CMS Critical Access CoPs Part 1 of 4

Introduction, Memos, New Laws, Safe Injections, Advance Directives, Emergency Services, Drugs and Equipment, and Observation

Speaker

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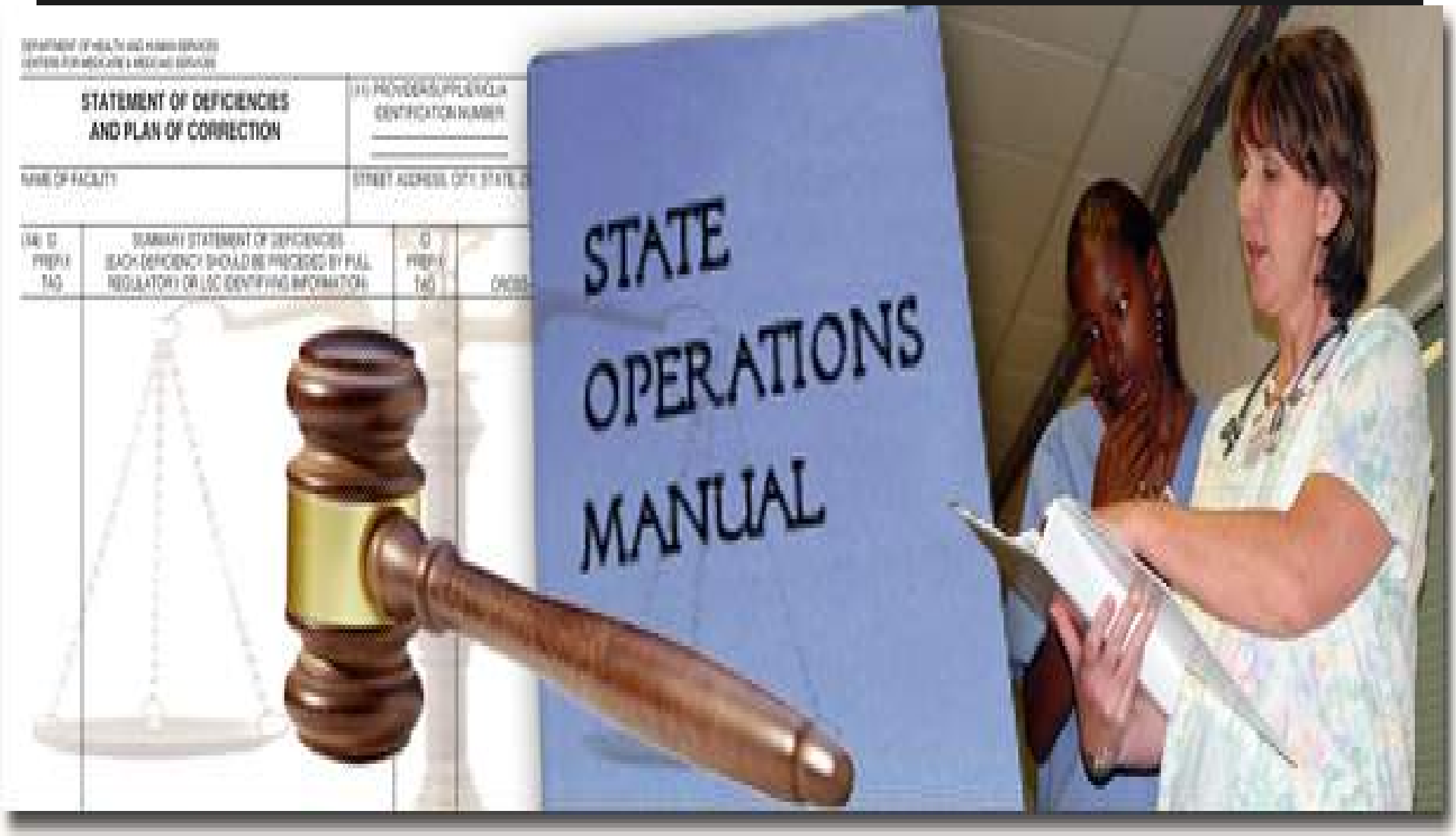
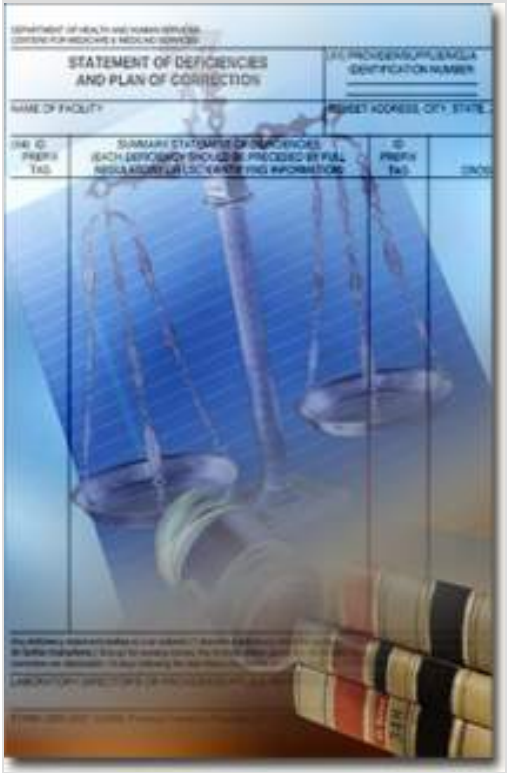
Introduction

You Don't Want One of These



Mandatory Compliance

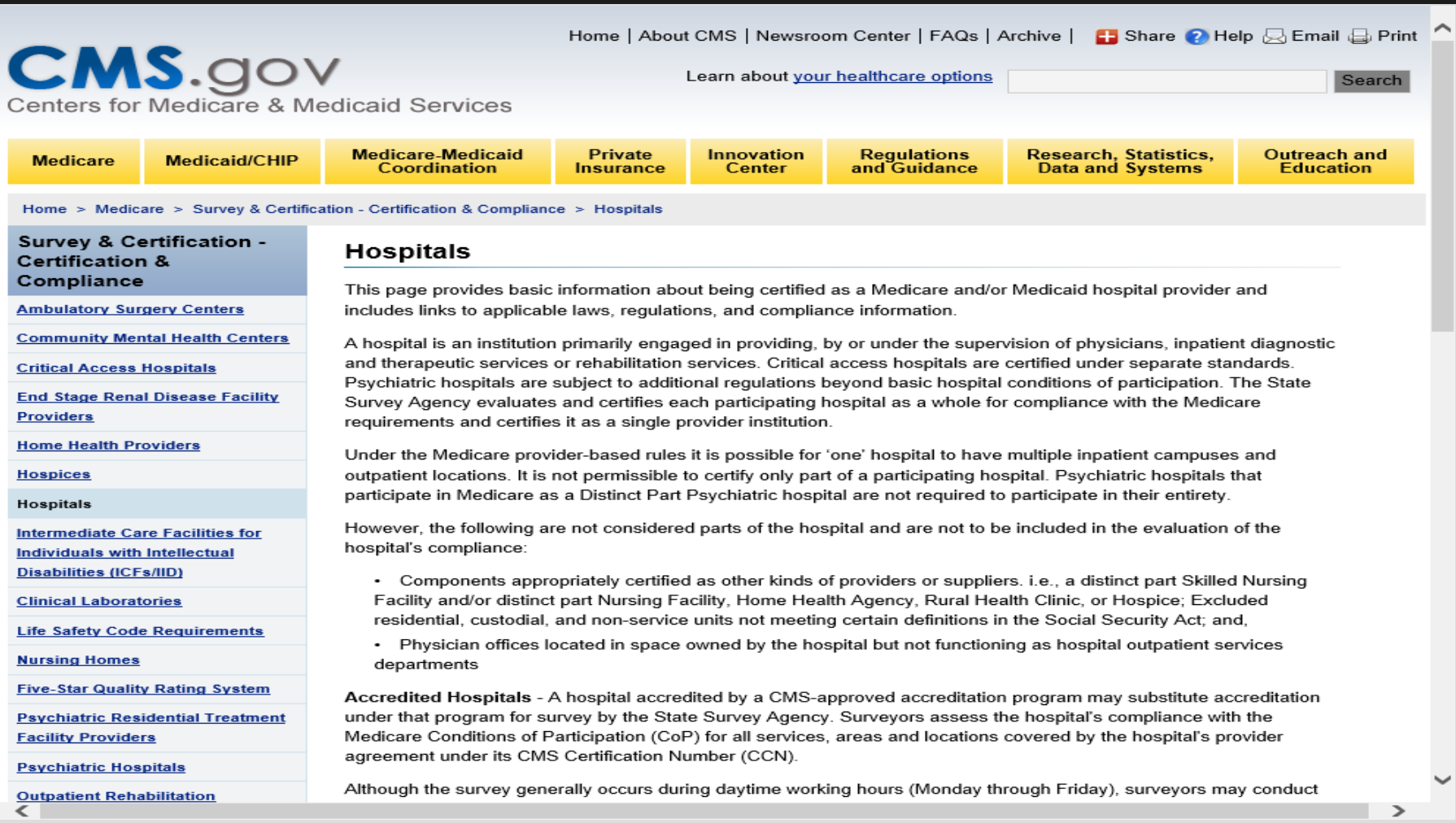


- Hospitals that participate in Medicare or Medicaid must meet the Conditions of Participation (COPs) for all patients in the facilities and not just those who are Medicare or Medicaid patients,
  - Hospitals accredited by the Joint Commission (TJC), HFAP, CIHQ, or DNV GL Healthcare have what is called deemed status
- Email questions to CMS at **QSOG_CAH@cms.hhs.gov**

Access to Hospital Complaint Data

- CMS issued Survey and Certification 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 and includes hospital's name and address

Updated Deficiency Data Reports



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Home > Medicare > Survey & Certification - Certification & Compliance > Hospitals

Survey & Certification - Certification & Compliance

- Ambulatory Surgery Centers
- Community Mental Health Centers
- Critical Access Hospitals
- End Stage Renal Disease Facility Providers
- Home Health Providers
- Hospices
- Hospitals
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID)
- Clinical Laboratories
- Life Safety Code Requirements
- Nursing Homes
- Five-Star Quality Rating System
- Psychiatric Residential Treatment Facility Providers
- Psychiatric Hospitals
- Outpatient Rehabilitation

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

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals.html

Updated Deficiency Data Reports

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 the survey at other times. This may include weekends and times outside of normal daytime (Monday through Friday) working hours. When the survey begins at times outside of normal work times, the survey team modifies the survey, if needed, in recognition of patients' activities and the staff available.

All hospital surveys are unannounced.

- Should an individual or entity (hospital) refuse to allow immediate access upon reasonable request to either a State Agency , CMS surveyor, a CMS-approved accreditation organization, or CMS contract surveyors, the hospital's Medicare provider agreement may be terminated.
- The CMS State Operations Manual (SOM) provides CMS policy regarding survey and certification activities.

See the **downloads** section below for the Patient's Rights Final Rule that includes more information on the hospital death reporting requirements related to restraint and seclusion.

Downloads

Patient's Rights Regulation published 12/8/2006 (PDF, 335 KB) (PDF)
EMTALA (PDF)
Chapter 2 - The Certification Process (PDF)
Full Text Statements of Deficiencies Hospital Surveys - 2020Q2 (ZIP)
Full Text Statements of Deficiencies Transplant Surveys - 2020Q2 (ZIP)

