CMS HOSPITAL CONDITIONS OF PARTICIPATION (COPS) 2022 Part 1 of 5

What Hospitals Need to Know

Introduction, Survey Memos, Medical Records, ED, OCR 1557, Contracts, Board and Medical Staff, ISMP IV Push Guidelines

Speaker

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  Acute hospitals: **qsog_hospital@cms.hhs.gov.**

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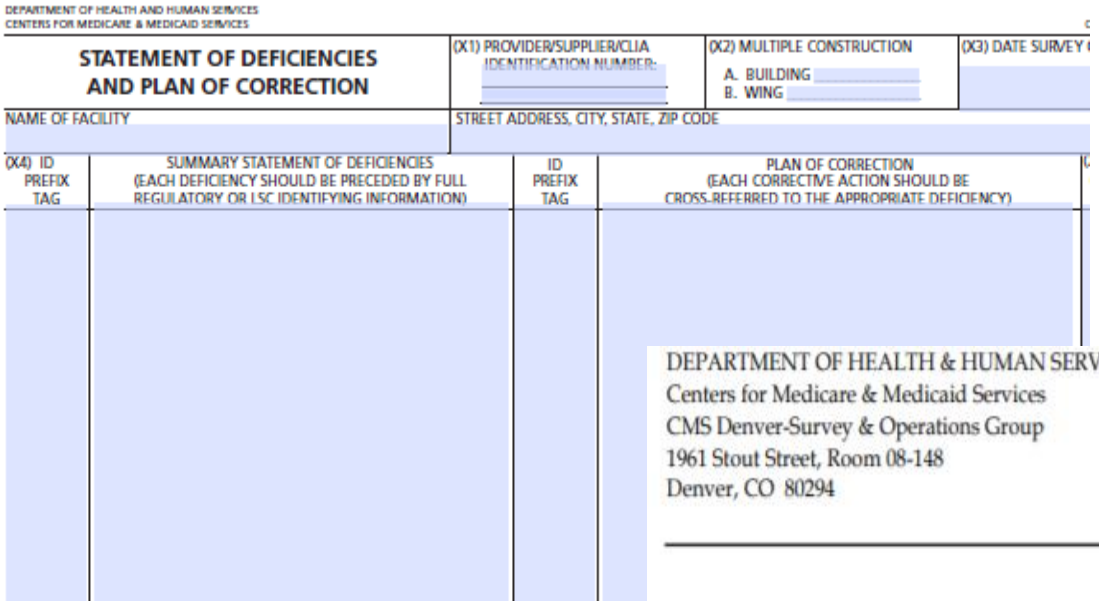
Introduction to the CMS Hospital Conditions of Participation (CoPs)

Why We are Here Today



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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

(X2) MULTIPLE CONSTRUCTION

(X3) DATE SURVEY

A. BUILDING _____ B. WING _____

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-REFERRED 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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

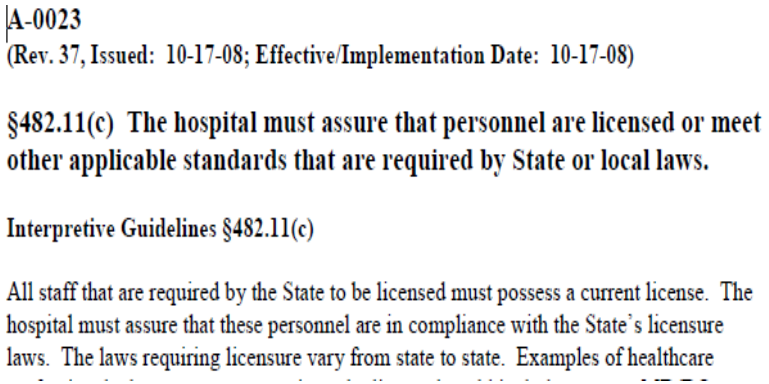
PUBLIC NOTICE FOR INVOLUNTARY TERMINATION OF MEDICARE/MEDICAID PROVIDER AGREEMENT

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 o 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.

The Conditions of Participation (CoPs)

- Manual first out 1986
  - Multiple updates
- Section numbers – “Tag” numbers
- Start in the Federal Register
  - Interpretive Guidelines
  - Survey procedures
  - Hospitals should check this website once a month for changes



A-0023
(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.11(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

Interpretive Guidelines §482.11(c)

All staff that are required by the State to be licensed must possess a current license. The hospital must assure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare

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How to Keep Up with Changes

- Confirm current CoP [1].
- Check the survey and certification website monthly [2].
- If new manual – check CMS transmittal page [3].
- Have one person in your facility who has this responsibility

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

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Subscribe to the Federal Register

