

# CMS Critical Access CoPs

## Part 1 of 4



**Introduction, General Information, Memos, Recent Laws, Safe Injections, Advance Directives, Emergency Services, and Observation Status**

# Speaker



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# Introduction



# Why We are Here Today

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: _____	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY _____
NAME OF FACILITY		STREET ADDRESS, CITY, STATE, ZIP CODE		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
CMS Denver-Survey & Operations Group  
1961 Stout Street, Room 08-148  
Denver, CO 80294



## PUBLIC NOTICE FOR INVOLUNTARY TERMINATION OF MEDICARE/MEDICAID PROVIDER AGREEMENT

Notice is hereby given that the agreement between Clear View Behavioral Health, 4770 Larimer Parkway, Johnstown, Colorado 80534, and the Secretary of Health and Human Services, as a provider of services in the Health Insurance for the Aged and Disable Program (Medicare) is to be terminated at the close of October 28, 2020.

The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted after the close of October 28, 2020. For patients admitted on October 28, 2020, or earlier, payment may continue for up to 30 calendar days of inpatient hospital services furnished after October 28, 2020.

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES		DATE PROVIDED/SUPPLEMENTAL IDENTIFICATION NUMBER	
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		FACILITY ADDRESS, CITY, STATE	
NAME OF FACILITY		STREET ADDRESS, CITY, STATE	
ID PREFIX TAG	SUMMARY OF DEFICIENCIES EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC WRITE-UP INFORMATION	ID PREFIX TAG	ID NO.

This deficiency worksheet is used to report deficiencies identified during a survey. It is to be completed by the surveyor and the provider. The surveyor should complete the worksheet and submit it to the provider. The provider should complete the plan of correction section. The worksheet should be submitted to the provider's compliance officer.

COMPLIANCE OFFICER'S SIGNATURE AND DATE

DATE: 02/01/2007

- 5



# Deficiency/Citation Reports



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## 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/CertificationandCompliance/Hospitals.html](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Hospitals.html)

# Deficiency Citation 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

# Deficiencies by Tag Number

	A	B	C	D	E	F	G	H	I	J	
240	DOCTORS' HOSPITAL OF MICHIGAN	230461	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	490500	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	050940	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	521111	WI	53534	Critical Access H-C	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	361500	OH	45640	Critical Access H-C	C	0205	BLOOD AND BLOOD PRODUCTS		1/20/2011	**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDEN
245	BRANDON REGIONAL HOSPITAL	100119	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	190524	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	340500	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	220450	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	100130	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	330455	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 t
251	MANATEE MEMORIAL HOSPITAL	100206	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	260301	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	100280	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	490185	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	210900	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	150220	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	340300	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	050300	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	340190	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	390575	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	340170	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	450320	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	2105	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	070300	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	450900	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	3100	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	390182	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 CENTER	490230	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



# CAH Problematic Standards

- Orders/entries dated and timed
- Verbal orders
- Cluttered hallways & other Life Safety Code issues
- H&Ps
- EMTALA
- Medications
- Meeting nutrition needs of patients
- Healthcare services per P&P
- Timing of medications
- Documentation reflecting nursing process

# CAH Problematic Standards

- Equipment and supplies used in life saving procedure
- Hand Hygiene & Gloving
- Restraint & Seclusion for Acute hospitals
- Suicide precautions
- Infection control
- Informed consent
- Privacy & whiteboard
- Legibility
- No orders
- Safe Injection practices

# Immediate Jeopardy

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



## Center for Clinical Standards and Quality/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 immediate jeopardy. Survey teams must use the immediate jeopardy template attached to

# Search for Hospital Inspections



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## HospitalInspections.org

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## Search hospital inspections


Welcome to hospitalinspections.org, a website run by the Association of Health Care Journalists (AHCJ) that aims to make federal hospital inspection reports easier to access, search and analyze. This site includes details about deficiencies cited during complaint inspections at acute-care, critical access or psychiatric hospitals throughout the United States since Jan. 1, 2011. It does not include results of routine inspections or those of long-term care hospitals. It also does not include hospital responses to deficiencies cited during inspections. Those can be obtained by filing a request with a hospital or the U.S. Centers for Medicare and Medicaid Services (CMS).

This effort follows years of advocacy by AHCJ to encourage federal officials to publish this information electronically. Until now, this information has only been available through Freedom of Information Act requests – and only in paper form. Funding for this project was provided by the Ethics & Excellence in Journalism Foundation.

Because CMS has just begun gathering this data and releasing it in electronic format, it remains incomplete. Some reports are missing narrative details, and those are noted on each hospital's page. Beyond that, CMS acknowledges that other reports that should appear may not. CMS has pledged to work with AHCJ to make future iterations of this data more complete. At this time, this data should not be used to rank hospitals within a state or between states. It can be used to review issues identified at hospitals during recent inspections.

Clicking on a state on the map will retrieve a list of all hospitals with their violations grouped together; choosing a state from the drop down menu will list all inspection reports separately, so a hospital may appear more than once.

**Last updated:** May 2018

 [Search your state](#)

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- [Resources page](#)
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All states



# Search for Hospital Survey Reports

## LUTHERAN MEDICAL CENTER

8300 W 38TH AVE WHEAT RIDGE, CO 80033 | Voluntary non-profit - Private

[View hospital's federal Hospital Compare record](#)

### Read complete reports

Report date	Number of violations	
Nov. 7, 2019	2 ( <a href="#">click for details</a> )	<a href="#">Read full report</a>
July 29, 2019	2 ( <a href="#">click for details</a> )	<a href="#">Read full report</a>
May 8, 2019	4 ( <a href="#">click for details</a> )	<a href="#">Read full report</a>
Oct. 19, 2016	1 ( <a href="#">click for details</a> )	<a href="#">Read full report</a>
June 29, 2016	2 ( <a href="#">click for details</a> )	<a href="#">Read full report</a>
March 24, 2016	2 ( <a href="#">click for details</a> )	<a href="#">Read full report</a>
Nov. 4, 2015	1 ( <a href="#">click for details</a> )	<a href="#">Read full report</a>
Aug. 7, 2015	2 ( <a href="#">click for details</a> )	<a href="#">Read full report</a>
Nov. 15, 2012	3 ( <a href="#">click for details</a> )	<a href="#">Read full report</a>



# Read the Report

LUTHERAN MEDICAL CENTER	8300 W 38TH AVE WHEAT RIDGE, CO 80033	Nov. 7, 2019
VIOLATION: <i>PATIENT RIGHTS</i>		Tag No: A0115
<p>Based on the manner and degree of the standard level deficiency referenced to the Condition, it was determined the Condition of Participation 482.13, PATIENT RIGHTS, was out of compliance.</p> <p>A-0144 The patient has the right to receive care in a safe setting. Based on interviews and document review, the facility failed to ensure all staff who were assigned to work on the orthopedic surgical floor were trained in order to care for patients with specific post-operative precautions for safety with transfers and bed mobility. This failure was identified in 1 of 3 medical records of patients who underwent total hip replacement surgeries (Patient # 2).</p>		
VIOLATION: <i>PATIENT RIGHTS: CARE IN SAFE SETTING</i>		Tag No: A0144
<p>Based on interviews and document review, the facility failed to ensure all staff who were assigned to work on the orthopedic surgical floor were trained in order to care for patients with specific post-operative precautions for safety with transfers and bed mobility. This failure was identified in 1 of 3 medical records of patients who underwent total hip replacement surgeries (Patient # 2).</p> <p>Findings include:</p> <p>Facility policy:</p> <p>The Nursing Service Staffing policy purpose was to give direction to nursing units regarding the use of staffing resources. The policy read it was the Staffing Coordinator, Shift Specialty Coordinator, and House Supervisors responsibility to serve as a liaison in floating staff to other units. Additionally, all associates were required to float to other units based on documented clinical competence, skill and patient care needs. The policy read staffing assignments were to be adjusted based on the judgement of the registered nurse (RN) in charge to provide special patient care needs depending on the patient's condition and to ensure the patient care needs were met.</p> <p>1. The facility failed to ensure nursing staff had been educated on posterior hip precautions when caring for Patient #2. Subsequently, during Patient #2's transfer from the bed the patient suffered further injury after being moved by untrained staff.</p> <p>a. A medical record review was conducted for Patient #2 who was admitted to the orthopedic surgical floor following a total hip arthroplasty (hip joint replacement) (THA) on</p>		



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# AHA Website

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[www.aha.org/advocacy/small-or-rural](http://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

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## What Works in Rural

## 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.

## 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.

## 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

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Choices

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# CMS Surveyor Training Website



# Surveyor Training Click on Catalog




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Welcome to the Quality, Safety & Education Portal (QSEP)

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Please select here to browse the Training Catalog and take any training.