Related Links

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals.html

Can Count the Deficiencies by Tag Number

	A	B	C	D	E	F	G	H	I	J	
240	DOCTORS' HOSPITAL OF MICHIGAN	23(	461	MI	48341	Short Term	A	0364	AUTOPSIES	7/18/2012	Based on record review and interview, the facility failed to ensure that 1
241	MARTHA JEFFERSON HOSPITAL	49(	500	VA	22911	Short Term	A	0364	AUTOPSIES	9/8/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
242	SAINT LOUISE REGIONAL HOSPITAL	05(	940(	CA	95020	Short Term	A	0364	AUTOPSIES	1/18/2012	Based on interview and record review, the hospital failed to have a syste
243	EDGERTON HOSPITAL AND HEALTH SERVICES	521	111(	WI	53534	Critical Access H	C	0201	AVAILABILITY	10/2/2012	Based on review of MR, review of staffing guidelines, review of P&P, and
244	HOLZER MEDICAL CENTER JACKSON	361	500	OH	45640	Critical Access H	C	0205	BLOOD AND BLOOD PRODUCTS	1/20/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
245	BRANDON REGIONAL HOSPITAL	10(	119	FL	33511	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	4/8/2011	Based on clinical record review, staff interview and review of policy and
246	CHRISTUS ST PATRICK HOSPITAL	19(	524	LA	70601	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	3/9/2012	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
247	COLUMBUS REGIONAL HEALTHCARE SYSTEM	34(	500	NC	28472	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	4/13/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
248	DANA-FARBER CANCER INSTITUTE	22(	450	MA	02115	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	9/7/2011	Based on review of documentation and confirmed by staff interviews, tw
249	GOOD SAMARITAN MEDICAL CENTER	10(	130	FL	33401	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	2/12/2013	Based on clinical record review and staff interview the facility failed to e
250	LONG BEACH MEDICAL CENTER	33(	455	NY	11561	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	12/22/2011	Based on record review, the facility failed to ensure that the patient ' s te
251	MANATEE MEMORIAL HOSPITAL	10(	206	FL	34208	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	4/16/2012	Based on record review, policy review and staff interview it was determi
252	MISSOURI BAPTIST MEDICAL CENTER	26(	301	MO	63131	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	4/11/2012	Based on observation, interview, and record review, the facility failed to
253	NORTHWEST MEDICAL CENTER	10(	280	FL	33063	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	8/2/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
254	RESTON HOSPITAL CENTER	49(	185(	VA	20190	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	11/2/2012	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
255	SAINT AGNES HOSPITAL	21(	900	MD	21229	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	2/22/2012	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
256	SAINT CATHERINE REGIONAL HOSPITAL	15(	220(	IN	47111	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	12/13/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
257	SOUTHEASTERN REGIONAL MEDICAL CENTER	34(	300	NC	28359	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	12/14/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
258	STANFORD HOSPITAL	05(	300	CA	94305	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	3/15/2012	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
259	WAKEMED, CARY HOSPITAL	34(	190(	NC	27518	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	3/14/2013	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
260	WILKES-BARRE GENERAL HOSPITAL	39(	575	PA	18764	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	1/14/2013	Based on review of facility policy, facility documents, medical records (M
261	WILSON MEDICAL CENTER	34(	170	NC	27893	Short Term	A	0409	BLOOD TRANSFUSIONS AND IV MEDICATIONS	2/10/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
262	RIVERSIDE GENERAL HOSPITAL	45(	320	TX	77004	Short Term	A	0063	CARE OF PATIENTS	11/9/2012	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
263	CIVISTA MEDICAL CENTER	21(	5 GA	MD	20646	Short Term	A	0067	CARE OF PATIENTS - MD/DO ON CALL	8/4/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
264	MILFORD HOSPITAL, INC	07(	300	CT	06460	Short Term	A	0067	CARE OF PATIENTS - MD/DO ON CALL	9/22/2011	Based on review of hospital documentation and interviews with facility
265	PLAZA MEDICAL CENTER OF FORT WORTH	45(	900	TX	76104	Short Term	A	0067	CARE OF PATIENTS - MD/DO ON CALL	7/1/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
266	CLARA MAASS MEDICAL CENTER	31(	ONE	NJ	07109	Short Term	A	0068	CARE OF PATIENTS - RESPONSIBILITY FOR CARE	6/2/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
267	GEISINGER - COMMUNITY MEDICAL CENTER	39(	182	PA	18510	Short Term	A	0068	CARE OF PATIENTS - RESPONSIBILITY FOR CARE	6/14/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
268	SENTARA NORTHERN VIRGINIA MEDICAL CEN	49(	230(	VA	22191	Short Term	A	0068	CARE OF PATIENTS - RESPONSIBILITY FOR CARE	12/6/2012	Based on a complaint investigation, document review and interview, the

Sheet1

CAH Problematic Standards

- Date and time on all orders and entries
- Verbal orders, Cluttered hallways and other Life safety code issues, H&Ps, 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 & safe injections

Search for Hospital Inspections

AHA Website

Small or Rural Hospitals

Add to your Interests

Current & Emerging Payment Models / Rural issues

www.aha.org/advocacy/small-or-rural

Some 57 million rural Americans depend on their hospital as an important source of care as well as a critical component of their area's economic and social fabric.

AHA ensures the unique needs of our members are a national priority. Location, size, workforce, payment and access to capital challenge small or rural hospitals and the communities they serve. Collaborating with state and regional hospital associations and with advice from its member council, the Section tracks the issues, develops policies and identifies solutions to our most pressing problems. We do this through:

- Representation and advocacy in Washington, DC
- Communication and education
- Executive leadership and technical assistance
- Innovation in payment and delivery

2020 Rural Advocacy Agenda

Join the AHA Advocacy Alliance for Rural Hospitals

American Hospital Association™
Advancing Health in America
Rural Health Services

33RD ANNUAL **AHA RURAL HEALTH CARE LEADERSHIP CONFERENCE**
FEBRUARY 2–5, 2020
ARIZONA GRAND RESORT & SPA
PHOENIX, AZ
AHA Events

See AHA Today Coverage of the Conference

AHA's Rural Report
A Podcast Series

Rural Health Resources

2020 Rural Advocacy Agenda

Rural Health Resources

Advocacy and Policy

The American Hospital Association has made improving access to rural health a top priority. Our advocacy agenda for lawmakers and policy recommendations to government agencies lay the groundwork for needed change to improve the system for patients. Click here for regulatory advisories, comment letters, fact sheets and our agendas.

Tools and Education

The American Hospital Association has a wealth of educational resources and tools available to rural hospitals and health systems. Click here for podcasts, webinars, toolkits, and more.

Case Studies

The American Hospital Association is proud to feature the success stories of its members. Read a variety of case studies highlighting best practices, innovative techniques and new ideas from the field.

Resources

The American Hospital Association hosts a wealth of resources available to rural members. Click here for external funding opportunities for your organization.

Explore Small or Rural Hospitals Topics

1. 2020 Rural Advocacy Agenda
2. Rural Report

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Daily and weekly custom alerts also available

Find Rural Data

The Rural Data Explorer and Chart Gallery provide access to a wide range of data on rural health issues.

Learn how to locate and use data in the Finding Statistics and Data Related to Rural Health topic guide.

Funding Opportunities

Discover the latest funding and opportunities to support rural health. Browse all funding opportunities.

Am I Rural?

Use the Am I Rural? Tool to find out if a location is considered rural based on various definitions of rural, including definitions that are used as eligibility criteria for federal programs.

What Works in Rural

Key Rural Health Issues

The Rural Monitor

Rural Health Predictions: Q&A with Alan Morgan

National Rural Health Association CEO Alan Morgan discusses his organization's work on the national and global stages and shares his rural health predictions for 2020.

Healthcare Professionals' Mental Health Needs: Where Can They Go?

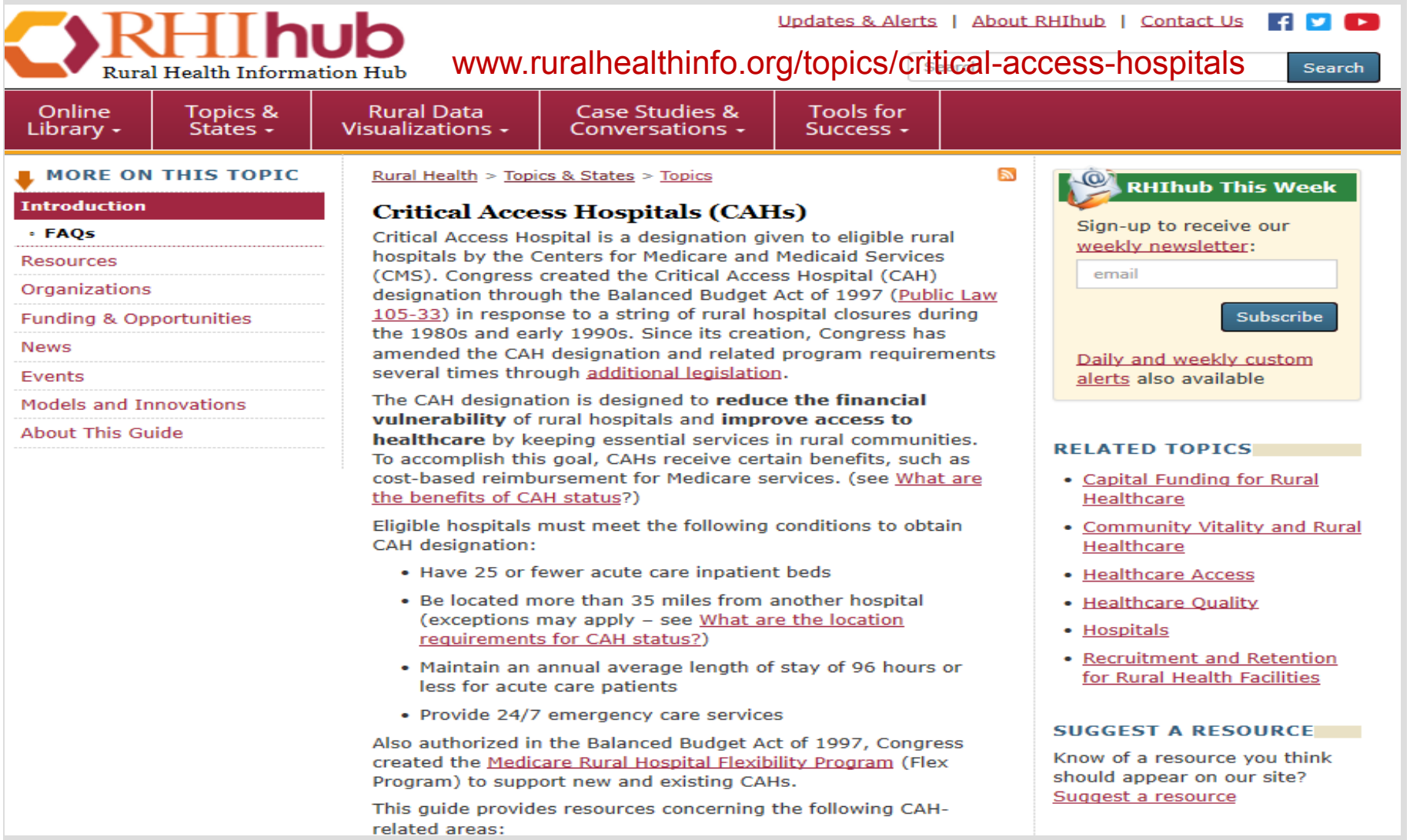
Recent research has found that not only are nearly 40% of surveyed physicians burned out, but 40% are also experiencing depression. For many reasons — stigma among them — these professionals are not getting mental health support. Physician health programs, in collaboration with professional societies, are trying to change that by working with state licensure boards and other groups.

News Headlines

- Study Links Three Key Variables to Higher Rural Mortality Rates in US
  Texas Tech University Health Sciences Center
- New Tool Empowers Local Leaders to Take Action Against Rural Drug Addiction
  The White House

More News »

FAQs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About This Guide
Rural Health > Topics & States > Topics
Critical Access Hospitals (CAHs)
Critical Access Hospital is a designation given to eligible rural hospitals by the Centers for Medicare and Medicaid Services (CMS). Congress created the Critical Access Hospital (CAH) designation through the Balanced Budget Act of 1997 (Public Law 105-33) in response to a string of rural hospital closures during the 1980s and early 1990s. Since its creation, Congress has amended the CAH designation and related program requirements several times through additional legislation.
The CAH designation is designed to reduce the financial vulnerability of rural hospitals and improve access to healthcare by keeping essential services in rural communities. To accomplish this goal, CAHs receive certain benefits, such as cost-based reimbursement for Medicare services. (see What are the benefits of CAH status?)
Eligible hospitals must meet the following conditions to obtain CAH designation:
Have 25 or fewer acute care inpatient beds
Be located more than 35 miles from another hospital (exceptions may apply – see What are the location requirements for CAH status?)
Maintain an annual average length of stay of 96 hours or less for acute care patients
Provide 24/7 emergency care services
Also authorized in the Balanced Budget Act of 1997, Congress created the Medicare Rural Hospital Flexibility Program (Flex Program) to support new and existing CAHs.
This guide provides resources concerning the following CAH-related areas:
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Daily and weekly custom alerts also available
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Healthcare Access
Healthcare Quality
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Home › Programs › TASC › State Flex Profiles

State Flex Profile Navigation

Jump to: - Select State -

State Flex Profiles

State Flex Profiles showcase the beneficial activities occurring at the state-level to support the critical access hospitals (CAHs) and their communities around the country. No two states have the same exact approaches and the profiles are updated annually as an opportunity for states to share their excellent work and to learn from one another. The profiles include information on the work occurring in the five Flex Program areas as well as successes, best practices and innovations. Use the State Flex Profiles to identify approaches to similar rural health issues, identify best practice opportunities and access contact information for individuals at the state-level who are supporting Flex Program activities.

Use the drop-down menu in the gray box at the top of this page to see a specific state's profile. If you are looking for examples of a particular activity, for example, revenue cycle management, use the keyword search provided below.

Search State Flex Profiles

CMS Updated Website www.cms.gov

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 orQSOG_CAH@cms.hhs.gov

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs

Quality, Safety & Oversight - Certification & Compliance

- Ambulatory Surgery Centers
- Community Mental Health Centers
- Critical Access Hospitals
- End Stage Renal Disease Facility Providers
- Home Health Providers
- Hospices
- Hospitals
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID)
- Clinical Laboratories
- Life Safety Code & Health Care Facilities Code Requirements
- Nursing Homes
- Five-Star Quality Rating System
- Psychiatric Residential Treatment Facility Providers
- Psychiatric Hospitals
- Outpatient Rehabilitation Providers
- Inpatient Rehabilitation Facilities

Critical Access Hospitals

This page provides basic information about being certified as a Medicare Critical Access Hospital (CAH) provider and includes links to applicable laws, regulations, and compliance information.

CAHs represent a separate provider type with their own Medicare Conditions of Participation (CoP) as well as a separate payment method. The CoPs for CAHs are listed in the "Code of Federal Regulations" at 42 CFR 485 subpart F.