FEDERAL REGISTER
The Daily Journal of the United States Government

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

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

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

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

Show entries: 5 per page | Filter On | Apply

Showing 1-10 of 521 entries

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

Example of Survey Memo

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

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

DATE: **April 3, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

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

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

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	Hospitals
AA	Psychiatric Hospitals- *Deleted (See Appendix A)*
B	Home Health Agencies

Also Called State Operation Manual

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

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

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Swing Bed and Psyche - Briefly

- Not covered in this series
- Swing beds – added to appendix A and W
  - Appendix T deleted
- Psych hospital added to appendix A
  - Appendix AA deleted
  - No longer subject to 2 separate on-site surveys

Informational Notice: Forthcoming Integration of the Psychiatric Hospital Program into the Hospital Program and State Operations Manual (SOM) Changes

Title	Informational Notice: Forthcoming Integration of the Psychiatric Hospital Program into the Hospital Program and State Operations Manual (SOM) Changes
Memo #	20-05-Hospital/Psych
Posting Date	2020-01-13
Fiscal Year	2020
Summary	To improve the identification of quality issues, the Centers for Medicare & MedicaidServices (CMS) is in the process of integrating the psychiatric hospital programsurvey into the hospital program survey: Currently the hospital and psychiatrichospital programs are reviewed separately for compliance with the Conditions ofParticipation. Our intent is to ensure psychiatric hospital services are evaluated in thecontext of the overall hospital program to better identify systemic quality issues. •Update and relocation of the Interpretive Guidelines for Psychiatric Hospitals: Theinterpretive guidelines in SOM Appendix AA for the special psychiatric Conditions ofParticipation (CoPs) will be updated and relocated in the interpretive guidance forHospitals in Appendix A. Appendix AA will be deleted. •Develop training to provide the necessary competencies for all State Survey Agencysurveyors to evaluate compliance with the psychiatric hospital CoPs: CMS isdeveloping training to assist surveyors in identifying compliance with the specialpsychiatric hospital CoPs. Currently, the SA surveys the hospital requirements in all non-deemed psychiatric hospitals as well as during validation and complaint surveys ofdeemed psychiatric hospitals. Once the psychiatric program is moved to the hospitalprogram, the hospital survey team will assess compliance with all requirements. Allinterpretive guidelines and survey procedures will be located in Appendix A.

Downloads

Admin Info -20-05-Hospital/Psych (PDF)

Important Change to Manual

- Reference to USP 747
  - Changes and additions such as USP 800
- Did not include detailed requirements of USP
- Now: compliance with
  - Federal and state law
  - Generally accepted standards of practice
  - Guidelines by nationally recognized professional organizations

Hospital Improvement Rule 2019

- Regulations effective November 2019 and in 2020
- Interpretive guidelines and survey procedures pending
- Same day implemented discharge planning standards

*See appendix for information to access the rules

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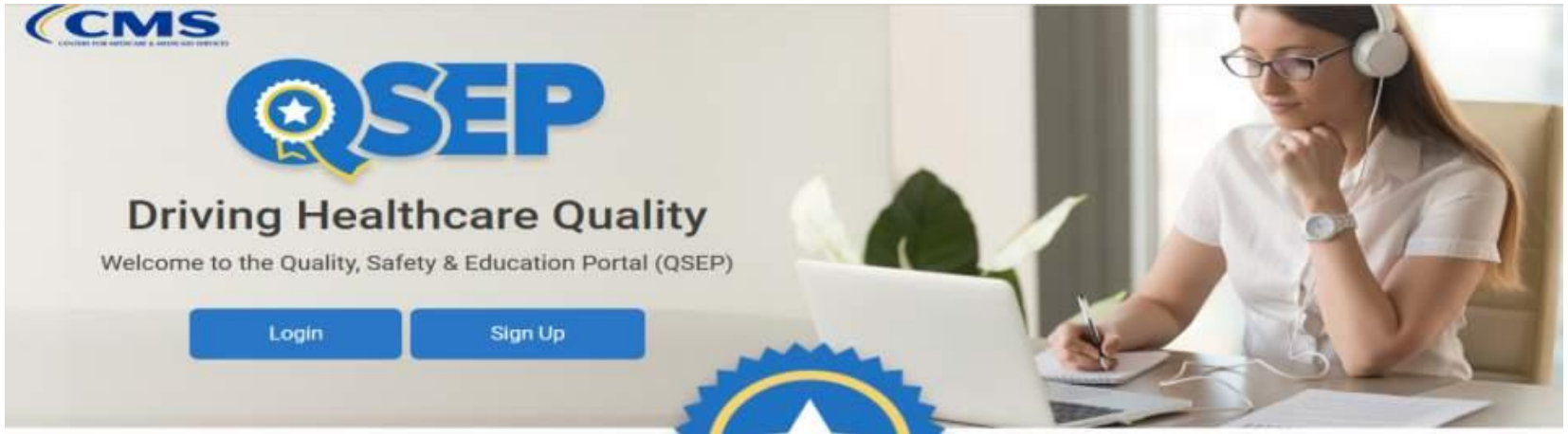
CMS Surveyor Training Website

Training Site for Surveyors



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.