<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

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Search Trainings

Name	Duration	Action
A		
Alzheimer's and Related Dementia -- Part I (The Medical Perspective)	1 hr., 50 mins.	 Launch 
Alzheimer's and Related Dementia -- Part II (The Surveyor's Perspective)	2 hrs., 30 mins.	 Launch 
Ambulatory Surgical Center Basic Training	35 hrs.	 Launch
Antibiotic Stewardship Program for Nursing Home Providers	4 hrs.	 Launch
ASPEN Overview	Variable	 Launch 
B		
Basic Life Safety Code Training	32 hrs.	 Launch
Basic Life Safety Code: The Survey Process Training	6 hrs.	 Launch
Basic Medications in Nursing Homes	2 hrs., 30 mins.	 Launch 
Basic Writing Skills for Survey Staff	2 hrs.	 Launch

# 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

[https://surveyortraining.cms.hhs.gov/pubs/ClassInformation.aspx?cid=0CMSCAHBasic\\_CEU\\_ONL](https://surveyortraining.cms.hhs.gov/pubs/ClassInformation.aspx?cid=0CMSCAHBasic_CEU_ONL)

**Location:** ISTW

**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](mailto: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 Conditions of Participation





# The Conditions of Participation (CoPs)

- Start in the Federal Register
- CMS publishes Interpretive Guidelines
- Some include survey procedures
- Different from “worksheets”

# Subscribe to the Federal Register



## FEDERAL REGISTER

The Daily Journal of the United States Government

<https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>

### Email Updates

To sign up for updates or to access your subscriber preferences, please enter your contact information below.

**Email Address**



**SUBMIT**

**CANCEL**

Your contact information is used to deliver requested updates or to access your subscriber preferences.

# CMS Hospital CoP Manual

- <https://www.cms.gov/files/document/som107appendicestoc.pdf>.

## Medicare State Operations Manual

### Appendix

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. **Click on the 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

Appendix Letter	Description
<a href="#"><u>A</u></a>	Hospitals
<a href="#"><u>AA</u></a>	Psychiatric Hospitals- <i>Deleted (See Appendix A)</i>
<a href="#"><u>B</u></a>	Home Health Agencies

# CMS CoP Manual

Appendix Letter	Description
	Guidance
<a href="#"><u>P</u></a>	Survey Protocol for Long-Term Care Facilities
<a href="#"><u>PP</u></a>	Interpretive Guidelines for Long-Term Care Facilities
<a href="#"><u>Q</u></a>	Determining Immediate Jeopardy
<a href="#"><u>R</u></a>	Resident Assessment Instrument for Long-Term Care Facilities
<a href="#"><u>S</u></a>	Mammography Suppliers - <b>Deleted</b>
<a href="#"><u>T</u></a>	Swing-Beds – <b>Deleted (See Appendix A and Appendix W)</b>
<a href="#"><u>U</u></a>	Responsibilities of Medicare Participating Religious Nonmedical Healthcare Institutions
<a href="#"><u>V</u></a>	Responsibilities of Medicare Participating Hospitals In Emergency Cases
<a href="#"><u>W</u></a>	Critical Access Hospitals (CAHs)
<a href="#"><u>Y</u></a>	Organ Procurement Organization (OPO)
<a href="#"><u>Z</u></a>	Emergency Preparedness for All Provider and Certified Supplier Types

# State Operation Manual – Critical Access

## **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**

Introduction

Regulatory and Policy Reference

Tasks in the Survey Protocol

Survey Team

Task 1 - Off-Site Survey Preparation



# 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](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions)

Show entries:

5 per page

Filter On

Apply

Showing 1-10 of 521 entries

Title	Memo #	Posting Date ▲	Fiscal Year
<a href="#">Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in nursing homes</a>	QSO-20-14-NH	2020-03-04	2020
<a href="#">Suspension of Survey Activities</a>	QSO-20-12-All	2020-03-04	2020
<a href="#">Guidance for Infection Control and Prevention Concerning Coronavirus Disease (COVID-19): FAQs and Considerations for Patient Triage, Placement and Hospital Discharge</a>	QSO-20-13-Hospitals	2020-03-04	2020
<a href="#">Release of Additional Toolkits to Ensure Safety and Quality in Nursing Homes</a>	20-11-NH	2020-02-14	2020
<a href="#">Information for Healthcare Facilities Concerning 2019 Novel Coronavirus Illness (2019-nCoV)</a>	20-09-ALL	2020-02-06	2020
<a href="#">Notification to Surveyors of the Authorization for Emergency Use of the CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel</a>	20-10-ALL	2020-02-	2020

# New Tag Numbers

	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
	<a href="http://www.cms.gov/files/document/c-tag-crosswalk.xlsx">www.cms.gov/files/document/c-tag-crosswalk.xlsx</a>					
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

# CMS Hospital Improvement Rule, Discharge Planning and Recent Changes



# Introduction

- Final regulations published September 2019, effective November 2019
- Addressed Emergency preparedness
- Made changes to swing bed requirements
- Updated discharge planning standards
- Rewrote QAPI requirements
- Changes to infection control
- Implementation of Antibiotic Stewardship Program

# Improvement Rule – cont'd

- Established staffing and staff responsibility
- Quality and appropriateness
  - Diagnosis by PA, NP, or CNS by MD/DO under contract with the CAH
  - Diagnosis and treatment by MD/DO is evaluated
    - QIO,
    - Hospital that is a member of the network or
    - Qualified individual identified in the state rural health plan
  - Includes a section to evaluate telemedicine providers

# Improvement Rule – cont'd

- Provision of services
  - P&P - nutritional needs being met
  - Diet order by physician or provider
  - Can C&P dietitian
  - Policies reviewed every two years vs. annually



# Manual Changes

- Changes/manual for 10 Bed Behavioral Health or Rehab, hospitals **and CAHs**
  - Interpretive guidelines and survey procedures pending
  - Tag numbers 1400, 1404, 1406, 1408, 1410, 1412, 1417, 1420, 1422, 1425, and 1430
  - Similar to Appendix A with a few minor exceptions

# February 2020 Updates

## ■ CAHs

- Deleted multiple tags number
- Renumbered all the tag numbers in 2020
- Revises table of content to include special requirement for CAH of LTC services
- Revised the survey protocol
  - Grant immediate access or can terminate Medicare
  - Cannot refuse to permit copying of records or information by the surveyor

# 2020 Updates continued

- Other changes:
  - No advanced notice of survey
  - Will assess compliance with all areas under CCN
  - Surveyor must complete basic surveyor course
- Revised swing bed section:
  - Eligibility, SNF service, admission, transfer and discharge
  - Freedom from abuse, neglect and exploitation
  - Services directed by qualified professional
  - Care plan and discharge planning

# 2020 Updates – continued

- New standard 410 on nutrition
- Will look at telemedicine contract
- Will not withhold areas of concern until the end
- Surveyor cannot touch or examine patients
- Surveyor may make copies of some of the EHRs

# 2020 Updates – continued

- Surveyor questions to the staff:
  - 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?
- Will determine if corrective actions “fix” the deficient practice
- If record session – surveyor must be given a copy

# 2020 Updates – continued

- Will not delay survey for staff to arrive
- Make sure surveyors have access to copiers and printers
- Surveyors 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
  - Cannot provide answers or interject information



# CMS Memo on Texting



# CMS Memo on Texting

- In medical record sections
  - Tags 438, 441, and 467
- RULE: texting of orders **not** allowed
- Patient information:
  - System must be secure, encrypted, and minimize privacy/confidentiality risks
  - Text consults, emergency notification etc.
- CPOE is the preferred way to enter an order
  - Questions to Marie.Vasbinder1@cms.hhs.gov

## ***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



# Memo

- CMS clarified ligature risk policy
  - In App A manual
  - CAH should carefully review
- 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
- If cited must provide monthly progress reports

# Draft Guidance

- CMS published draft of the clarification of ligature risk interpretive guidelines
- Revised to provide clarity to the surveyors and hospitals
- Amends how to request an extension for a deficiency for psych hospitals and units



# CMS Memo on Safe Injection Practices



# Question

- Our facility has experienced a shortage of medications over the past year
  - Yes
  - No
  - Prefer not to answer
  - Not sure