The following providers may be eligible to become CAHs:

- Currently-participating Medicare hospitals;
- Hospitals that ceased operations on or after November 29, 1989; or
- Health clinics or centers (as defined by the State) that previously operated as a hospital before being downsized to a health clinic or center.

A Medicare-participating hospital must meet the following criteria to be designated by CMS as a CAH:

- Be located in a State that has established a State Medicare Rural Hospital Flexibility Program;
- Be designated by the State as a CAH;
- Be located in a rural area or an area that is treated as rural;
- Be located either more than 35-miles from the nearest hospital or CAH or more than 15 miles in areas with mountainous terrain or only secondary roads; OR prior to January 1, 2006, were certified as a CAH based on State designation as a "necessary provider" of health care services to residents in the area.
- Maintain no more than 25 inpatient beds that can be used for either inpatient or swing-bed services;
- Maintain an annual average length of stay of 96 hours or less per patient for acute inpatient care (excluding swing-bed services and beds that are within distinct part units);
- Demonstrate compliance with the CAH CoPs found at 42 CFR Part 485 subpart F; and
- Furnish 24-hour emergency care services 7 days a week;

A CAH may also be granted "swing-bed" approval to provide post-hospital Skilled Nursing Facility-level care in its

CMS CAH Website

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Centers for Medicare & Medicaid Services

www.cms.gov/Center/Provider-Type/Critical-Access-Hospitals-Center

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Critical Access Hospitals Center

Spotlights

- **Clinical Laboratory Data Reporting: Enforcement Discretion** On March 30, CMS announced that it will exercise enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting applicable information under the Clinical Laboratory fee Schedule (CLFS) and the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information.
  View the announcement (PDF) and PAMA regulations page.

- **Additional Clarification of Guidance on the Physician Order and Physician Certification for Hospital Inpatient Admissions (PDF)**
  On August 19, 2013, in the FY2014 IPPS/LTCH final rule CMS clarified and revised the conditions of payment for hospital inpatient services under Medicare Part A related to patient status. On September 5, 2013, CMS released guidance (PDF) that discussed the provisions of the final rule regarding the physician order and physician certification of hospital inpatient services. This document includes further clarification of issues addressed in the previous guidance.

- **Prior Guidance on the Physician Order and Physician Certification for Hospital Inpatient Admissions (PDF)**
  The guidance provided in this document has been further clarified in **Additional Clarification of Guidance on the Physician Order and Physician Certification for Hospital Inpatient Admissions.** This version of the guidance document will remain online for comparison purposes.

Emergency Preparedness

- The emergency preparedness standards reference now to Appendix Z for the interpretive guidelines and survey procedures
- Appendix Z was amended in Feb of 2019 with three changes
- There were many changes effective November 29, 2019 and regulation starts at tag 950
- These were in the hospital improvement rule
  - Basically, changes everything from every year to every two years except the drills are still twice a year
- This will be discussed later

Emergency Preparedness is Appendix Z

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO19-06-ALL

DATE: **February 1, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Emergency Preparedness- Updates to Appendix Z of the State Operations Manual (SOM)

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-06-ALL.pdf

Amended November 29, 2019

Memorandum Summary

- **Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers:** On September 16, 2016, the *Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers* (Emergency Preparedness Rule) final rule was published in the Federal Register.
- Health care providers and suppliers affected by the rule were required comply and implement all regulations by November 15, 2017.
- We are updating Appendix Z of the SOM to reflect changes to add emerging infectious diseases to the definition of all-hazards approach, new Home Health Agency (HHA) citations and clarifications under alternate source power and emergency standby systems.

Immediate Jeopardy

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-19-09-ALL

DATE: **March 5, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Revisions to Appendix Q, Guidance on Immediate Jeopardy

Memorandum Summary

- **Core Appendix Q and Subparts** - Appendix Q to the State Operations Manual (SOM), which provides guidance for identifying immediate jeopardy, has been revised. The revision creates a Core Appendix Q that will be used by surveyors of all provider and supplier types in determining when to cite immediate jeopardy. CMS has drafted subparts to Appendix Q that focus on immediate jeopardy concerns occurring in nursing homes and clinical laboratories since those provider types have specific policies related to immediate jeopardy.
- **Key Components of Immediate Jeopardy** – To cite immediate jeopardy, surveyors determine that (1) noncompliance (2) caused or created a likelihood that serious injury, harm, impairment or death to one or more recipients would occur or recur; and (3) immediate action is necessary to prevent the occurrence or recurrence of serious injury, harm, impairment or death to one or more recipients.
- **Immediate Jeopardy Template** – A template has been developed to assist surveyors in documenting the information necessary to establish each of the key components of

CAH Checklist

North Dakota Critical Access Hospital Conditions of Participation (CoP) Checklist Updated: November 2018

Funded by:
ND Medicare Rural Hospital Flexibility Program
Federal Office of Rural Health Policy
Health Resources and Services Administration
U.S. Department of HHS

Center for Rural Health
University of North Dakota
School of Medicine & Health Sciences

New Updates from the last issue

(Updates highlighted in yellow)

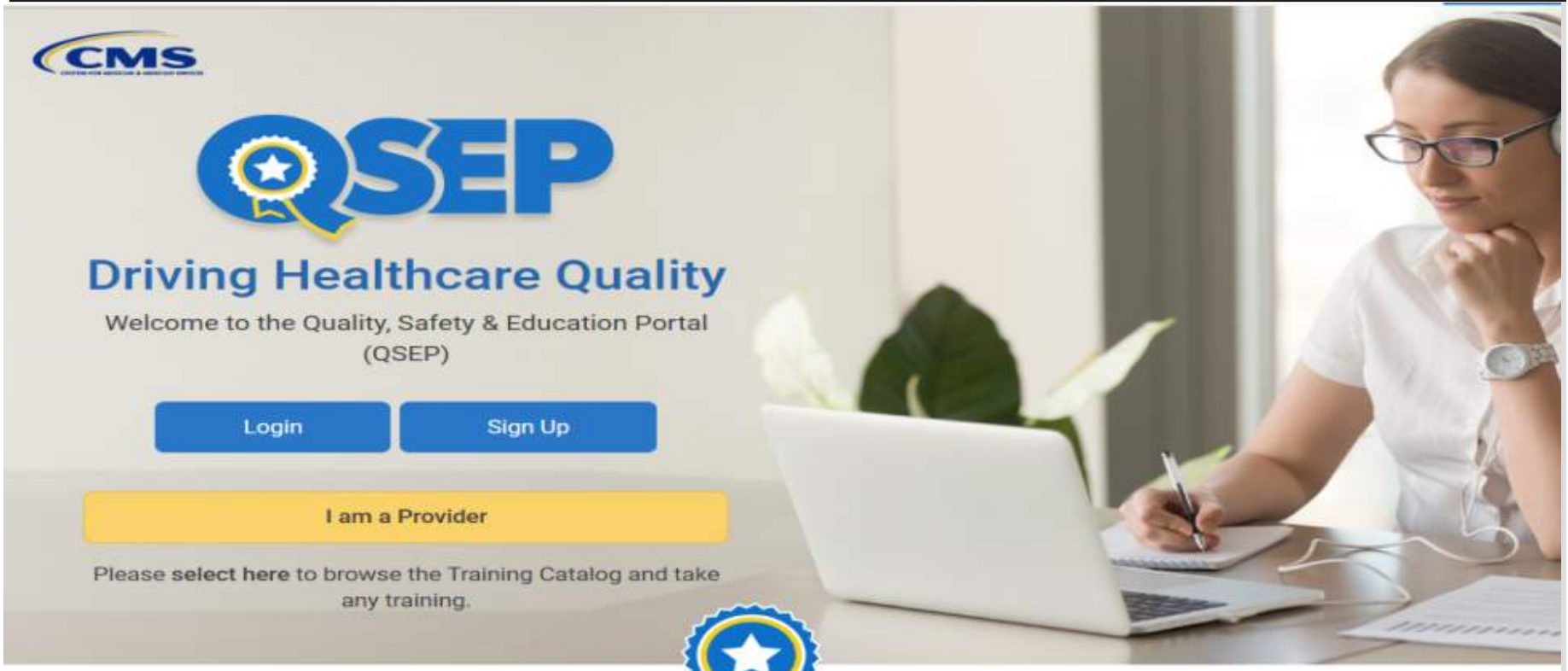
TAG	REQUIREMENT
ADVANCED DIRECTIVES & PATIENT RIGHTS C-0151	◻ Does facility have policy and procedure regarding advance directives? ◻ Does the hospital provide written information to patients at the time of admission concerning their rights under state law to make decisions concerning medical care? ◻ CAH & staff compliance with federal, state and local laws & regulations ◻ Staff must comply with their advance directives and are educated to policy and procedures ◻ Provide advance directive information to the competent patient when admitted ◻ Inpatients and Outpatients have the right to make advance directives ◻ Advance directive applies to ED, observation and same day surgery patient ◻ Have advance directives to designate a support person for person of exercising the visitation rights ◻ If patient is incapacitated, a durable power of attorney (DPOA) must be used to inform 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 ◻ Prominent documentation in MR of completing advance directive ◻ Provide community education regarding issues concerning advance directives and the hospital must document its efforts (video and audible tapes acceptable) ◻ Patient has the right to refuse treatment ◻ Must disclose if physician owned hospital ◻ Physician's must also disclose to patients who they refer ◻ Disclose in writing if physician is not on premise 24 hours a day for

CMS Surveyor Training Website

CMS Surveyor Training Website

- CMS has a surveyor training website
- Hospitals can also take the training classes and access webcasts and videos
  - Has CAH basic training course and infection control
  - Has 28 hour EMTALA course
  - https://qsep.cms.gov/welcome.aspx
  - Click on calendar
- There is a help desk to assist if you need assistance
  - 855 791-8900 or cmstraininghelp@hendall.com
  - Course catalog to see available resources

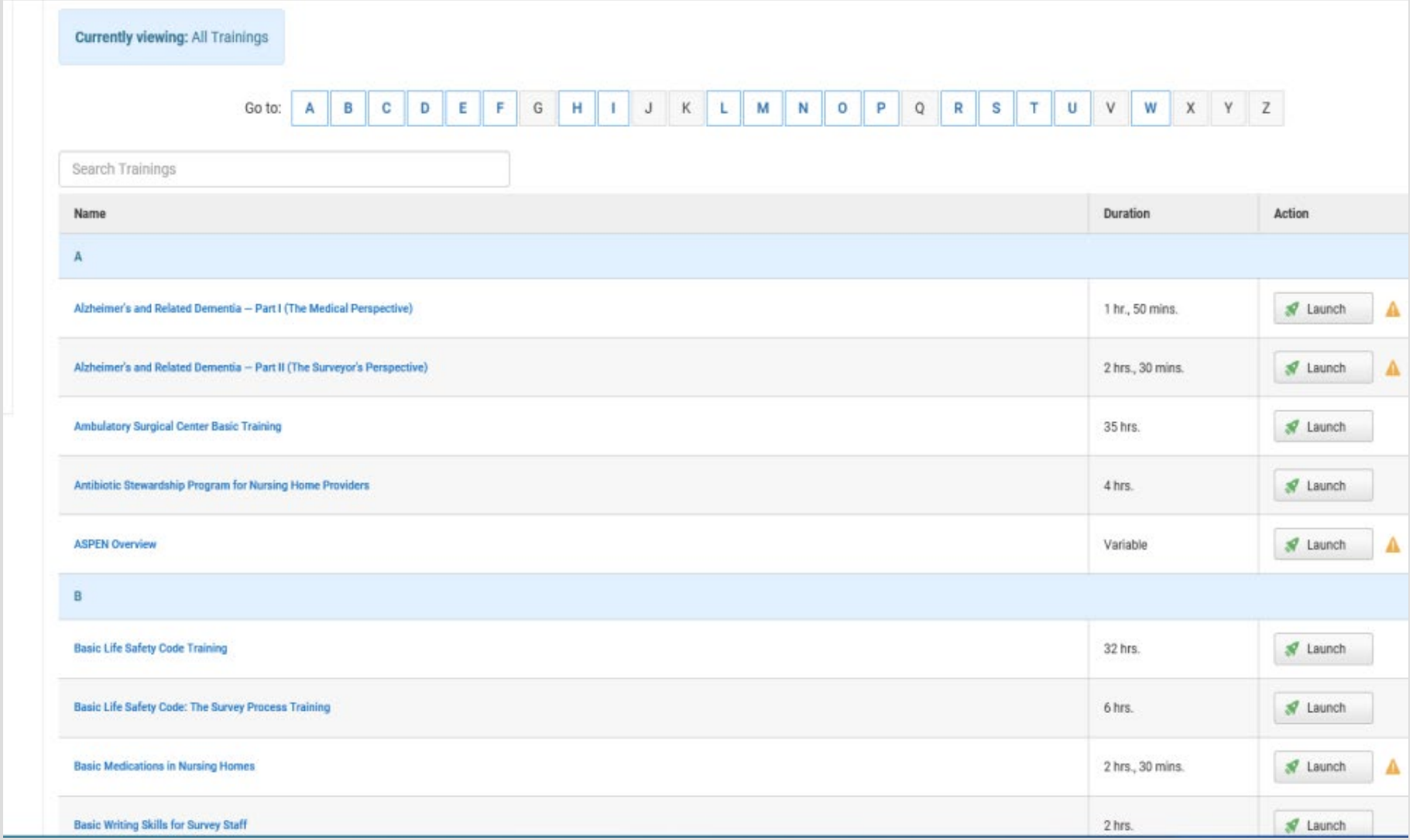
Surveyor Training Click on Catalog



https://qsep.cms.gov/welcome.aspx

The Quality, Safety & Education Portal (QSEP) provides the full curriculum of surveyor training and guidance on health care facility regulations.

