - Make sure address monitor that alarms timely
Staffing  254

- MD, DO, NP, PA, or CNS must be available at all times to furnish care,
- Must show practitioner is available and shows up when patient presents to the hospital,
- Doesn’t mean they have to be there 24 hours a day,
Nurse on Duty  255

- Standard: Must have a RN, CNS, or LPN on duty whenever there is one or more inpatients,
- Surveyor will review staff schedules to make sure,
Physician Responsibilities  257

- **Standard**: MD/DO must provide medical directions and supervision of staff,
- **Surveyor** will make sure is available for consultation and supervision of staff,
- **PA or NP** participate in developing and reviewing written P&P (258)
- **Physicians** must periodically review charts of PA and NP and surveyor will look for documentation of same (259),
Must have a doctor on staff and must perform medical oversight,
- Must be present for sufficient period
- No longer says must be present at least once every two week to provide direction

Will want evidence that the Dr. provides oversight and is available for consultation or patient referral,

What evidence the there is periodic review of patient records by the doctor?
Physician Supervision 2015

- Periodically reviews and signs records of all inpatients cared by PA, NP, or CNS
  - MD/DO signs records after review completed
  - If case is managed by doctor and care given by non-physician review is not required

- Periodically reviews and signs sample of outpatient records
  - Of NP, CNS, PA, or CNM
  - ONLY if state law requires review or co-signature or state requires collaborating physician to sign
Physician Supervision 2015

- There is no time frame in the rule for the periodic review of PA or NP for inpatient
- CAH must specify a time frame in P&P for the maximum interval between inpatient reviews
- Must take into account the volume and types of services provided in developing the P&P
- 4 bed CAH would have different time frame than 25 bed CAH
- Also does CAH have EHR that can be reviewed and signed off remotely?
MD or DO must be present in the CAH for sufficient periods of time

- No longer says every two weeks
- To provide medical direction, consultation and supervision

And is available through radio or telephone or electronic communication (telemedicine)

- Develop P&P on this and document compliance
- CAH with busy ED and large outpatient unit would expect more frequent visits
Biweekly visit might be burdensome for small CAH in a remote area with low patient volume

Remember the federal EMTALA law

MD, DO, PA, CNS, or NP must be on call and available to provide emergency care

Must have list of on-call physicians

Must make sure MD or DO is available via phone, radio, video conferencing etc to handle patient emergencies and refer patients to other facilities
Must be members of CAH staff,
Must participate in development and review of P&P,
Interview them to determine their participation and knowledge of policies,
Will interview to determine their level of involvement in development of P&Ps and make updated,
Policies also need to be consistent with state standards of practice,
Transfer of Patients 267

- Standard: Arrange for transfer of patients who need services that can not be furnished,
- Must sent the patient’s medical records,
- Remember EMTALA is a separate CoP that every CAH must follow,
- Make sure you have a transfer policy and it should be consistent with EMTALA,
Patient Admission 268

- Standard: Whenever a patient is admitted by NP, PA, or CNS, a physician on the staff must be notified,
- CMS requires that Medicare and Medicaid patients be under the care of a MD/DO if patient has medical or psych problems that are outside of the scope of their practice,
- Admitting privileges must be consistent with what state law allows,
- Surveyor will look to make sure MD/DO monitor care for any medical problem outside their scope of practice,
Patient Care Policies 2015

- Standard: Services are provided in accordance with appropriate P&P (271)
- Provision of Services: Related to P&P and services and services provided including through contract (270)
- Need P&P governing the healthcare services that are available
- Must follow them in delivering care
- Will review policies on healthcare services that are provided in the CAH
- Observe staff delivering care to the patient
Patient Care Policies 272 2015

- P&P need to be developed by group of professional staff and include:
  - 1 MD/DO
  - 1 or more PA, NP, CNS if on staff (if CAH has these individuals on their staff)
  - Removed requirement for one member is who is not a member of the staff

- Removed section that said will interview CNO to determine role in policy development

- Review annually by above and as needed such as when change in a law
Patient Care Policies 272

- Must maintain documentation of the P&P committee’s activity
  - Must show evidence that group reviewed all the P&P at least yearly
  - Must reflect any changes made
- To review existing and new P&P
- Final decision on P&P is made by the board
- If the P&P recommendations by the advisory group are rejected, then board must include in the record the rational for the change
Standard: Need P&P on description of services provided by CAH directly or through contract

- Often called scope of services or provision of care

Should include statements like “taking complete medical histories, providing complete physical examinations, laboratory tests including” (with a list of tests provided) would satisfy this requirement,

Should include arrangements made with Hospital X for providing the following services with list of specialized diagnostic and lab testing,
Emergency Medical Services 274 2015

- Need P&P for providing emergency medical services
- Policies should show how the CAH would meet all of its emergency services requirements
- Will look at what equipment, supplies, medications, and blood is available on site
- How does CAH coordinate with local EMS?
- What type of staff are available to provide care in the ED?
Guideline for Medical Management 275 2015

➢ Need guidelines on managing health problems that include when medical consultation or referral is needed

➢ Need written guidelines on maintaining medical records and procedure for periodic review and evaluation of the services provided at the CAH

  ▪ Such as general instructions or protocols on how to medically manage the patient’s health problems commonly seen in the CAH
Medical Management 275

- Needs to include P&P on the scope of medical acts which may be done by PA, CNS, or NP
- When should physician be consulted or referred outside the CAH?
- What medical procedures can PA or NP do?
- Guidelines need to describe the medical conditions, signs or development that require consultation,
The End! Questions??

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