# Memo on Safe Injection Practices

- Discussed use of single dose medication
  - Prevent healthcare associated infections (HAI)
- Notes new exception - important especially in medications shortages
- General rule: single dose vial (SDV) can only be used on one patient
- Will allow on multiple patients if - prepared by pharmacist under laminar hood following USP 797 guidelines

# Safe Injection Practices – cont'd

- Entries for repackaging must be completed within 6 hours
  - One exception when SDV can be used on multiple patients
- Can be cited under infection control standards since must provide sanitary environment

# Safe Injection Practices – cont'd

- Bottom line: cannot use a single dose vial on multiple patients
- Must follow nationally recognized standards of care
  - CDC guidelines has 10 practices
- SDV typically lack an antimicrobial preservative
- The vials must have a beyond use date (BUD) and storage conditions on the label
- If use off-site vendor or compounding facility
  - Ask for evidence have adhered to 797 standards

# Single vs. Multi Dose Vials

- If make it in a single dose vial - need to buy it in a single dose vial
- If only multi-dose – use as single dose vial
- Do not take multi-dose vial into patient room or into OR
  - In OR treat 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



# 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.*



**1 ONE NEEDLE,  
ONE SYRINGE,  
ONLY ONE TIME.**

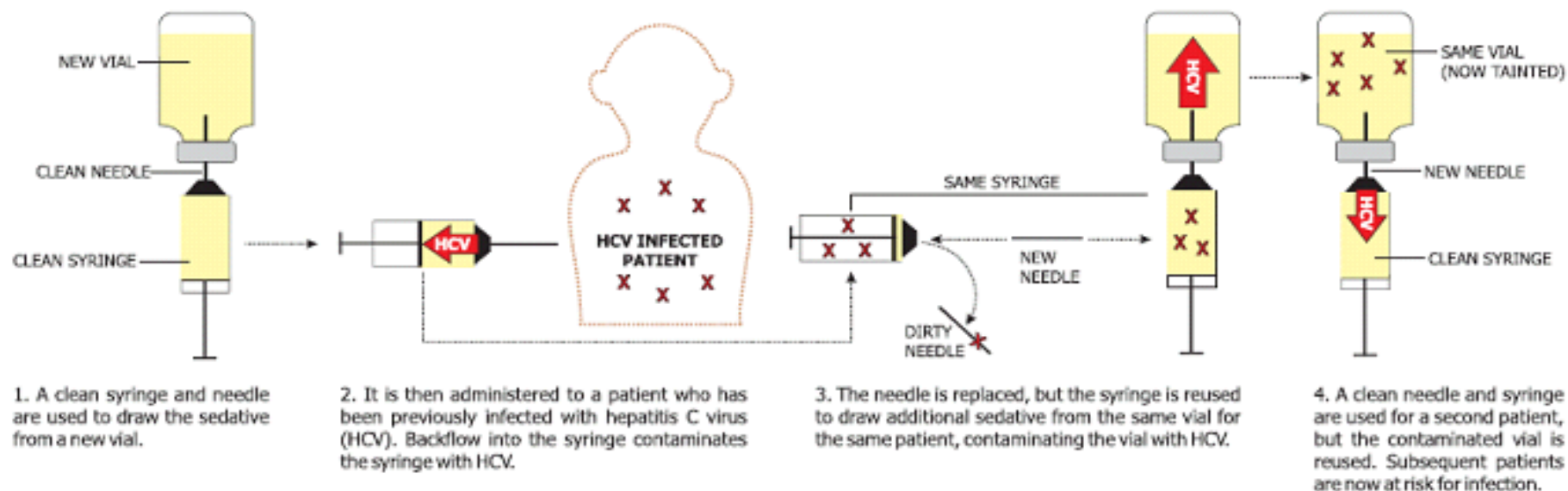


Safe Injection Practices Coalition  
[www.ONEandONLYcampaign.org](http://www.ONEandONLYcampaign.org)

ONEANDONLYCAMPAIGN.ORG

## 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.



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

# ISMP IV Push Medication Guidelines



# 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)



# 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 vascular access devices
- If available in a single dose vial – buy in single dose vial
- Use aseptic technique when preparing and administering IV medication
  - Includes hand hygiene before and after administration

## IV Push Guidelines – cont'd

- Disinfect the diaphragm
- If use glass ampule – use filter needle unless the specific drug precludes such
- Medication should only be diluted when:
  - Recommended by the manufacturer or
  - Per evidence-based practice
  - Approved hospital policies

# IV Push Guidelines – cont'd

- If IV require dilution
  - Performed in a clean, uncluttered, and separate location
- Should not be withdrawn from a commercially cartridge type syringe into another syringe for administration
- Medication not drawn up into prefilled 0.9% saline flushes

# IV Push Guidelines – cont'd

- Combination of more than one medication is seldom necessary
- Never use IV solution/mini bags as a common IV flush source or dilutant
- Label syringes
  - Unless prepared and immediately given with no break
- Administer IV push medication at manufacturer recommended rate
  - Or supported by evidenced-based practices



# ISMP Subq Insulin

- Insulin is a high alert medication
- Associated with more medication errors than any other drug
  - 16% of all medication errors
  - Leading cause of harmful errors (24%)



2017

## **ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults**

[www.ismp.org/Tools/guidelines/Insulin-Guideline.pdf](http://www.ismp.org/Tools/guidelines/Insulin-Guideline.pdf)

# CMS Worksheets

## Safe Injection Practices




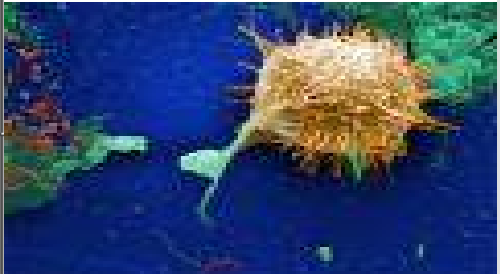
# Hospital Worksheets

- CMS had 3 worksheets for surveys – part of pilot programs
  - Discharge planning
  - Infection control
  - QAPI (performance improvement)

# Infection Control Worksheet

## 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).	<input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> Yes <input type="radio"/> 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.	<input type="radio"/> Yes <input type="radio"/> No	
1.A.5 The Infection Control Officer can provide evidence that hospital complies with the reportable diseases requirements of the local health authority.	<input type="radio"/> Yes <input type="radio"/> 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	<input type="radio"/> Yes <input type="radio"/> No	

# Discharge Planning Worksheet

## Section 2 Discharge Planning – Policies and Procedures

Elements to be assessed		Surveyor Notes
<b>2.1 Implementation of discharge planning policies and procedures for inpatients:</b>		
2.1a For every inpatient unit surveyed is there evidence of applicable discharge planning activities?	<input type="radio"/> Yes <input type="radio"/> No	
2.1b Are staff members responsible for discharge planning activities correctly following the hospital's discharge planning policies and procedures?	<input type="radio"/> Yes <input type="radio"/> No	
If no for either 2.1a or 2.1b, cite the applicable standard for identification of patients needing discharge planning, 42 CFR 482.43(a) (Tag A-0800); discharge planning evaluation, 42 CFR 482.43(b) (Tag A-0806); and/or developing and implementing the discharge plan, 42 CFR 482.43(c) (Tag A-0818)		
2.2 Does the discharge planning process apply to certain categories of outpatients?	<input type="radio"/> Yes <input type="radio"/> No	
If yes, check all that apply: <input type="radio"/> Same day surgery patients <input type="radio"/> Observation patients who are not subsequently admitted <input type="radio"/> ED patients who are not subsequently admitted <input type="radio"/> Other		
2.3 Is a discharge plan prepared for each inpatient?	<input type="radio"/> Yes, skip to question 2.8 <input type="radio"/> No, go to question 2.4	
<b>NOTE: No citation risk related to responses to questions 2.2 and 2.3; for information only.</b>		

# QAPI Worksheet

## PART 2: DATA COLLECTION AND ANALYSIS - QUALITY INDICATOR TRACERS

### Instructions for Part #2 Questions:

Select 3 distinct quality indicators (not patient safety analyses) and trace them answering the following multipart question. Focus on indicators with related QAPI activities or projects. At least one of the indicators must have been in place long enough for most questions to be applicable.