Alphabetical Lists of Training



Select CAH Basic Training 24 hr

CRITICAL ACCESS HOSPITAL BASIC TRAINING (CAH)

Class Information

Activity Code: 0CMSCAHBasic_CEU_ONL

Class Dates: Web-based Training

Status: Guest

Location: ISTW

https://surveyortraining.cms.hhs.gov/pubs/ClassInformation.aspx?cid=0CMSCAHBasic_CEU_ONL

Class Description: Critical Access Hospitals (CAH) are required to comply with the Federal requirements set forth in the Medicare Conditions of Participation (CoPs) in order to receive Medicare or Medicaid payment. The goal of a CAH survey is to determine if the CAH complies with CoPs at 42 CFR 485, Subpart F.

Therefore, to ensure beneficiaries receive quality care and services, the Critical Access Hospitals Basic Training Online Course is designed to increase surveyor proficiency in the CAH survey process.

The estimated course completion time for this training is 24 hours.

If you have any questions regarding course related content, please direct all correspondence to CAHSCG@cms.hhs.gov.

Prerequisites:

1. Principles of Documentation for Long Term Care *OR* Principles of Documentation for Non-Long Term Care *OR* Principles of Documentation for Non-Long Term Care
2. Electronic Code of Federal Regulations Simulation
3. S & C Policy Memo Navigation Simulation
4. SOM Navigation Simulation
5. Introduction to Surveying for Non-Long Term Care *OR* Introduction to Surveying for Long Term Care
6. Basic Writing Skills for Survey Staff
7. Foundational Investigative Skills
8. Hospital Basic Training Part 1 *OR* Hospital Basic: Part 1 (Blackboard) *OR* CMS Basic Hospital Via Attestation - Prior to LMS set up in 2002 *OR* CMS Basic Hospital Surveyor Training Course *OR* Live Webinar Basic Hospital April 2013
9. Hospital Basic Training Part 2 *OR* Hospital Basic: Part 2 (Blackboard) *OR* CMS Basic Hospital Via Attestation - Prior to LMS set up in 2002 *OR* CMS Basic Hospital Surveyor Training Course *OR* Live Webinar Basic Hospital April 2013

Introduction Into the CMS CoPs

The Conditions of Participation CoPs

- First, published in the Federal Register
  - **Federal Register** available at no charge
- Next, CMS publishes **Interpretive Guidelines** and some include **survey procedures**
  - CMS made many changes effective June 7, 2013 and 93 page memo January 16, 2015, effective April 7, 2015
  - Changes made October 12, 2018 to rewrite all the swing bed regulations
  - November 29, 2019 changes and tags renumbered

New Tag Numbers

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-07-ALL

www.cms.gov/files/document/burden-reduction-discharge-planning-som-package.pdf

DATE: **December 20, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Burden Reduction and Discharge Planning Final Rules Guidance and Process

Memorandum Summary

- On September 30, 2019, the Centers for Medicare & Medicaid Services (CMS) published the *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction* Final Rule, as well as the *Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies* Final Rule.
- This policy memorandum provides guidance to the CMS Regional Offices (ROs), the State Survey Agencies (SAs) and the Accrediting Organizations (AOs) regarding the changes to the regulations and our approach for updating the State Operations Manual (SOM) and applicable surveyor systems.

Background

On September 30, 2019, CMS published two final rules which revised regulatory requirements for the various certified provider and supplier types.

The two final rules are as follows:

Crosswalk to New Tag Numbers

www.cms.gov/files/document/c-tag-crosswalk.xlsx

	A	B	C	D	E	F
1	NEW TAG #	CFR	Critical Access Hospital (CAH) Tag Title	Condition of Participation	OLD TAG #	Tag Changes Effective 03/30/20
2	C-0800	§485.601	BASIC AND SCOPE	NA	NA	NA
3	C-0802	§485.603	RURAL HEALTH NETWORK	NA	NA	NA
4	C-0804	§485.604	PERSONNEL QUALIFICATIONS	NA	NA	NA
5	C-0808	§485.606	DESIGNATION AND CERTIFICATION OF CAHS	NA	NA	NA
6	C-0810	§485.608	COMPLIANCE WITH FED, ST, AND LOCAL LAWS AND REGULATIONS	Compliance W/ Fed., State, and Local Laws and Regulations	C-0150	NA
7	C-0812	§485.608(a)	COMPLIANCE WITH FED, ST LAWS AND REGULATIONS	Compliance W/ Fed., State, and Local Laws and Regulations	C-0151	NA
8	C-0814	§485.608(b)	COMPLIANCE WITH STATE AND LOCAL LAWS AND REGULATIONS	Compliance W/ Fed., State, and Local Laws and Regulations	C-0152	NA
9	C-0816	§485.608(c)	LICENSURE OF CAH	Compliance W/ Fed., State, and Local Laws and Regulations	C-0153	NA
10	C-0818	§485.608(d)	LICENSURE, CERTIFICATION OR REGISTRATION OF PERSONNEL	Compliance W/ Fed., State, and Local Laws and Regulations	C-0154	NA
11	C-0822	§485.610	STATUS AND LOCATION	Status and Location	C-0160	NA

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Location of CMS Hospital CoP Manual

New Email questions to CAH at qsog_cah@cms.hhs.gov

Medicare State Operations Manual

Appendix

- Each Appendix is a separate file that can be accessed directly from the SC... 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 corresponding letter in the "Appendix Letter" 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

New **www.cms.gov/files/document/appendices-table-content.pdf**

Appendix Letter	Description
A	Hospitals
AA	Psychiatric Hospitals
B	Home Health Agencies

M	Hospice	720 KB
N	Pharmaceutical Service Requirements in Long-Term Care Facilities	Deleted
P	Survey Protocol for Long-Term Care Facilities	929 KB
PP	Interpretive Guidelines for Long-Term Care Facilities	1,440 KB
Q	Determining Immediate Jeopardy	326 KB
R	Resident Assessment Instrument for Long-Term Care Facilities	38 KB
S	Mammograpy Suppliers	Deleted
T	Swing-Beds	363 KB
U	Responsibilities of Medicare Participating Religious Nonmedical Healthcare Institutions	452 KB
V	Responsibilities of Medicare Participating Hospitals In Emergency Cases	393 KB
W	Critical Access Hospitals (CAHs)	1,597 KB

www.cms.gov/manuals/Downloads/som107ap_w_cah.pdf

and is critical access hospital CoP

CAH CoP or State Operations Manual

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

(Rev. 200, 02-21-20)

Transmittals for Appendix W

INDEX

Survey Protocol

Manuals at www.cms.gov/files/document/appendices-table-content.pdf

Regulations and Interpretive Guidelines for CAHs

Questions to qsog_cah@cms.hhs.gov

CMS Survey and Certification Website

CMS.gov
Centers for Medicare & Medicaid Services

Search

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

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- CMS Federal Grant Opportunity
- Contact Information
- Diabetic Self-Management Training

Policy & Memos to States and Regions

CMS Quality Safety & Oversight memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.

Show entries: 5 per page | Filter On | Apply

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Title	Memo #	Posting Date	Fiscal Year
Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in nursing homes	QSO-20-14-NH	2020-03-04	2020
Suspension of Survey Activities	QSO-20-12-All	2020-03-04	2020
Guidance for Infection Control and Prevention Concerning Coronavirus Disease (COVID-19): FAQs and Considerations for Patient Triage, Placement and Hospital Discharge	QSO-20-13-Hospitals	2020-03-04	2020
Release of Additional Toolkits to Ensure Safety and Quality in Nursing Homes	20-11-NH	2020-02-14	2020

Survey Memo on COVID-19 Reporting

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-21-03-Hospitals/CAHs

DATE: **October 6, 2020**

TO: CMS Locations State Agencies, Hospitals/CAHs, and other stakeholders

FROM: Director Quality, Safety & Oversight Group- Division of Continuing and Acute Care Providers

SUBJECT: Interim Final Rule (IFC), CMS-3401-IFC; Requirements and Enforcement Process for Reporting of COVID-19 Data Elements for Hospitals and Critical Access Hospitals

Memorandum Summary

- CMS is committed to continuing to take critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On September 2, 2020, the Federal Register published an interim final rule with comment period (IFC) (85 FR 54820).
- CMS has released new regulatory requirements for all hospitals and critical access hospitals (CAHs) at 42 C.F.R. §§482.42(e) and 485.640(d), respectively, to report information in accordance with a frequency and in a standardized format as specified by the Secretary during the PHE for COVID-19.
- Failure to report the specified data needed to support broader surveillance of COVID-19 may lead to the imposition of the remedy to terminate a provider's participation from the Medicare and Medicaid programs.

Background

On March 4, 2020, we issued guidance stating that hospitals should inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a person under investigation for COVID-19.[1]

CMS Final Changes
The Hospital Improvement Rule and Discharge Planning and Most Recent Changes

Introduction

- CMS published the final regulations on September 30, 2019 and these became effective on November 29, 2019 and IGs out in 2020 or 2021
  - Regulations are effective 60 days after publication in the Federal Register with two exceptions for CAH on QAPI 18 months and ASP 6 months
- CMS will publish interpretive guidelines and survey procedures to match so monitor the survey memo website
  - This included the discharge planning standards
  - Also implemented the hospital improvement rule
- Made 4 changes to swing bed requirements

Hospital Improvement Rule

This document is scheduled to be published in the Federal Register on 09/30/2019 and available online at **https://federalregister.gov/d/2019-20736**, and on **govinfo.gov**

[Billing Code: 4120-01-P]

https://federalregister.gov/d/2019-20736 and 393 Pages

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 488, 491, and 494

[CMS-3346-F; CMS-3334-F; CMS-3295-F]

RIN 0938-AT23

Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

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

ACTION: Final rule.

SUMMARY: This final rule reforms Medicare regulations that are identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. This final rule also

Hospital Improvement Rule

- Requirements for emergency preparedness (which are now in Appendix Z)
- Rewrote all the QAPI requirements
- Staffing and staff responsibility
  - Quality and appropriateness of diagnosis by PA, NP, or CNS is evaluated by the MD/DO under contract with the CAH
  - Quality and appropriateness of diagnosis and treatment by MD/DO is evaluated by QIO, hospital that is a member of the network or qualified individual identified in the state rural health plan
  - Also a section to evaluate telemedicine providers

Hospital Improvement Rule

- Many changes to infection control and implementation of an antibiotic stewardship program
- Provision of services
  - Need P&P to ensure nutritional needs of patients are being met
  - Need diet order by physician or provider
  - Can C&P dietician to order diet if allowed by state law
  - Policies can be reviewed every two years by the policy committee instead of annually

Discharge Planning Changes

- November 3, 2015 CMS proposed to revise the hospital discharge planning standards
  - Gets 1 year extension until Nov 2, 2019
  - Published final regulation Sept 30, 2019
  - Effective date **November 29 2019** Manual for 10 Bed Behavioral Health or Rehab, hospitals **and CAHs**
  - CMS will issue interpretive guidelines and survey procedures **in 2020 or 2021**
  - 11 tag numbers and starts at tag 1400
  - 1400, 1404, 1406, 1408, 1410, 1412, 1417, 1420, 1422, 1425, and 1430
  - Similar to Appendix A with a few minor exceptions

Discharge Planning 201 Pages

This document is scheduled to be published in the Federal Register on 09/30/2019 and available online at **https://federalregister.gov/d/2019-20732**, and on **govinfo.gov**

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482, 484, and 485

[CMS-3317-F and CMS-3295-F]

RIN 0938-AS59

www.federalregister.gov/documents/2019/09/30/2019-20732/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals

Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

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

ACTION: Final rule.

SUMMARY: This final rule empowers patients to be active participants in the discharge planning process and complements efforts around interoperability that focus on the seamless exchange of patient information between health care settings by revising the discharge planning requirements that Hospitals (including Short-Term Acute-Care Hospitals, Long-Term Care Hospitals (LTCHs), Rehabilitation Hospitals, Psychiatric Hospitals, Children's Hospitals, and Cancer Hospitals), Critical Access Hospitals

October 12, 2018 Changes

- 73 pages and 46 pages affect CAHs
  - Deleted tags 360, 362-372, 374, 376, 377, 379, 380, 382-384, 389, 390, 395-401, 403 and 405-408
  - Remember renumbered all the tag numbers in 2020
- Revises table of content to include special requirement for CAH of LTC services
- Revises survey protocol
  - Makes it clear must grant immediate access upon a reasonable request or can terminate Medicare
  - Makes it clear cannot refuse to permit copying of records or information by the surveyor
  - Required to be in compliance with CoPs to receive M/M payment

October 12, 2018 Changes

- Won't receive advanced notice of survey
- Will assess compliance with all areas under CCN
- Surveyor must complete basic surveyor course

- Revises swing bed section
  - Revises 350 on swing beds, 351 on eligibility, 361 on SNF service, 373 on admission, transfer and discharge, 381 on freedom from abuse, neglect and exploitation, 385 services directed by qualified professional, 386 on care plan and discharge planning, 402 on specialized rehab services, and 404 on dentists
  - 4 changes to swing beds that went into effect November 29, 2019

October 12, 2018 Changes

- New standard 410 on nutrition
- Will look at telemedicine contract
- Will not withhold areas of concern to the final conclusion
- Surveyor can not touch or examine patients and if concerned about bedsores, bruises, or incontinence will ask staff to move patient or will be present while physical exam is done
- Surveyor may need to make copies of some of the EHRs but will try and not print entire record

October 12, 2018 Changes

- Will ask what happens if the computer system goes down?
  - How do you register a patient, transfer or admit?
  - How do you order or get lab results?
- All team members must review their finding and concerns and be prepared to discuss during the daily meeting
- Will determine if corrective actions make it unlikely for the deficient practice to reoccur
- If want to record surveyor must be given a copy

October 12, 2018 Changes

- Will not delay survey to wait for additional staff to arrive
- Make sure surveyors have access to copiers
- If use EHRs or electronic P&P surveyors will need access to printers
- Surveyors can make an extra copy of every document that surveyors copy, if requested
- Will not provide the hospital with a list of the records reviewed or patients, staff or visitors that they talked to
- Staff can accompany surveyors as long as do not provide the answers or interject information
- Will not delay process waiting for a staff person to come

How to Find Changes

- Have one person in your facility who goes out to this website once a month and checks for updates to survey memos and if manual updated,
  - 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 so can check for these also

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CMS Survey Memos

Policy & Memos to States and Regions

CMS Quality Safety & Oversight memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices. www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions

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Release of Additional Toolkits to Ensure Safety and Quality in Nursing Homes	20-11-NH	2020-02-14	2020
Information for Healthcare Facilities Concerning 2019 Novel Coronavirus Illness (2019-nCoV)	20-09-ALL	2020-02-06	2020
Notification to Surveyors of the Authorization for Emergency Use of the CDC		2020-02-	

CAH CoP or State Operations Manual

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

(Rev. 200, 02-21-20)

Transmittals for Appendix W

INDEX

Survey Protocol

Manuals at www.cms.gov/files/document/appendices-table-content.pdf

Regulations and Interpretive Guidelines for CAHs

Questions to qsog_cah@cms.hhs.gov cahscg@cms.hhs.gov

CMS Memo on Texting

CMS Memo on Texting

- Cites and mentions the CMS Medical record sections under tags 438, 441, and 467 but no amendments made except to CAHs CoPs and manual will be amended
- Issued survey memos December 22, 2017 and January 5, 2018
- The rule is that texting of orders is **not** allowed regardless of the platform used
- Regarding texting of other patient information; the system must be secure, encrypted, and minimize the risks to privacy and confidentiality as per the CMS CoPs and HIPAA
  - Text consults, emergency notification wtc.
- CPOE is the preferred way to enter an order
  - Questions to Marie.Vasbinder1@cms.hhs.gov

CMS Memo on Texting #2

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/ Quality, Safety and Oversight Group

Ref: QSOG 18-10-*Hospital, CAHs*
REVISED 01.05.2018

DATE: **December 28, 2017**

TO: State Survey Agency Directors

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-18-10-ALL.pdf

FROM: Director
Quality, Safety and Oversight Group *(formerly Survey & Certification Group)*

SUBJECT: Texting of Patient Information among Healthcare Providers *in Hospitals and Critical Access Hospitals (CAHs)*

****Revised to clarify providers affected by this policy are Hospitals and CAHs****

Memorandum Summary

- **Texting patient information** among members of the *Hospital and CAHs* health care team is permissible if accomplished through a secure platform.
- **Texting of patient orders** is prohibited regardless of the platform utilized.
- **Computerized Provider Order Entry (CPOE)** is the preferred method of order entry by a provider.

Critical Access Hospitals:

§485.638(a) Standard: Records System:
(1) The CAH maintains a clinical records system in accordance with written policies and procedures.
(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.
The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable—

> *(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;*
> *(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;*
> *(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and*
> *(iv)Dated signatures of the doctor of medicine or osteopathy or other health care professional.*

(b) Standard: Protection of record information:
(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.
(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.
(3) The patient's written consent is required for release of information not required by law.

CMS Memo on Ligature Risks

Ligature Risk

- CMS issues a 13 page memo on clarification of ligature risk policy- now tag 144 and 701 and added to December 29, 2018 App A manual but **CAH should carefully review** this for legal and RM reasons (proposed guidelines published)
  - Preventing inpatient suicide and creating a safe care setting is important to both TJC and CMS
- Want a safe environment to prevent patients from hanging themselves or strangulation
  - Focuses on the care and safety of behavioral health patient and staff
- No waivers for ligature risk deficiencies and hospitals cited will be required to provide monthly progress reports

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

S&C Memo: 18-06- Hospitals

DATE: December 08, 2017

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarification of Ligature Risk Policy

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

Memorandum Summary

- **Ligature Risks Compromise Psychiatric Patients' Right to Receive Care in a Safe Setting:** The care and safety of psychiatric patients and the staff that provide that care are our primary concerns. The Centers for Medicare & Medicaid Services (CMS) is in the process of drafting comprehensive ligature risk interpretive guidance to provide direction and clarity for Regional offices (RO), State Survey Agencies (SAs), and accrediting organizations (AOs).
- **Definition of a Ligature Risk:** A ligature risk (point) is defined as anything which could be used to attach a cord, rope, or other material for the purpose of hanging or strangulation. Ligature points include shower rails, coat hooks, pipes, and radiators, bedsteads, window and door frames, ceiling fittings, handles, hinges and closures.
- **Focus of Ligature Risks:** The focus for a ligature "resistant" or ligature "free" environment is primarily aimed at Psychiatric units/hospitals.
- **Interim Guidance:** Until CMS' comprehensive ligature risk interpretive guidance is released, the ROs, SAs and AOs may use their judgment as to the identification of

Draft Guidance

- CMS published 15 page document on April 19, 2019
- It is a draft of the clarification of ligature risk interpretive guidelines
- This would update the December 8, 2017 memo
- CMS gave a 60 day comment period
- It is being revised to provide clarity to the surveyors and hospitals
- Also amends how to request an extension for a deficiency for psych hospitals and units

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: DRAFT-QSO-19-12-Hospitals

DATE: **April 19, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-12-Hospitals.pdf

SUBJECT: DRAFT ONLY-Clarification of Ligature Risk Interpretive Guidelines – FOR ACTION

Memorandum Summary

- **This draft policy memorandum would update S&C: 18-06-Hospitals released by the Centers for Medicare & Medicaid Services (CMS) on December 8, 2017.**
- **This Memo is Being Released in Draft:** We seek comment on these draft revised policies by June 17, 2019 (60 days from the date of this release).
- **Ligature Risks Compromise Patients' Right to Receive Care in a Safe Setting:** The care and safety of psychiatric patients at risk of harm to themselves or others, and the staff providing care are our primary concerns. The comprehensive ligature risk interpretive guidance in the CMS State Operations Manual (SOM) Appendix A for Hospitals is being revised to provide direction and clarity for CMS Regional Offices, State Survey Agencies, accrediting organizations and hospitals.
- **Ligature Risk Extension Request Process Update:** The SOM Chapter 2, Section 2728G - Major Deficiencies Requiring Long-Term Correction in Psychiatric Hospitals and Hospital Psychiatric Units, Ligature Risk-Ligature Risk Extension Requests is also being

CMS Memo on Safe Injection Practices

CMS Memo on Safe Injection Practices

- CMS issues a 7 page memo on safe injection practices
- Discusses the safe use of single dose medication to prevent healthcare associated infections (HAI)
- Notes new exception which is important especially in medications shortages
- General rule is that a 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
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Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-35-ALL

DATE: **June 15, 2012**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html?redirect=/SurveyCertificationGenInfo/PMSR/list.asp

Memorandum Summary

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

CMS Memo on Safe Injection Practices

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

CMS Memo on Safe Injection Practices

- Bottom line is you can not use a single dose vial on multiple patients
- CMS requires hospitals to follow nationally recognized standards of care like the CDC guidelines which has 10 practices
- SDV typically lack an antimicrobial preservative
- Once the vial is entered the contents can support the growth of microorganisms
- The vials must have a beyond use date (BUD) and storage conditions on the label

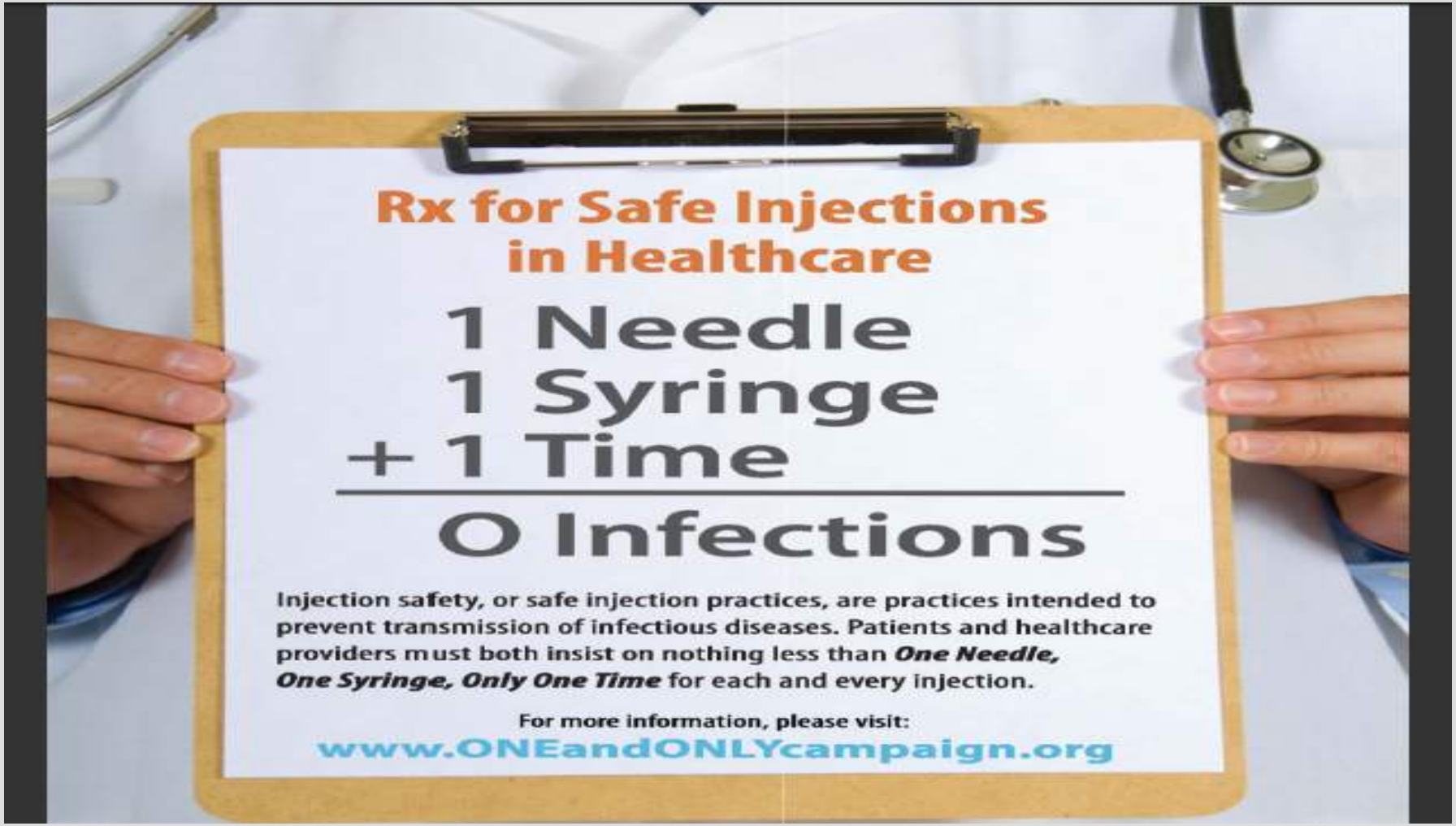
CMS Memo on Safe Injection Practices

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

CMS Memo on Safe Injection Practices

- So if make it in a single dose vial then you need to buy it in a single dose vial
  - If they only make it in a multi-dose vial then try and use it as a single dose vial
  - If not then try and use it only on one patient
- Do not take multi-dose vial into patient room or into OR
  - Unless in OR you treat it as a single dose vial and discard
  - Mark multi-dose vial expires in 28 days unless sooner by manufacturer
- Clean off lid even if new vial for 10-15 seconds and let dry

Safe Injection Practices Posters



Not All Vials Are Created Equal

SINGLE-DOSE OR MULTI-DOSE?

NOT ALL VIALS ARE CREATED EQUAL.

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

This information can literally save a life.

ONEANDONLYCAMPAIGN.ORG

DO YOU PROVIDE TREATMENT FOR PATIENTS WITH CANCER?

PROTECT YOUR PATIENTS, YOURSELF, AND YOUR BUSINESS

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

REMEMBER! WHEN PREPARING MEDICATIONS AND INJECTIONS...