Elements to be Assessed	Indicator #1	Indicator #2	Indicator #3
Write in indicator selected:			
2.1.a Can the hospital provide evidence that each quality indicator selected is related to improved health outcomes? (e.g., based on QIO, guidelines from a nationally recognized organization, hospital specific evidence, peer-reviewed research, etc.)	<input type="radio"/> YES <input type="radio"/> NO	<input type="radio"/> YES <input type="radio"/> NO	<input type="radio"/> YES <input type="radio"/> NO
2.1.b Is the scope of data collection appropriate to the indicator, e.g., an indicator related to labor and delivery might be appropriate to all areas of that unit and the ED, but indicators related to hand hygiene would require data from multiple parts of the hospital.	<input type="radio"/> YES <input type="radio"/> NO	<input type="radio"/> YES <input type="radio"/> NO	<input type="radio"/> YES <input type="radio"/> NO
2.1.c Is the method (e.g., chart reviews, monthly observations, etc.) and frequency of data collection specified?	<input type="radio"/> YES <input type="radio"/> NO	<input type="radio"/> YES <input type="radio"/> NO	<input type="radio"/> YES <input type="radio"/> NO

# Injection Practices & Sharps Safety

- Injections prepared using aseptic technique in area cleaned and free of blood and bodily fluids
- Rubber septum disinfected with alcohol before piercing
- Single dose vials, IV bags/connectors used on only one patient
- Multidose vials dated when opened and discarded in 28 days unless shorter time by manufacturer
- Expiration date is clear as per P&P
- If multidose vial in patient care area used on only one patient



# Other Survey Memos on Infection Control



# Legionnaires' Disease (LD)

- Can cause type of pneumonia called LD
- Grows in hospital water systems that are continuously wet
- Check waterborne pathogen compliance
  - Surveyors will likely pay more attention to it
- Conduct a facility risk assessment

# CDC Resources Legionnaires' Disease

JUNE 2016

CDC  
**Vital**signs™

## 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](http://www.cdc.gov/legionella/downloads/toolkit.pdf)

# Infection Control Breaches

- When breaches warrant referral to the public health authorities
- This includes a finding by the state agency or an accreditation organization
  - TJC, DNV GL Healthcare, CIHQ, or HFAP
- State authority – state epidemiologist or State HAI Prevention Coordinator

# Needles – Syringes – Lancing Device

- Using same needle
- Using same syringe, pen or injection device
- Re-using a needle or syringe
  - To re-enter a medication container
  - Then using contents from that medication container for another individual
- Using the same lancing/fingerstick device
  - Even if the lancet is changed

# Memo on Insulin Pens

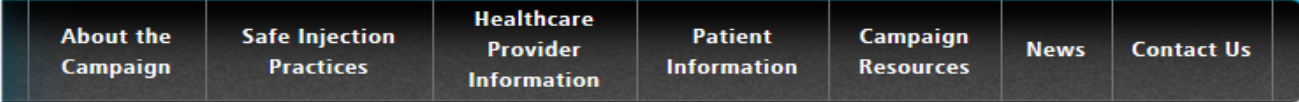
- Used on one patient only
- Insulin pens were used on more than one patient
  - Like sharing needles
- Every patient must have their own insulin pen
- Insulin pens must be marked with the patient's name

# Insulin Pens – cont'd

- Blood regurgitates into cartridge after injection
- Needs policy and procedure
- Educate staff on safe use of insulin pens
- CDC issues reminder on same and has free flier
  - (see Appendix)



# Pen Posters and Brochures Available



## Insulin Pen Safety – One Insulin Pen, One Person



[www.oneandonlycampaign.org  
/content/insulin-pen-safety](http://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)

# CDC Vaccine Storage and Handling Toolkit

- 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
  - Monitors temperature and set at mid range (40 degrees)
- E-mail specific questions to CDC: [NIPInfo@cdc.gov](mailto:NIPInfo@cdc.gov)

# CMS CAH Hospital CoPs



# CMS Hospital CoPs - Generally

- Appendix W, Starts at tag **C-800**,
  - Tag numbers renumbered in 2020 and reflected in Feb 2020 manual update
- Interpretive guidelines updated frequently
- Manual includes swing bed regulation
  - Interpretive guidelines and Survey Procedures in Appendix PP – LTC manual – F standards

# Gap Analysis

- Take each section and document how you comply
  - Include tag numbers in policies
- Include policies
  - Highlight section that corresponds to the required P&P in the CoP
- Have one person in charge
  - To keep up with changes and who
  - Knows what to do if CMS shows up survey

# Rehab or Behavioral Health Unit

- CAH can have up to a ten-bed **rehab** or **psych** (behavioral health) unit
  - Surveyed under Appendix A program
- Psych bed standards were in Appendix AA but moved to Appendix A now
  - Tag number 1600 to 1726

# Manual for 10 Bed Behavioral or Rehab

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

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

### **Transmittals for Appendix A**

#### **Survey Protocol**

##### **Introduction**

Task 1 - Off-Site Survey Preparation

Task 2 - Entrance Activities

Task 3 - Information Gathering/Investigation

Task 4 - Preliminary Decision Making and Analysis of Findings

Task 5 - Exit Conference

Task 6 – Post-Survey Activities

##### **Psychiatric Hospital Survey Module**

##### **Psychiatric Unit Survey Module**

##### **Rehabilitation Hospital Survey Module**

##### **Inpatient Rehabilitation Unit Survey Module**

##### **Hospital Swing-Bed Survey Module**

#### **Regulations and Interpretive Guidelines**

§482.1 Basis and Scope

§482.2 Provision of Emergency Services by Nonparticipating Hospitals

§482.11 Condition of Participation: Compliance with Federal, State and Local Laws

# TJC Revised Requirements

- TJC or the Joint Commission made many changes
  - Bring standards into closer alignment with CMS
- Having less differences is helpful to hospitals
- Have for hospitals that use them to get deemed status (DS) or payment for M/M patients
  - Will specify “DS” after the standard



# General Information

- Can make copies of things
  - Have surveyor make you a copy also
  - Ask surveyor not to make copy of peer review material
    - Abstract out what is needed

# Resources to Keep Handy

- Appendix W Hospital CoPs (“C”)
  - If have “distinct” rehab or behavioral health unit will need Appendix A
- 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
- Have **survey procedure** instructions
- Will ask patients if the hospital told them about their rights
- Deficiency citation show how the entity failed to comply with regulatory requirements

# Survey Protocol

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

# Question

- Our facility has seen an increase in the utilization of our Swing Beds due to COVID.
  - Yes
  - No
  - Not sure/Do not know

# Swing Beds



# Swing Bed Module

- Will survey under CAH swing-bed requirements
- Reimbursement is for Skilled Nursing care as opposed to Acute Care
- Term is for reimbursement
  - Not geographical

# Swing Bed Module

- In acute care status one day – Swing bed status the next day
- 3-day qualifying inpatient stay required
  - Not observation
  - Give Notice letter to outpatient observation patients (MOON Form)
- Swing-bed survey requirements are in 42 CFR 483



# Swing Bed Counts

- Will count:
  - Inpatient beds
  - Birthing beds – if remain after giving birth
- Will do open record review on ALL swing bed patients
- Do not count:
  - Observation beds
  - Surgery, PACU
  - L&D, newborn nursery
  - ED stretchers
  - Sleep lab beds
  - Exam tables
  - Medicare rehab/psyche distinct units

# Basic Information & New Tags

- Start with tag 800 – “C” = CAH CoPs
- Tag 800 Basis and Scope
  - Conditions to meet to be a CAH
- Tag 802 Rural Health Network
  - At least one hospital the state designated as a CAH and one 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 – cont'd

- 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 - qualifications of a CNS, NP, PA (804)
  - Remember the state defines the scope of practice
  - CMS will enforce the state law and scope of practice

# Basic Information – cont'd

- Tag 808 – designation and certification of CAHs
- States has a Medicare rural hospital flex program and can designate a CAH meeting the CoPs
- Criteria for certification
  - Hospital has been surveyed by the state agency
  - Is in compliance with the CAH CoPs

- Standard: CAH must comply with all federal, state, and local laws
- Surveyor may interview CEO to determine
- May refer non-compliance to proper agency with jurisdiction such as OSHA or OCR
  - TB, blood borne pathogen, universal precautions, or EPA (hazardous material or waste issues)

- Standard: CAH must comply with federal laws and regulations related to the health and safety of patients
  - PSDA or Patient Self Determination Act is a federal law
- Right to make advance directives
- Staff must comply with their advance directives
- Right to refuse treatment
- May have a DPOA or a **support person**/patient advocate

# Advance Directives – cont'd

- May use to designate a support person - to exercise visitation rights
- If patient incapacitated and DPOA – must give 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

# Advance Directives – cont'd

- Must provide information to the competent patient when admitted
- Should consider giving to outpatient as applicable
  - ED
  - Observation
  - Same Day surgery
- Document in medical record
- If incapacitated, give to family or surrogate
- Has conscience objector clause



# Advance Directives – cont'd

- Cannot require one
- Must make sure staff is educated on the P&P
- Includes the right to make a psychiatric advance directive or mental health declaration
  - Give consideration even if no state specific law
- Must provide community education

- Must disclose if physician owns the hospital
  - Includes ownership by immediate family member and must be in writing
  - If physician owners do not refer to the hospital – must sign attestation to this effect
- Physicians must also disclose to patients who they refer
  - This must be as a condition for getting MS privileges
- Disclose on public websites for advertising for the hospital – is owned/invested in by physicians

# Physician Ownership Disclosures - continued

- Disclose in writing if a physician is not on the premises 24 hours a day for emergencies
  - Sign acknowledgement if patient admitted
  - Need not to give individual notices to patients in the emergency department (ED)
  - 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
  - Will review sample of personnel files

# Laws/Licensure – cont'd

- Ensure staff meet all state laws for certification, qualification, training and education requirements
- Can verify licensure on the board of nursing website
- The surveyor to check and make sure licensure information is up to date
  - Will look at policies on certification and licensure



- Tag 822
  - Criteria for determining mountainous terrain
  - Revised definitions of primary and secondary roads
  - Documentation needed to relocate CAH
  - 75% rule
  - Covers exception for CAH designated as necessary provider (830)

# Status and Location – cont'd

- Must meet location requirements at the time of the initial survey
- Compliance is reconfirmed at the time of every subsequent full survey
- Discusses CAH classified as an urban hospital
- Discusses CAH located outside any area that is a metropolitan statistical area
- CAH must be in a rural area

# Agreement with Network Hospitals

- **Standard:** if a member of a rural network must have agreement with at least one hospital that is also a member of the network (Tag 860 and 862)
- Agreements related to:
  - Patient referral and transfer
  - Communication
  - Emergency and non-emergency patient transportation
- Will ask how CAH communicates with other hospitals



- **Standard:** Must have an agreement with a hospital that is a member of the network or QIO for quality improvement and credentialing
  - State networking requirements vary
- QA agreements need to include medical record review as part of quality
  - And to establish medical necessity of care at CAH
- Review of P&P – determine how information is obtained, used and how confidentiality is maintained

# Working with the Other Hospital

- P&P related to communication system
  - May review any written agreements with local EMS
- Patient referral and transfer (864)
- Electronic sharing of patient data, telemetry and medical records (862 and 866)
- Providing transport between the two facilities (868) whether emergency or non-emergency transfers

# Agreements: Credentialing and QA 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
  - 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 complete for PA and NP
  - Consider the findings and make necessary changes

- **Standard:** Agreements for C&P telemedicine physicians
- Board duties:
  - Ensure there is a written agreement with distant-site hospital (DSH) or entity (DSTE)
  - Decide what category of practitioners are eligible for appointment to the MS
  - Appoints with recommendation of the MS
  - Approves the MS bylaws and other rules and regulations

# Agreements for C&P – continued

- MS is accountable to the board for quality of care provided to the patients
- Must have and follow criteria for selection of MS
  - Based on individual character, competence, training, experience, and judgment
- Privileges cannot be based solely on certification, fellowship, or membership in a special body or society
- Contract must specify certain things (874)

# Telemedicine Contracts

- CAH must have in writing:
  - Choose to rely on the C&P DSH or DSTE (Tag 874)
- The contract must say
  - Distant site MS C&P process and standards meet the requirements in the CMS CoPs
  - The physician privileged at the other hospital
  - Physician must be licensed in state patient is located
  - Must communicate any adverse events to the other entity

# **Emergency Services**

# Question

- Our Emergency Department is:
  - Very busy
  - Moderately busy
  - Not busy
  - Closes frequently due to no patients
  - Do not have enough information to answer





- **Standard:** Must provide emergency care necessary to meet the needs of its inpatients and outpatients
  - Cannot be a provider-based off-site location
- Must comply with acceptable standards of practice
  - National professional organizations

# Emergency Services Requirements

- Qualified medical director
  - Criteria established by Medical staff
- MS P&P re: care provided in the ED
- Policies current and revised based on QAPI activities
- MS established qualifications for privileges to provide ED care
- ED must be adequately staffed with trained personnel
- Have adequate equipment

# Emergency Services – continued

- Reassessment of emergency needs to anticipate policies, staffing, training etc.
- Determine categories and numbers of staff needed
  - MD/DO, RN, ward clerks, PA, NP, EMTs,
- The scope of diagnostic and/or therapeutic respiratory services
  - Intubation, breathing treatments, ABGs, etc.
  - Other tests such as CT scans, venous Doppler's, ultrasound et. al.,

# 14 ED Written Policies

- Developed and approved by MS
  - Include mid-level practitioners who work in the ED
- 1. Each type of service
- 2. Qualifications and experience of personnel performing respiratory services and supervision if needed
- 3. Equipment assembly and operation
- 4. Safety practices including infection control

# Written Policies – continued

- 5. Handling, storage and dispensing therapeutic gasses
- 6. Cardiopulmonary resuscitation
- 7. Response to adverse reactions to treatments or interventions
- 8. Pulmonary function testing
- 9. Therapeutic percussion and vibration

# Written Policies – continued

- 10. Bronchopulmonary drainage
- 11. Mechanical ventilator and oxygenation support
- 12. Aerosol, humidification, and therapeutic gas administration
- 13. Administration of medications and
- 14. Procedures for obtaining and analyzing ABGs
  
- Consider:
  - Triage protocols

# Survey Procedures – Staff Training

- Surveyor will interview ED staff:
  - Parenteral administrations
  - Care and management of injuries to extremities and central nervous system
  - Prevention of contamination and cross infections
  - Provisions of emergency respiratory services



- Must have 24-hour emergency services available
- If no inpatients – not required to have emergency staff on site 24 hours a day
  - CAH may remain open
- Must still meet EMTALA requirements
- If no ED patients – qualified provider on site within 30 minutes
  - As allowed by state law which sets forth the scope of practice



# EMTALA, CAH & Telemedicine Memo

- Not required to have a doctor to appear when patient comes to the ED
- 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
- (See memo at end)

- Types and numbers of supplies, drugs, blood and blood products, and equipment
- Required by state and local law
- In accordance with accepted standards of practice
- Surveyor will ask how ensure above items are always available

- Antidotes and emetics
- Serums and toxoids
- Antiarrhythmics
- Cardiac glycosides
- Antihypertensive
- Electrolytes & replacement solutions
- Analgesics
- Local anesthetics
- Antibiotics
- Anticonvulsants
- Diuretics

# Emergency Equipment

888

- Airways
- Endotracheal tubes
- Ambu bag/valve/mask
- Oxygen
- Tourniquets
- Immobilization devices
- Nasogastric tubes
- Splints
- IV therapy supplies
- Suction machine
- Defibrillator
- Cardiac monitor
- Chest tubes
- Indwelling urinary catheters

# Education and Survey Procedure

- Ensure staff know where equipment located
- How supplies are replaced and who is responsible
- Surveyors
  - Will examine sterilized equipment for expiration dates
  - Will check for equipment maintenance schedule (defibrillator)
  - Will check force of suction equipment

- Procurement, safekeeping, and transfusion of blood
  - Includes availability of blood products needed for emergencies on a 24-hours a day basis
- No requirement to store blood on site
- Can provide directly or through arrangement



# Blood and Blood Products – cont'd

- If do tests on blood
  - Must have CLIA certificate
  - Surveyed under CLIA
- If collecting blood – must register with FDA
- If only storing blood for transfusion and refers all tests to outside lab – not performing test as defined by CLIA
- Need written agreement regarding the provision of blood between CAH and testing lab

# Blood and Blood Products – continued

- Appropriately stored to prevent deterioration
- If type and cross match blood must have necessary equipment
- Option: can keep 4 units O-Negative on hand at all times
- If not crossed matched:
  - Can release if signed by doctor
  - In an emergency



- Must be under the control and supervision of a pathologist or other qualified doctor
- If blood banking under arrangement
  - Arrangement must be approved by MS and administration
- Surveyor will look for an agreement

- Must have practitioner – MD/DO/PA/NP/CNS
  - Trained in emergency care
  - On call and immediately available within 30 minutes
- 60 minutes if in frontier area
  - Less than 6 residents per sq. mile
  - Area meets criteria for remote by the state and CMS
  - State determines longer time than 30 minutes needed is only way to provide care

# RN Will Meet Requirement

- RN will satisfy requirement if:
  - Is on site and immediately available
  - Nature of patient's request for care within scope of practice, consistent with all laws
  - For temporary period
  - CAH has less than 10 beds
  - Is in frontier area