NEVER reuse these items:

Needles or syringes that have been used for any purpose

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

Saline bags

Intravenous tubing

ALWAYS follow aseptic technique* when:

Preparing any medication

Disinfecting a vial's septum

Accessing a central line

Injecting any medications

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

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

LEARN MORE ABOUT WAYS YOU CAN KEEP YOUR PATIENTS

Safe Injection Practices www.empsf.org

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

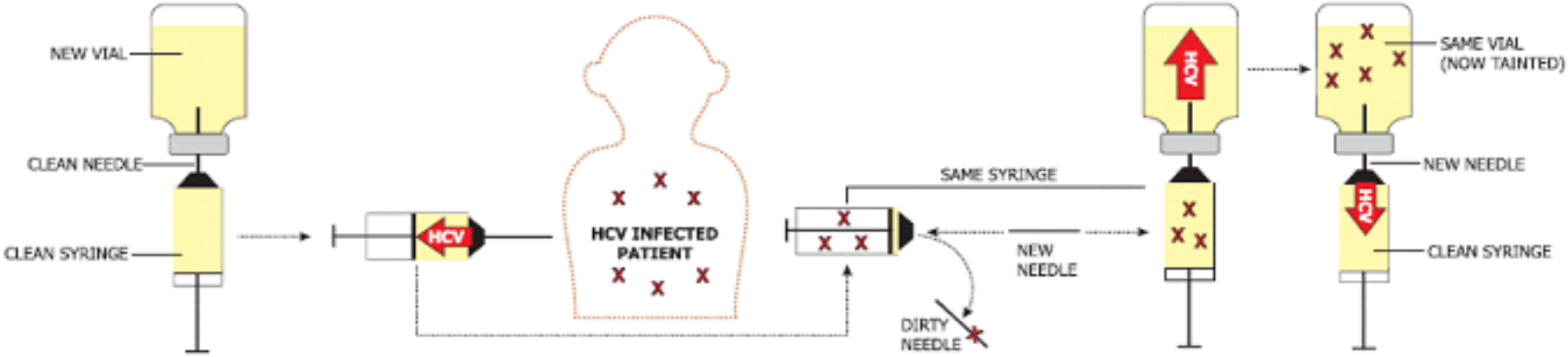
Safe Injection Practices Patient Safety Brief
Emergency Medicine Patient Safety Foundation

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

July 2012

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

CDC One and Only Campaign

ISMP IV Push Medication Guidelines

ISMP IV Push Medications Guidelines

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

IV Push Medicine Guidelines

ISMP Safe Practice Guidelines for Adult IV Push Medications

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

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

Prepared by the Institute for Safe Medication Practices (ISMP)

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

IV Push Medications Guidelines

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

IV Push Medications Guidelines

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

IV Push Medications Guidelines

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

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

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

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

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

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

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

IV Push Medications Guidelines

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

ISMP Subq Insulin

- ISMP publishes 34 pages of recommendations on subq insulin use in adults
  - Available at no charge
- Insulin is a high alert medication
- Insulin is associated with more medication errors than any other drug
  - 16% of all medication errors
  - Leading cause of harmful errors (24%)
  - Results from reliance on only sliding scale to control, failure to increase to control blood sugar, dosing errors and omissions

2017 ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults

www.ismp.org/Tools/guidelines/Insulin-Guideline.pdf

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

CMS Infection Control Worksheet

Section on Safe Injection Practices

CMS Hospital Worksheets History

- October 14, 2011 CMS issues a 137 page memo in the survey and certification section and it was pilot tested three times
- Memo discusses surveyor worksheets for hospitals by CMS during a hospital survey
- Addresses discharge planning, infection control, and QAPI (performance improvement)
  - Issued November 26, 2014
  - Infection control one is especially important to CAH to review even though not using in CAH

Final 3 Worksheets

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

REF: S&C: 15-12-Hospital

DATE: November 26, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Public Release of Three Hospital Surveyor Worksheets

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

Memorandum Summary

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

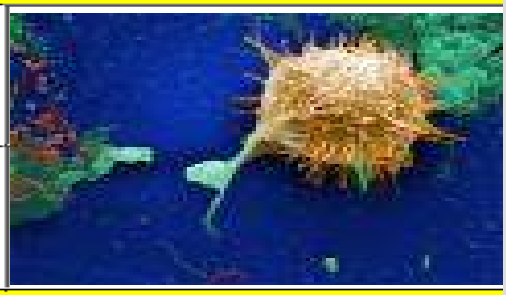
CMS Hospital Worksheets

- Will use whenever a validation survey or certification survey is done at a hospital by CMS for PPS hospitals so **not** currently being used for CAH by the surveyors
- However, highly suggest that every CAH review and be aware of what is in these three forms since IC standards, QAPI, and Discharge Planning are similar
- One of the best documents to help ensure compliance
- Helps to understand how the guidelines are interpreted

Infection Control Program and Resources

Module 1: Infection Prevention Program

Section 1.A. Infection Prevention Program and Resources

Elements to be assessed		Sur
1.A.1 The hospital has designated one or more individual(s) as its Infection Control Officer(s).	◯ Yes ◯ No	
1.A.2 The hospital has evidence that demonstrates the Infection Control Officer(s) is qualified and maintain(s) qualifications through education, training, experience or certification related to infection control consistent with hospital policy.	◯ Yes ◯ No	
1.A.3 The Infection Control Officer(s) can provide evidence that the hospital has developed general infection control policies and procedures that are based on nationally recognized guidelines and applicable state and federal law.	◯ Yes ◯ No	
If no to any of 1.A.1 through 1.A.3, cite at 42 CFR 482.42(a) (Tag A-748)		
1.A.4 The Infection Control Officer can provide an updated list of diseases reportable to the local and/or state public health authorities.	◯ Yes ◯ No	
1.A.5 The Infection Control Officer can provide evidence that hospital complies with the reportable diseases requirements of the local health authority.	◯ Yes ◯ No	
No citation risk for questions 1.A.4 and 1.A.5		
1.A.6 The hospital has infection control policies and procedures relevant to construction, renovation, maintenance, demolition, and repair, including the requirement for an infection control	◯ Yes ◯ No	

CMS Infection Control Pilot

- In the first year of the pilot, in 2016, the draft infection control worksheet was developed for LTC
  - This was developed with the CDC and tested in 10 pilot surveys and used in 40 hospitals
- The hospital infection control worksheet was also revised
- In the second year of the pilot project, assessed the continuum of infection prevention efforts between hospitals and nursing homes
- The new LTC regulations have been finalized and will be phased in over three years

Draft Hospital Infection Control Worksheet

This draft pilot worksheet does not reflect current CMS policy and will not be used during current surveys. The questions on the worksheet reflect NPRM language and will be tested during pilot surveys that will not result in citations. There is no CMS commitment to use this tool, or any version, on future surveys after the regulatory language is finalized and implemented.

***Draft* Centers for Medicare and Medicaid Services**
Pilot Hospital Infection Control Worksheet

The following is a list of items that will be assessed during on-site surveys, in order to determine federal regulatory compliance with the Infection Prevention and Control in hospitals. Criteria are to be evaluated through a combination of observation; interviews with staff, patients and their family/support persons; review of medical records and of any necessary infection control program documentation. During the survey, observations or concerns may prompt the surveyor to request and review specific hospital policies and procedures. Surveyors are expected to use their judgment and review only those documents necessary to investigate their concern(s) or to validate their observations.
For these unique educational pilot testing surveys, the contracted surveyors will be reviewing ***all*** program documentation for which the worksheet prompts. Additionally, the facilities chosen for sampling will be such that support the increased opportunity for surveyors to observe ***all*** care required to adequately answer worksheet questions. It is understood this approach is for testing purposes only and does not prohibit the final product from utilizing a different survey information gathering process such as one that bases further investigation upon "triggered" areas of concern.

As stated in the SC17-09 policy memorandum released on November 18, 2016; while no citations will be issued, if an Immediate Jeopardy deficiency is noted, a referral to the CMS Regional Office will be made.

Note: Significant breaches of infection control practices would require notification of state health department.

Hospital Characteristics

Hospital Name:	
CMS Certification Number	☐☐☐ ☐☐☐

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

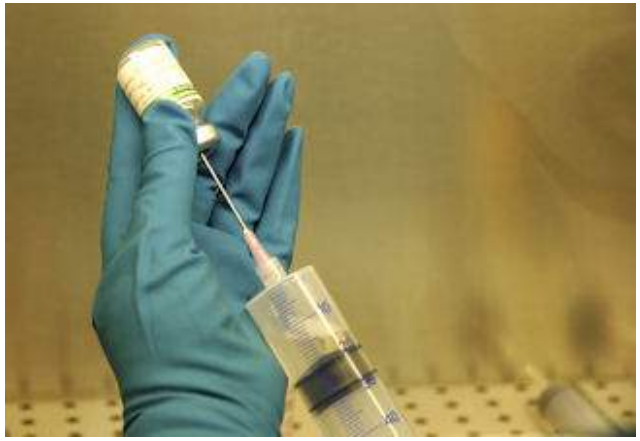
Elements to be assessed		Manner of Assessment Code (check all that apply) & Surveyor Notes			Manner of Assessment Code (check all that apply) & Surveyor Notes	
Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:						
2. B.1 Injections are prepared using aseptic technique in an area that has been cleaned and free of visible blood, body fluids, or contaminated equipment.	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5		☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	
2. B.2 Needles are used for only one patient.	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5		☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	
2. B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes and insulin pens).	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5		☐ Yes ○ No ○ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	

Interview = 1 Observation = 2 Infection Control Document Review = 3 Medical Record Review = 4 Other Document Review = 5

Injection Practices & Sharps Safety 2 B

- Injections prepared using aseptic technique in area cleaned and free of blood and bodily fluids
- Is rubber septum disinfected with alcohol before piercing?
- Are single dose vials, IV bags, IV tubing and connectors used on only one patient?
- Are multidose vials dated when opened and discarded in 28 days unless shorter time by manufacturer?
- Make sure expiration date is clear as per P&P
- If multidose vial found in patient care area must be used on only one patient

CMS Other Survey Memos



Legionnaires' Disease (LD)

- The bacterium Legionella can cause a serious type of pneumonia called LD as well as Pontiac fever
- Grows in parts of hospital water systems that are continuously wet such as water heaters and filters, fountains, shower heads and hoses, water storage tanks, eyewash stations, ice machines, etc.
- Badly maintained water systems are linked to 286% increase in LD between 2000-2014
- 5,000 cases reported to the CDC in 2014
- 15% of outbreaks associated with hospitals
- Hospitals should check their waterborne pathogen compliance as surveyors will likely pay more attention to it
- Conduct a facility risk assessment to determine if it could spread in your facility water system

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 17-30-*Hospitals/CAHs/NHs*
REVISED 06.09.2017

DATE: **June 02, 2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Requirement to Reduce *Legionella* Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires' Disease (LD)
Revised to Clarify Provider Types Affected*

Memorandum Summary

- ***Legionella* Infections**: The bacterium *Legionella* can cause a serious type of pneumonia called LD in persons at risk. Those at risk include persons who are at least 50 years old, smokers, or those with underlying medical conditions such as chronic lung disease or immunosuppression. Outbreaks have been linked to poorly maintained water systems in buildings with large or complex water systems including hospitals and long-term care facilities. Transmission can occur via aerosols from devices such as showerheads, cooling towers, hot tubs, and decorative fountains.

Legionnaires' Disease

Use water management programs in buildings to help prevent outbreaks

www.cdc.gov/vitalsigns/legionnaires/index.html

Language: English

Overview

CDC investigated the first outbreak of Legionnaires' disease, a serious lung infection (pneumonia), in 1976. An increasing number of people in the US are getting this disease, which is caused by breathing in small water droplets contaminated with *Legionella germs*. About 5,000 people are diagnosed with Legionnaires' disease and there are at least 20 outbreaks reported each year. Most identified outbreaks are in buildings with large water systems, such as hotels, long-term care facilities, and hospitals. *Legionella* grows best in building water systems that are not well maintained. Building owners and managers should adopt newly published standards that promote *Legionella* water management programs, which are ways to reduce the risk of this germ in building water systems.

Building owners and managers can:

- Learn about and follow newly published standards for *Legionella* water management programs. http://bit.ly/1Ph3wQP
- Determine if the water systems in their buildings are at increased risk of growing and spreading *Legionella*.
- Develop and use a *Legionella* water management program as needed. www.cdc.gov/legionella/WMPtoolkit
- Monitor and respond to changes in water quality.

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CDC Resources Legionnaires' Disease

JUNE 2016

CDC Vitalsigns™

Legionnaires' Disease

Use water management programs in buildings to help prevent outbreaks

CDC investigated the first outbreak of Legionnaires' disease, a serious lung infection (pneumonia), in 1976. An increasing number of people in the US are getting this disease, which is caused by breathing in small water droplets contaminated with *Legionella* germs. About 5,000 people are diagnosed with Legionnaires' disease and there are at least 20 outbreaks reported each year. Most identified outbreaks are in buildings with large water systems, such as hotels, long-term care facilities, and hospitals. *Legionella* grows best in building water systems that are not well maintained. Building owners and managers should adopt newly published standards that promote *Legionella* water management programs, which are ways to reduce the risk of this germ in building water systems.