# Letter to CMS

- State governor must send letter to CMS as part of rural health plan
- CAH must submit letter to surveyor
  - Plus demonstrate shortage and unable to provide care
- If state law has more stringent staffing requirements – must follow
  - See CMS Memo

# Survey Procedures

- Will review call schedules
- Will ask staff if they know who is on call
- Will review documentation that provider on site within time frame

- Must establish a procedure
  - MD/DO available by phone or radio
  - On 24-hour basis to receive calls
  - Provide information on treatment of patients
  - Refer patients to CAH or other appropriate location
- Surveyor will
  - Verify P&P present to ensure MD/DO available
  - Ask for evidence procedures followed and evaluated
  - Talk to staff – How MD/DO contacted when needed

# **Location and Length of Stay**

- Maintain no more than **25** inpatient beds
    - Does not include observation beds, sleep studies or ED
  - Can be used to provide acute or Swing-bed care
  - Distinct 10 bed rehab or behavioral health unit not included
  - Average basis of **96 hours per patient\***
- 
- \*Waived with COVID-19



# Observation Services

- Is a well-defined set of specific, clinically appropriate services
  - Usually – prolonged recovery from outpatient surgery or needs longer period of treatment/monitoring in ED
- Inappropriate use could subject beneficiary to increased coinsurance liability
  - 20% of CAH customary charges then if properly admitted as inpatient
- No prescheduled observations services

# Observation Not Appropriate

- Substitute for inpatient admission
- Continuous monitoring
- Medically stable patients needing diagnostic testing or outpatient procedure (blood chemo, dialysis)
- Awaiting nursing home placement
- Convenience to the patient or family
- Routine prep or recovery prior to/after diagnostic/surgical services
- Routine “stop” between the ED and inpatient admission

# What Needed

- Order prior to initiation – not backdated
  - Saying “admit for observation” is NOT violation of CoPs
- Documentation – show observation bed not an inpatient bed
  - Specific criteria for observation services
  - Must be different than inpatient criteria
- Observation begins and ends with the order of the physician
- No standing orders for observation

# Length of Stay and Observation

- Medicare will not pay if last more than **48** hours
  - Unless more strict state limit of 24 hours
- Rewrite policy on observation beds
- Observation beds not counted in calculating average LOS
- Are memos on the two-midnight rule
  - Place in an outpatient observation bed
  - Admit as an inpatient to telemetry

# Observation Not Inpatient

- Must show evidence that observation beds are not used for inpatient services
- CMS expects reasonable relationship between size of inpatient and observation operations
- EX: Red Flag – disproportionately large 10 bed observation unit
  - Surveyor may determine observation is an inpatient overflow unit

# Not Counted in “25 Beds”

- OR tables
- PACU bed
- OB beds exclusive for OB pts in labor or recovery after delivery
- Newborn bassinets and isolettes for well baby boarders unless baby held for treatment
- Examination or procedure tables
- Stretchers
- Stretchers in Emergency department
- Inpatient in distinct rehab or psyche units
- Observation beds

# Hospice Beds

- Hospice – can be dedicated beds
  - Are counted in maximum bed count
  - Except 96-hour average LOS rule does **not** apply
- Medicare does not reimburse the CAH for hospice patients only the Hospice
- Negotiate payment from the Hospice via agreement

- Does not exceed, on an annual average basis, 96 hours\* per patient (4 days)
  - State Fiscal Intermediary (FI) will determine compliance with this CoP
- Calculated based on patient census data
- If exceed – FI sends a report to the CMS-RO as well as a copy of the report to the SA
- Requires a plan of correction

■ \*96-hours waived during COVID-19



# Final Question

Dover CAH was set for a State Agency survey pre-COVID due to multiple patient complaints. The hospital was short-staffed for months due to the pandemic. RCAs conducted after a patient care event showed staffing issues did not contribute to the event. The survey was rescheduled to be completed in two weeks. The hospital remains short of adequate staff. The CNO is covering nursing duties.

Should Dover expect CMS to show up?

Discuss

# The End

# Questions???



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- Email questions to CMS: qsog\_CAH@cms.hhs.gov

# APPENDIX

## **WEBSITE LINKS AND GENERAL RESOURCES**

# AHA Website

## Small or Rural Hospitals

➔ Add to your interests

🏠 / Current & Emerging Payment Models / Rural issues

[www.aha.org/advocacy/small-or-rural](http://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:

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Advancing Health in America  
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## 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.



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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.



### Resources

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

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Discover the latest funding and opportunities to support rural health. [Browse all funding opportunities](#).

## What Works in Rural

## 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.

## 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.

## 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

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## 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:

 **RHIhub This Week**

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Summaries of the latest and ongoing funding and opportunities for rural communities

- [What's New](#)
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### Organizations

Government agencies, research organizations, non-profits and others with an interest in rural communities

- [National Rural Organizations with an Interest in Health](#)
- [Federal Advisory Bodies and Committees](#)
- [Federal Agencies and Councils Addressing Rural Health](#)
- [Rural Health Research Centers](#)
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- Help you find necessary information and make informed decisions
- Ensure you don't miss out on important opportunities

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[Home](#) > [Programs](#) > [TASC](#) > State Flex Profiles

### State Flex Profile Navigation

Jump to:

## 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

#### [Flex Program](#)

[Flex Program Fundamentals](#)

[Federal Flex Updates](#)

[Flex Program Grant and Cooperative Agreement](#)

[Guidance](#)

[Core Competencies](#)

[Self-Assessment](#)

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[Flex Program Forum](#)

[2019 Flex Program Reverse Site Visit \(RSV\)](#)

#### [MBQIP](#)

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# CMS Updated Website [www.cms.gov](http://www.cms.gov)

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# New Tag Numbers

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



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

**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

[www.cms.gov/files/document/burden-reduction-discharge-planning-som-package.pdf](http://www.cms.gov/files/document/burden-reduction-discharge-planning-som-package.pdf)

Ref: OSO-20-07-ALL

### 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:

Medicare

Medicaid/CHIP

Medicare-Medicaid  
Coordination

Private  
Insurance

Innovation  
Center

Regulations &  
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Outreach &  
Education

[Home](#) > [Medicare](#) > [Quality, Safety & Oversight - Certification & Compliance](#) > [Critical Access Hospitals](#)

[www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/CAHs](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/CAHs)

## Quality, Safety & Oversight - Certification & Compliance

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[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

Home | About CMS | Newsroom | Archive |  Sha



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

Medicare

Medicaid/CHIP

Medicare-Medicaid  
Coordination

Private  
Insurance

Innovation  
Center

Regulations &  
Guidance

Research, Statistics,  
Data & Systems

Home > Critical Access Hospitals Center

## 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.

# CAH Checklist



Center for Rural Health

University of North Dakota  
School of Medicine & Health Sciences

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<https://ruralhealth.und.edu/projects/cah-quality-network/cop>

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## CAH Quality Network Conditions of Participation

Centers for Medicare and Medicaid Services develops Conditions of Participation (CoPs) that Critical Access Hospitals (CAHs) must meet in order to participate in the Medicare and Medicaid programs. These health and safety standards are the foundation for improving quality and protecting the health and safety of patients. CoPs apply to all areas of a healthcare organization.

### CoPs Resources

- [State Operations Manual Appendix W](#)
- [North Dakota CAH CoPs Checklist, November 2018](#)
- [Conditions for Coverage \(CfCs\) & CoPs](#)
- [Life Safety Code](#)
- For more information on the Division of Health Facilities, visit the [North Dakota Department of Health website](#)

### CAH Deficiencies and Plans of Correction

To view results of other North Dakota CAHs state surveys, please visit the [Virtual Library of Shared Tools](#). Also, remember to share your survey results and plans of correction with the Network. If you need sign-in information for the Virtual Library, contact [Julie Frankl](#), Project Assistant at (701) 777-6781.