Building owners and managers can:

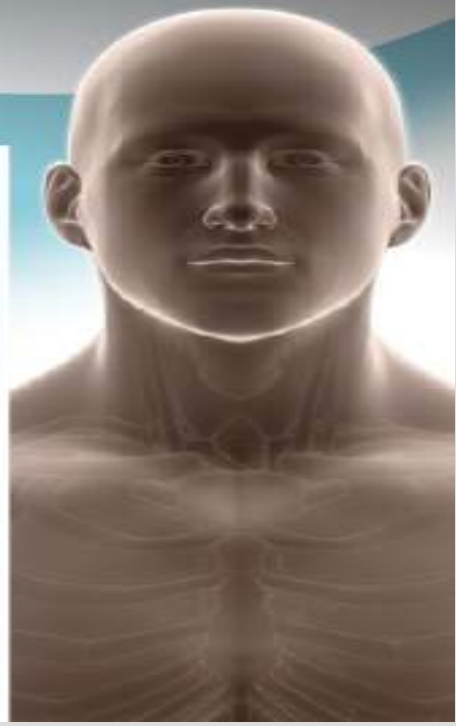
- Learn about and follow newly published standards for *Legionella* water management programs.

4x

The number of people with Legionnaires' disease grew by nearly 4 times from 2000–2014.

1 in 10

Legionnaires' disease is deadly for about 10% of people who get it.



CDC Water Management Program

June 5, 2017 Version 1.1

Developing a Water Management Program to Reduce *Legionella* Growth & Spread in Buildings

A PRACTICAL GUIDE TO IMPLEMENTING INDUSTRY STANDARDS

www.cdc.gov/legionella/downloads/toolkit.pdf

CDC Resource Slides

Centers for Disease Control and Prevention

www.cdc.gov/stltpublichealth/townhall/2017/downloads/06-jun-presentation.pdf

Welcome

Office for State, Tribal, Local and Territorial Support

presents

CDC *Vital Signs* Town Hall

Health Care-Associated Legionnaires' Disease: Protect Patients with Prevention and Early Recognition

June 13, 2017

2:00–3:00 PM (ET)

CMS Memo on 4 IC Breaches

- 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 GL Healthcare, CIHQ, or HFAP
- CMS has a list and any breaches should be referred
- Referral is to the state authority such as the state epidemiologist or State HAI Prevention Coordinator

Infection Control Breaches

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-36-All

DATE: **May 30, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities

Memorandum Summary

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

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

CMS Memo Infection Control Breaches

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

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-15-32 Hospitals/CAHs/ASCs

DATE: **April 3, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

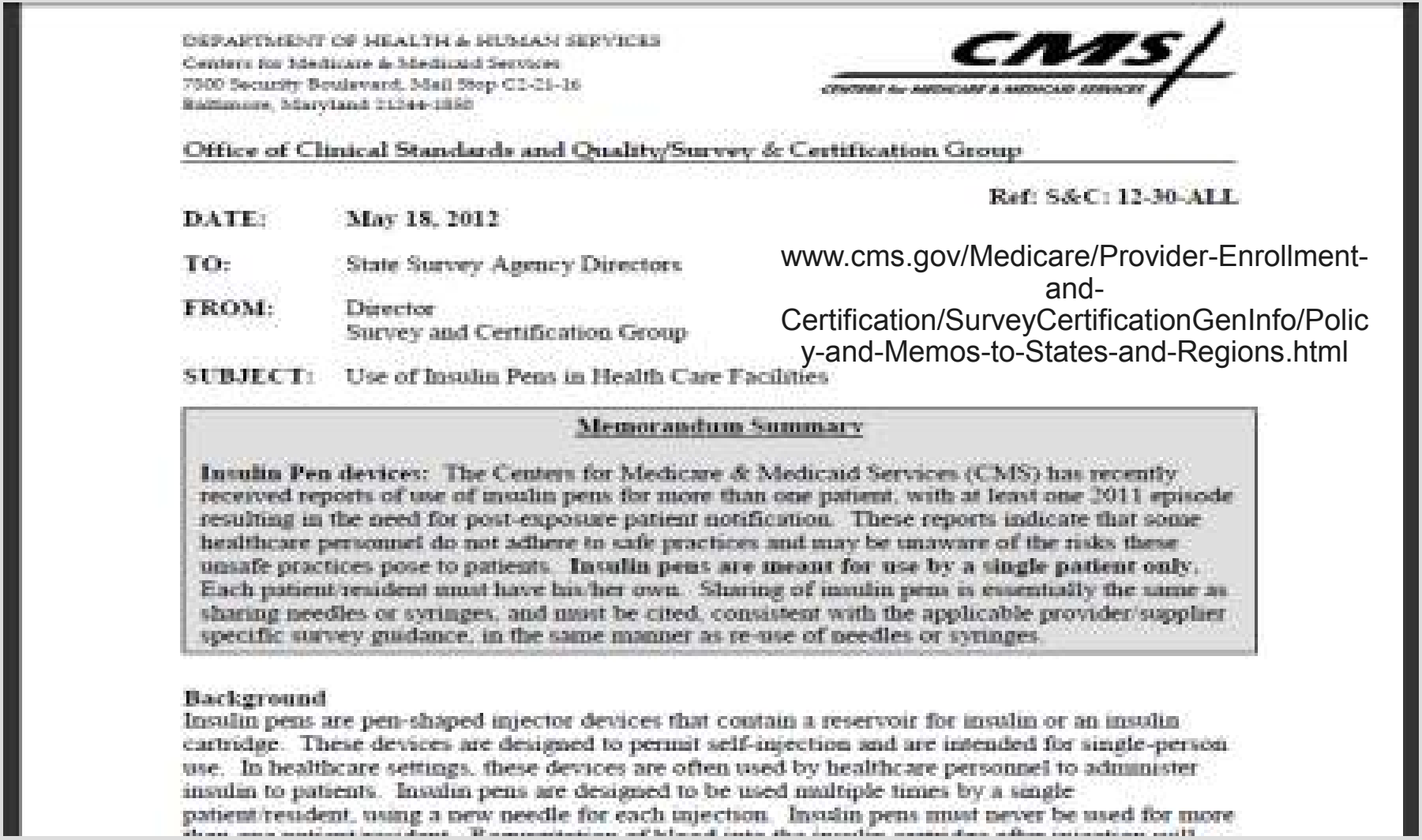
Memorandum Summary

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

CMS Memo on Insulin Pens

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

Insulin Pens



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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-30-ALL

DATE: May 18, 2012

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Use of Insulin Pens in Health Care Facilities

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

Memorandum Summary

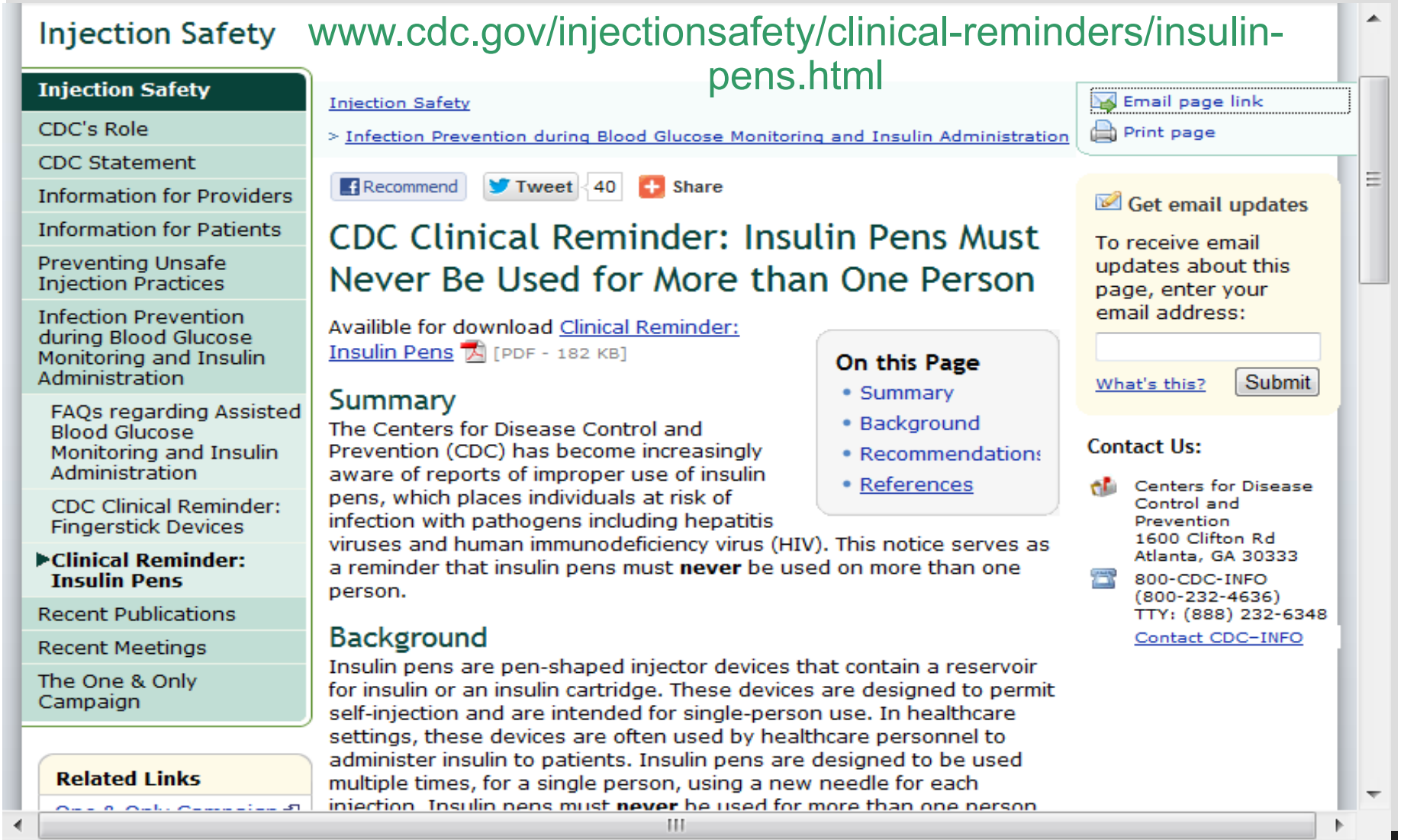
Insulin Pen devices: The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients. **Insulin pens are meant for use by a single patient only.** Each patient/resident must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be cited, consistent with the applicable provider/supplier specific survey guidance, in the same manner as re-use of needles or syringes.

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

CMS Memo on Insulin Pens

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

CDC Reminder on Insulin Pens



CDC Flier 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

Insulin Pen Posters and Brochures Available

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

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

Insulin Pen Safety – One Insulin Pen, One Person

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

The Safe Injection Practices Coalition created an insulin pen poster and brochure for healthcare providers as a reminder that insulin pens and other injectable medications are meant for one person and should never be shared. PDFs of these educational materials are linked below:

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

- Poster
- Brochure

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

Additional Resources

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

BE AWARE
DON'T SHARE

Insulin pens that contain more than one dose of insulin are only meant for one person.

They ***should never be used for more than one person***, even when the needle is changed.

ONE INSULIN PEN, ONLY ONE PERSON

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

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

Pt Safety Briefs Free at www.empsf.org

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

Safe Injection Practices Patient Safety Brief
Emergency Medicine Patient Safety Foundation

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

July 2012

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

CMS Issues 3rd Ebola Memo

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-24-Hospitals

DATE: **February 13, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

***EMTALA & Ebola Requirements*:**

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

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

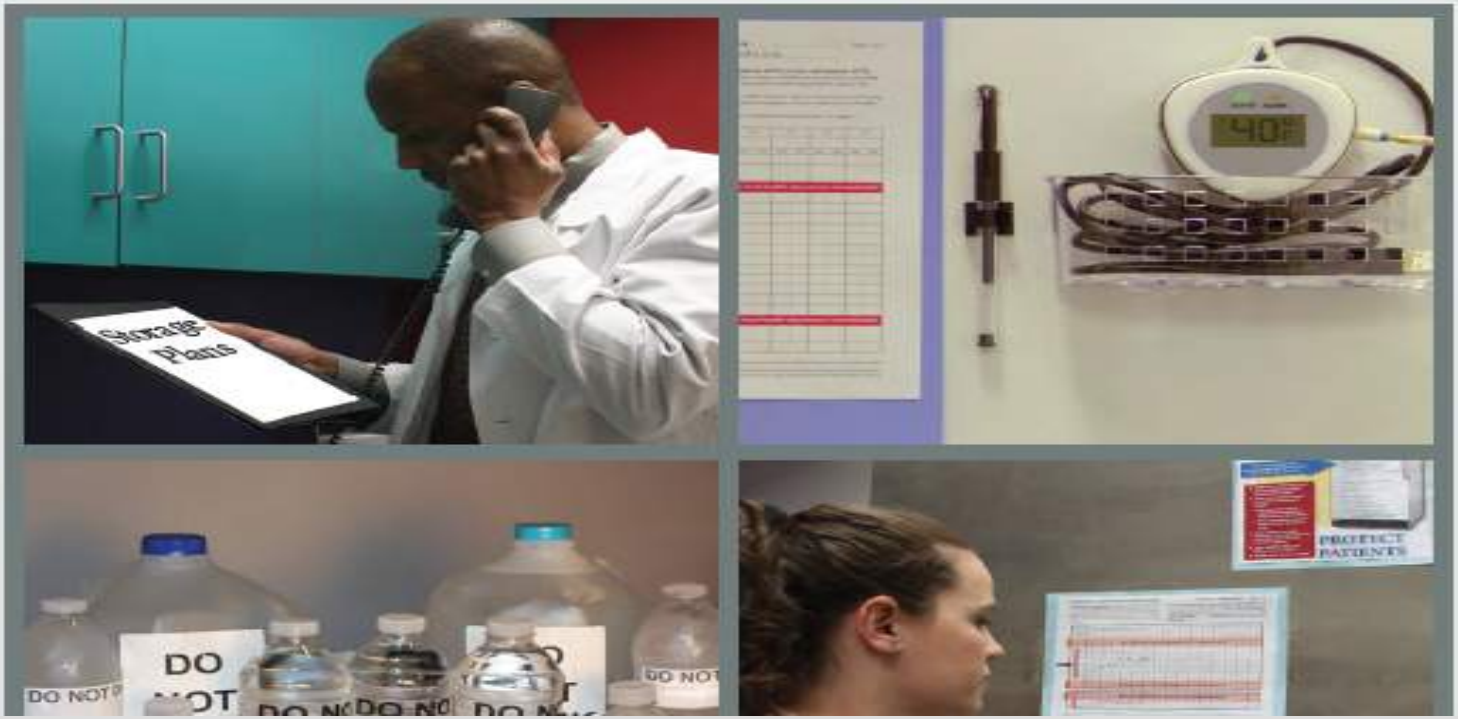
CDC Vaccine Storage and Handling Toolkit

- CDC has 82 page document on vaccine storage
  - Published June 2016 and updated February of 2018 to maintain the cold chain
  - Do not store vaccines in dorm like refrigerators
  - Temperature revised to range between **36 and 46 degrees** (previously 35-46 degrees F)
  - State may also have specific requirements and monitor daily
- Use a medical (biological) refrigerator that monitors temperature and set at mid range (40 degrees)
- E-mail specific questions to CDC: NIPInfo@cdc.gov

Vaccine Storage & Handling Toolkit

June 2016

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



CMS CAH Hospital CoPs

CMS Hospital CoPs

- Appendix W, Starts at tag **C-800**,
  - Rewrote all of the swing bed regulations in October of 2018 with 4 changes November 29, 2019
  - Tag numbers renumbered in 2020 and reflected in Feb 2020 manual update
- Interpretive guidelines updated more frequently now so check monthly for updates
  - Manual includes swing beds regulations in CAHs but interpretive guidelines and survey procedures in Appendix PP (LTC Manual, F standards)

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 help with compliance,
  - Include tag numbers in policies
- Include policies and highlight 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**
- Manuals changing frequently so always check the CMS website
- Psych bed standards were in Appendix AA but moved to Appendix A now
  - Tag number 1600 to 1726

Manual for 10 Bed Behav or Rehab

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

Table of Contents
(Rev. 200, 02-21-20)

www.cms.gov/files/document/appendices-table-content.pdf

Email questions to qsog_hospital@cms.hhs.gov or hospitalscg@cms.hhs.gov

CAH CoP or State Operations Manual

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

(Rev. 200, 02-21-20)

Transmittals for Appendix W

INDEX

Survey Protocol

Manuals at www.cms.gov/files/document/appendices-table-content.pdf

Regulations and Interpretive Guidelines for CAHs

Questions to qsog_cah@cms.hhs.gov cahscg@cms.hhs.gov

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

- 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, Z-emergency preparedness
- W-Hospital swing beds-if you have these,
- B- Home health
- I-Life safety code

Survey Procedure

- 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!

Survey Protocol

- 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 as an inpatient (not observation) prior to admission to swing-bed status for Medicare patients,
  - Give Notice letter to outpatient observation patients (MOON Form)
- 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,
- 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 tag number 800
- 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,

Basic Information & New Tags

- Some basic information was added in 2020
- Tag 800 Basis and Scope which sets out the conditions to meet to be a CAH which are discussed later
- Tag 802 Rural Health Network which includes at least one hospital the state has designated as a CAH and one hospital that provides acute care
  - Entered into an agreement for patient referral and transfer
  - Use of communication systems such as telemetry and sharing of patient data
  - Transport among members

Basic Information & New Tags

- Each CAH has an agreement for C&P and QAPI with one of the following: (Tag 802 continued)
  - One hospital that is a member of the network when applicable;
  - One QIO or equivalent entity; or
  - One other appropriate and qualified entity identified in the State rural health care plan.
- Personnel Qualifications-discusses qualifications of a CNS, NP, PA (804)
  - Remember the state defines the scope of care and CMS will just enforce the state law and scope of practice

Basic Information & New Tags

- Tag 808 discusses designation and certification of CAHs
- States has a Medicare rural hospital flex program and can designate a CAH meeting the CoPs
- Criteria for certification includes that the hospital has been surveyed by the state agency and in compliance with the CAH CoPs
- The old numbers were tags 150 through 450 and 1000 to 1002
- Now starts at tag number 800

Compliance with Laws C-810

- 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 or OCR
  - TB, blood borne pathogen, universal precautions, or EPA (haz mat or waste issues),

Advance Directives 812

- Standard: CAH must be in compliance with federal laws and regulations related to the health and safety of patients
  - PSDA or Patient Self Determination Act is a federal law
- Inpatients and outpatients have the right to make advance directives
- Staff must comply with their advance directives
- Patients have the right to refuse treatment
- May have a DPOA or another person such as a **support person**/patient advocate

Advance Directives 812

- May use advance directives to designate a support person for a person for 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 the shoes of patient when incompetent

Advance Directives 812

- Must provide advance directive information to the competent patient when admitted
  - Must also give to the **outpatien**t 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 the decision if the patient is **i**ncapacitated

Advance Directives 812

- 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 812

- Must disclose if physician owns the hospital
  - This includes ownership by immediate family member and must be in writing
  - If none of the physician owners refer to the hospital then 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

Physician Ownership Disclosures 812

- Disclose in writing if a physician is not on the premises 24 hours a day for emergencies
  - **Sign acknowledgement** if patient admitted
  - Do not need to give individual notices to patients in the emergency department (ED)
  - However, a notice must be posted in the ED in a conspicuous place
  - It must cover how the hospital will meet the needs of the patient in an emergency
  - If separate location and no physician must give notice

Compliance with Laws/Licensure

- **Standard:** Patient care services must be provided with in accordance with laws (814),
- Ensure delegation as allowed by law,
- Ensure practicing according to scope of practice, such as NP, CNS, or PA,
- **Standard:** Hospital must be licensed (816)
- Personnel must be licensed or certified if required by state (Tag 818: 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,

Compliance with Laws/Licensure

- Must make sure staff meet all state laws for certification, qualification, and training and education requirements
  - For example, many states require nurses to have continuing education requirements to renew their licenses
- Many states the hospitals can verify licensure on the board of nursing website
- The surveyor is suppose to check and make sure licensure information is up to date
  - Will look at policies on certification and licensure

Status/Location 822

- If CAH moves then status and location must be reassessed
  - Harder to relocate now (see tag 832)and review this section if CAH wants to relocate
- 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,
  - Discusses exception for CAH designated as necessary provider (830)

Status and Location 822-840

- CAH must meet the location requirements at the time of the initial survey
- Compliance is reconfirmed at the time of every subsequent full survey
- 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

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 16-08-CAH

DATE: **February 12, 2016**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Critical Access Hospital (CAH) Recertification Checklist for Evaluation of Compliance with the Location and Distance Requirements

Memorandum Summary

CAH Recertification Checklist: In order to routinely re-evaluate the compliance of currently certified CAHs with the status and location requirements at 42 CFR 485.610, the Centers for Medicare & Medicaid Services (CMS) has revised the attached *CAH Recertification Checklist: Rural and Distance or Necessary Provider Verification* for use by the CMS Regional Office (RO) staff when processing CAH recertifications. The revised checklist includes:

- Procedures on determining whether a CAH that was certified by CMS prior to January 1, 2006 had been designated by the State as a necessary provider.
- Examples of documentary evidence to demonstrate necessary provider designation

CRITICAL ACCESS HOSPITAL (CAH) RECERTIFICATION CHECKLI

Rural and Distance or Necessary Provider Verification

Date: _____ **CCN:** _____

CAH Name: _____

Address: _____

City/State/Zip/County: _____

Administrator: _____

Last Survey Date: _____

If deemed: Accrediting Organization (AO): _____

Accreditation expiration date: _____

Rural Status:

Does the Office of Management and Budget (OMB) Metropolitan Statistical Area (MSA) Li
adopted by the CMS indicate that the county is designated as rural? Yes_____ No_____

If no, does the Division of Financial Management (DFM) confirm alternative rural status?
Yes_____ No_____ Date confirmed by the DFM: _____

Distance from other CAHs or Hospitals:

Necessary Provider Designation: Yes_____ No_____ [*Source*: _____

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 (Tag 860 and 862)
- 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?

Credentialing and QA Agreement 862

- **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,

Working with the Other Hospital

- What P&P related to communication system?
- May review any written agreements with local EMS
- Regarding patient referral and transfer (864)
- Do the two hospitals have electronic sharing of patient data, telemetry and medical records? (862 and 866)
- Need to provide for transport between the two facilities (868) whether emergency or non-emergency transfers

Hospital Improvement Rule 870

- Must have an agreement related to credentialing (C&P) and quality (QAPI) with a hospital that is a member of the rural health network
  - Must have a qualified person identified in the state rural health plan that can evaluate the quality and to make sure diagnosis and treatment is appropriate by doctors at the CAH
    - Or a QIO or other qualified entity
  - Must have a medical record review as part of this
- A physician will make sure this is done for PA and NP and consider the findings and make necessary changes

Telemedicine Agreements C&P 872

- **Standard:** Agreements for C&P Telemedicine Physicians
  - Total of 4 tag numbers on telemedicine and surveyor may look at telemedicine contracts
  - Board must make sure there is a written agreement with distant-site hospital (DSH) or distant-site telemedicine entity (DSTE)
  - Board must 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

Agreements for C&P 872

- Make sure the 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 are privileges based solely on certification, fellowship, or membership in a special body or society
- Contract must specify certain things such as contracted services allows CAH to comply with all the hospital CoPs (874)

Telemedicine Contracts

- CAH must state they choose to rely on the C&P decisions by the board of the hospital contracted with (DSH or DSTE) Tag 874
- The contract must say that the distant site MS C&P process and standards meet the requirements in the CMS CoPs
  - The contract must say the physician if privileged at the other hospital
  - CAH must have a current list of those providing services
  - Physician must be licensed in state patient is located
  - Must communicate any adverse events to the other entity

Emergency Services 880

- **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 QAPI activities,
- MS must establish qualifications to get privileges to provide ED care,
- ED must be adequately staffed,
- Must have adequate equipment,

Emergency Services 880

- Must ensure reassessment of emergency needs to anticipate policies, staffing, training etc.
- 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
  - Intubation, breathing treatments, ABGs, etc.
  - Also other tests such as 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 (such as PAs, NPs, CNS),
- 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 880

- 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 ventilator and oxygenation support;
- Aerosol, humidification, and therapeutic gas administration;
- Administration of medications; and
- Procedures for obtaining and analyzing ABGs.

ED Staff Training 880

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 882

- 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 still remain open),
- Must still meet EMTALA (anti-dumping) requirements,
  - Revised July 19, 2019 and 68 pages,
- If no ED patients then can have NP, PA, CNS, or MD on site within 30 minutes,
  - As allowed by state law which sets forth the scope of practice

EMTALA, CAH & Telemedicine Memo

- 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

CMS S&C Memo EMTALA & CAH

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

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-38-CAH/EMTALA

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

Availability of Drugs 884

- 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 886

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 888

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.

Emergency Equipment 888

- 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 890

- 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 type and cross match blood must have necessary equipment
- Or can keep 4 units O Negative on hand at all times,
- Release to give, signed by doctor, is needed if not cross matched when indicated in an emergency

Blood Storage 892

- 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 894

- Must have practitioner (physician, PA, CNS, 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 894

- Will review documentation that PA, NP, CNS, 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

RN Tag 894

- CMS also added December 16, 2016 that RN with training and experience in emergency care can be used to conduct specific medical screening exam
- Must be on site and immediately available when a patient requests care and
- The nature of the request must be within the scope of practice for a RN and consistent with state law, medical staff bylaws and R/R
  - Note most state boards of nursing do not allow a RN who is not an advance practice nurse to independently do ordering and interpretation of things like x-rays, lab, and EKGs

Coordination with EMS 898

- 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,

25 Available Beds 900 & 902

- 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 902

- 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 memos on the two midnight rule,
  - Place in an outpatient observation bed,
  - Admit as an inpatient to telemetry

Observations 902

- Have specific criteria for placing patient in and discharging from observation
- Inappropriate use of observation beds could subject 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 902

- 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

Beds/ LOS Hospice 902

- Observation starts and ends with order
  - No standing orders for observation
  - Note in Claims Process Manual it says ends when all medically necessary services are completed…
- 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 902

- 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,

The End Questions???

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