**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
<b>ADVANCED DIRECTIVES &amp; PATIENT RIGHTS</b>  <b>C-0151</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Does facility have policy and procedure regarding advance directives?</li> <li><input type="checkbox"/> 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?</li> <li><input type="checkbox"/> CAH &amp; staff compliance with federal, state and local laws &amp; regulations</li> <li><input type="checkbox"/> Staff must comply with their advance directives and are educated to policy and procedures</li> <li><input type="checkbox"/> Provide advance directive information to the competent patient when admitted</li> <li><input type="checkbox"/> Inpatients and Outpatients have the right to make advance directives</li> <li><input type="checkbox"/> Advance directive applies to ED, observation and same day surgery patient</li> <li><input type="checkbox"/> Have advance directives to designate a support person for person of exercising the visitation rights</li> <li><input type="checkbox"/> If patient is incapacitated, a durable power of attorney (DPOA) must be used to inform decisions and consent for the patient</li> <li><input type="checkbox"/> CAH must also seek the consent of the patient's representative when informed consent is required for a care decision</li> <li><input type="checkbox"/> Prominent documentation in MR of completing advance directive</li> <li><input type="checkbox"/> Provide community education regarding issues concerning advance directives and the hospital must document its efforts (video and audible tapes acceptable)</li> <li><input type="checkbox"/> Patient has the right to refuse treatment</li> <li><input type="checkbox"/> Must disclose if physician owned hospital</li> <li><input type="checkbox"/> Physician's must also disclose to patients who they refer</li> <li><input type="checkbox"/> Disclose in writing if physician is not on premise 24 hours a day for</li> </ul>



# 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](https://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

# 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](https://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](https://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,

# Update re: Mandatory Disclosures

- <https://www.govinfo.gov/content/pkg/FR-2021-05-20/pdf/2021-10680.pdf>.

Federal Register / Vol. 86, No. 96 / Thursday, May 20, 2021 / Notices

27435

number: 0938–1148); *Frequency*: Once, quarterly, and on occasion; *Affected Public*: State, Local, or Tribal Governments; *Number of Respondents*: 56; *Total Annual Responses*: 616; *Total Annual Hours*: 1,344. (For policy questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

Dated: May 14, 2021.

**William N. Parham, III,**  
Director, Paperwork Reduction Staff, Office  
of Strategic Operations and Regulatory  
Affairs.

[FR Doc. 2021–10574 Filed 5–19–21; 8:45 am]  
BILLING CODE 4120–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier CMS–10536, CSM–  
10225 and CMS–10764]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare &  
Medicaid Services, Health and Human  
Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance

information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

**FOR FURTHER INFORMATION CONTACT:**  
William Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template; *Use*: To assess the appropriateness of states' requests for enhanced federal financial participation for expenditures related to

*Hours*: 2,688. (For policy questions regarding this collection contact Edward Dolly at 410–786–8554.)

2. *Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title of Information Collection*: Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership; *Use*: This information collection relates to the required third party disclosures by certain Medicare-participating hospitals and Critical Access Hospitals (CAHs) and physicians to their patients. There are 5 types of disclosures required. The intent of the disclosure notice is to assist the patient in making an informed decision regarding their care. The first disclosure requires physician owned hospitals and CAHs to disclose to its patients whether the hospitals/CAHs are physician-owned and, if so, the names of the physician-owners. The second disclosure requires the physician owner or investor in the hospital, as part of his or her continued medical staff membership or admitting privileges, to disclose to the patient being referred to the hospital any ownership or investment interest held by the physician or an immediate family member of the physician. The third disclosure requires physician owned hospitals to disclose on all public websites for and in any public advertising for the hospital that the hospital is owned or invested in by physicians. The fourth and fifth disclosures apply to all hospitals and CAHs that do not have a Doctor of Medicine (MD) or a Doctor of Osteopathic Medicine (DO) on the premises at all times to disclose this to patients upon admission or registration for both inpatient and specified outpatient services. These hospitals and CAHs must provide a written disclosure to the patients admitted to the hospital and must also post a conspicuous notice in the Emergency Departments (ED) which states that the hospital does not have a physician present 24 hours per day, 7 days per week. *Form Number*: CMS–10225 (OMB control number: 0938–1034); *Frequency*: Occasionally; *Affected Public*: Private sector—Businesses or other for-profit and Not

# CMS Memo on Texting #2

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



Center for Clinical Standards and Quality/ 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](http://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.



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](http://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

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

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**Ref: DRAFT-QSO-19-12-Hospitals**

**DATE:** April 19, 2019  
**TO:** State Survey Agency Directors  
**FROM:** Director  
Quality, Safety & Oversight Group  
**SUBJECT:** DRAFT ONLY-Clarification of Ligature Risk Interpretive Guidelines – FOR ACTION

[www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-12-Hospitals.pdf](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-12-Hospitals.pdf)

**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

# Safe Injection Practices

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



## Office of Clinical Standards and Quality/Survey & Certification Group

**DATE:** June 15, 2012  
**TO:** State Survey Agency Directors  
**FROM:** Director  
Survey and Certification Group  
**SUBJECT:** Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections

Ref: S&C: 12-35-ALL

[www.cms.gov/Medicare/Provider-Enrollment-and-](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html?redirect=/SurveyCertificationGenInfo/PMSR/list.asp)

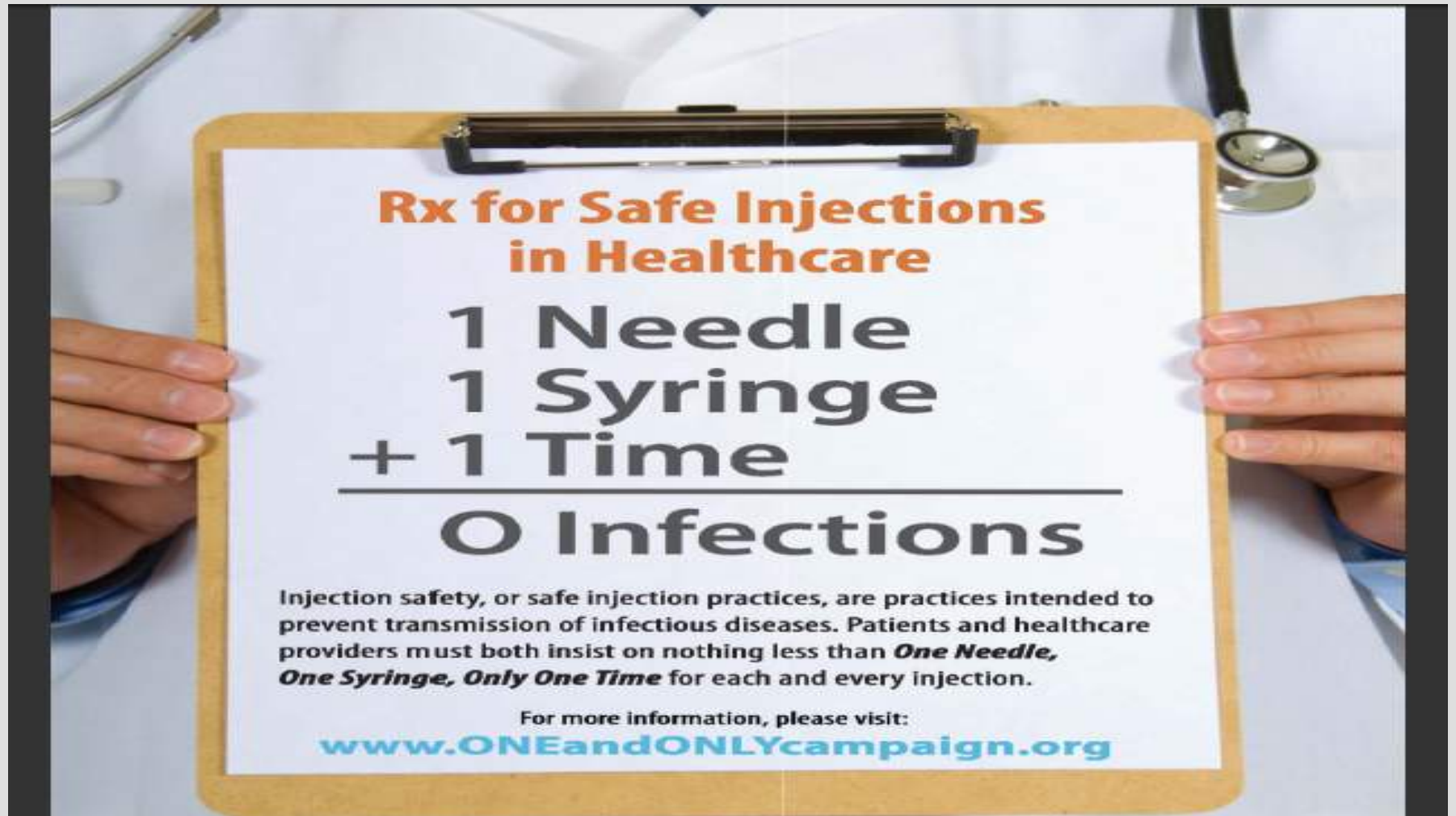
[Certification/SurveyCertificationGenInfo/index.html?redirect=/SurveyCertificationGenInfo/PMSR/list.asp](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html?redirect=/SurveyCertificationGenInfo/PMSR/list.asp)

### 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.



# Safe Injection Practices Posters





# 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.

LEARN MORE ABOUT WAYS YOU CAN KEEP YOUR PATIENTS

**1** ONE NEEDLE,  
ONE SYRINGE,  
ONLY ONE TIME.



# CDC One and Only Campaign



1 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](#)




## ONLY ONCE.

Safe injection practices are a set of measures to perform injections in an optimally safe manner for patients, healthcare providers and others.  
[Learn about Safe Injection Practices >](#)

## About the Campaign

The One & Only Campaign is a public health campaign, led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC), to raise awareness among patients and healthcare providers about safe injection practices. The campaign aims to eradicate outbreaks resulting from unsafe injection practices.

### Injection Safety Toolkits




### Featured Content

- ▶ [CDC releases toolkit to assist with patient notification events after unsafe medical practices](#)
- ▶ [Safe Injection Practices in Dentistry](#)

### Become a Member

Help us promote safe injection practices to healthcare professionals, patients and/or the public. Become a One & Only Campaign member today.  
[Contact us](#)

### Campaign Resources



The SIPC has print materials, videos and more to educate consumers and remind healthcare providers about the basics of injection safety.  
[Read more](#)

Sign up for email updates:  [SIGN UP](#) [Privacy Policy](#)

[http://oneandonlycampaign.org/safe\\_injection\\_practices](http://oneandonlycampaign.org/safe_injection_practices)

### **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.<sup>31</sup>

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.<sup>31</sup> 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**



# Final 3 Worksheets

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



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

REF: S&C: 15-12-Hospital

**DATE:** November 26, 2014

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

[www.cms.gov/SurveyCertificationGroupInfo/PMSR/list.asp#TopOfPage](http://www.cms.gov/SurveyCertificationGroupInfo/PMSR/list.asp#TopOfPage)

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

### Memorandum Summary

- **Three Hospital Surveyor Worksheets Finalized:** The Centers for Medicare & Medicaid Services (CMS) has finalized surveyor worksheets for assessing compliance with three Medicare hospital Conditions of Participation (CoPs): Quality Assessment and 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.

# 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	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>



## 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.	<input type="checkbox"/> Yes	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5		<input type="checkbox"/> Yes	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	
2. B.2 Needles are used for only one patient.	<input type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> N/A	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5		<input type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> N/A	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	
2. B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes and insulin pens).	<input type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> N/A	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5		<input type="checkbox"/> Yes  <input type="radio"/> No  <input type="radio"/> N/A	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	

Interview = 1

Observation = 2

Infection Control Document Review = 3

Medical Record Review = 4

Other Document Review = 5

11.00 x 8.50 in

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](http://www.cdc.gov/vitalsigns/legionnaires/index.html)

## 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](http://www.cdc.gov/legionella/WMPtoolkit)
- Monitor and respond to changes in water quality.

Language: English

## On this Page

- Overview
- Problem
- Infographic
- What Can Be Done
- Issue Details



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# CDC Resource Slides

Centers for Disease Control and Prevention

[www.cdc.gov/stltpublichealth/townhall/2017/downloads/06-jun-presentation.pdf](http://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 Issues 3<sup>rd</sup> Ebola Memo

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



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

**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:

# Infection Control Breaches

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



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

Ref: S&C: 14-36-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>

# CRE and ERCP Scopes

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



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

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

**DATE:** April 3, 2015

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

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

### Memorandum Summary

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

# Insulin Pens

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



## Office of Clinical Standards and Quality/Survey & Certification Group

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](http://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 than one patient/resident. Recommendations will be issued soon that describe specific instructions on the

# CDC Reminder on Insulin Pens

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

## Injection Safety

CDC's Role

CDC Statement

Information for Providers

Information for Patients

Preventing Unsafe  
Injection Practices

Infection Prevention  
during Blood Glucose  
Monitoring and Insulin  
Administration

FAQs regarding Assisted  
Blood Glucose  
Monitoring and Insulin  
Administration

CDC Clinical Reminder:  
Fingerstick Devices

► **Clinical Reminder:  
Insulin Pens**

Recent Publications

Recent Meetings


The One & Only  
Campaign


[Injection Safety](#)

> [Infection Prevention during Blood Glucose Monitoring and Insulin Administration](#)


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

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

### Summary

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



### Background

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

### On this Page

- [Summary](#)
- [Background](#)
- [Recommendations](#)
- [References](#)

### Contact Us:

 Centers for Disease  
Control and  
Prevention  
1600 Clifton Rd  
Atlanta, GA 30333  
 800-CDC-INFO  
(800-232-4636)  
TTY: (888) 232-6348  
[Contact CDC-INFO](#)

### Related Links

[One & Only Campaign](#)



# 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



# 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.

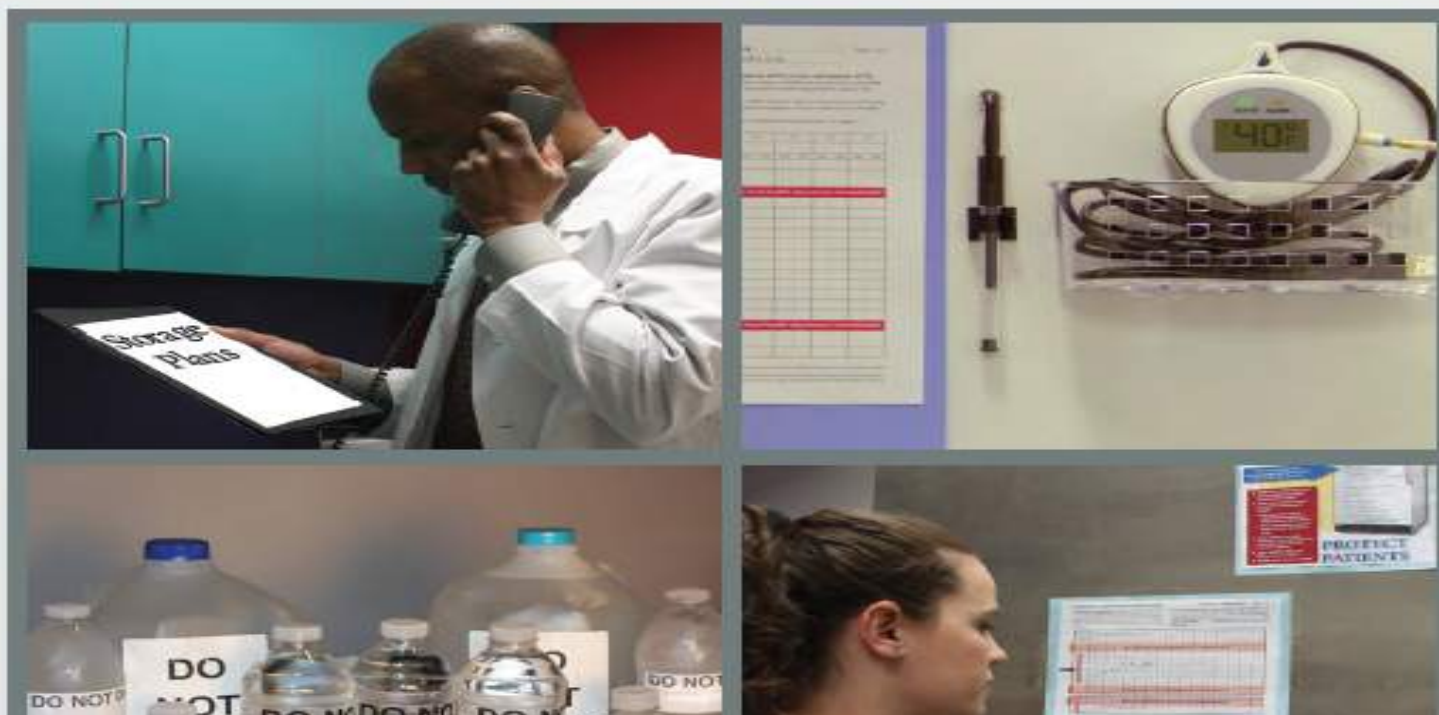
For more information,  
please visit:  
[www.ONEandONLYcampaign.org](http://www.ONEandONLYcampaign.org)



# Vaccine Storage & Handling Toolkit

June 2016

[www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)





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 CHECKLIST**

## **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) List 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: \_\_\_\_\_]

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# CMS S&C Memo EMTALA & CAH

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



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

Ref: S&C: 13-38-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