QSEP is an online platform that empowers learners to lead and manage their own learning in order to master the content. All training is available on-demand on a top-notch self-service portal. 24/7 access means you have the freedom to learn what you

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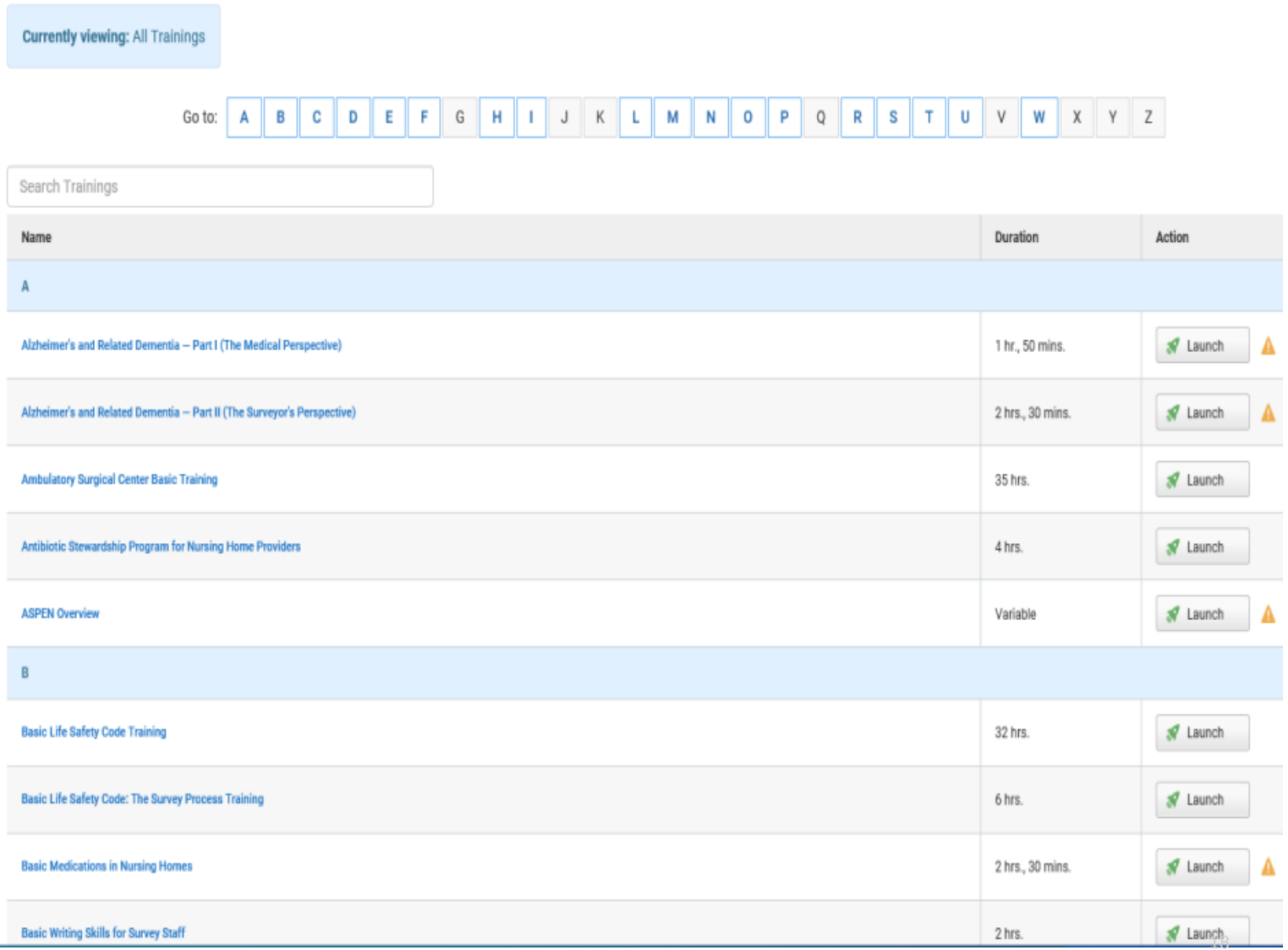
Alphabetical Lists of Training



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CMS Deficiency Reports

Can Access Hospital Deficiency Data

- Includes acute care and CAH hospitals
  - List tag numbers
  - Does not include the plan of correction but can request
  - Questions to bettercare@cms.hhs.com
- Updated quarterly

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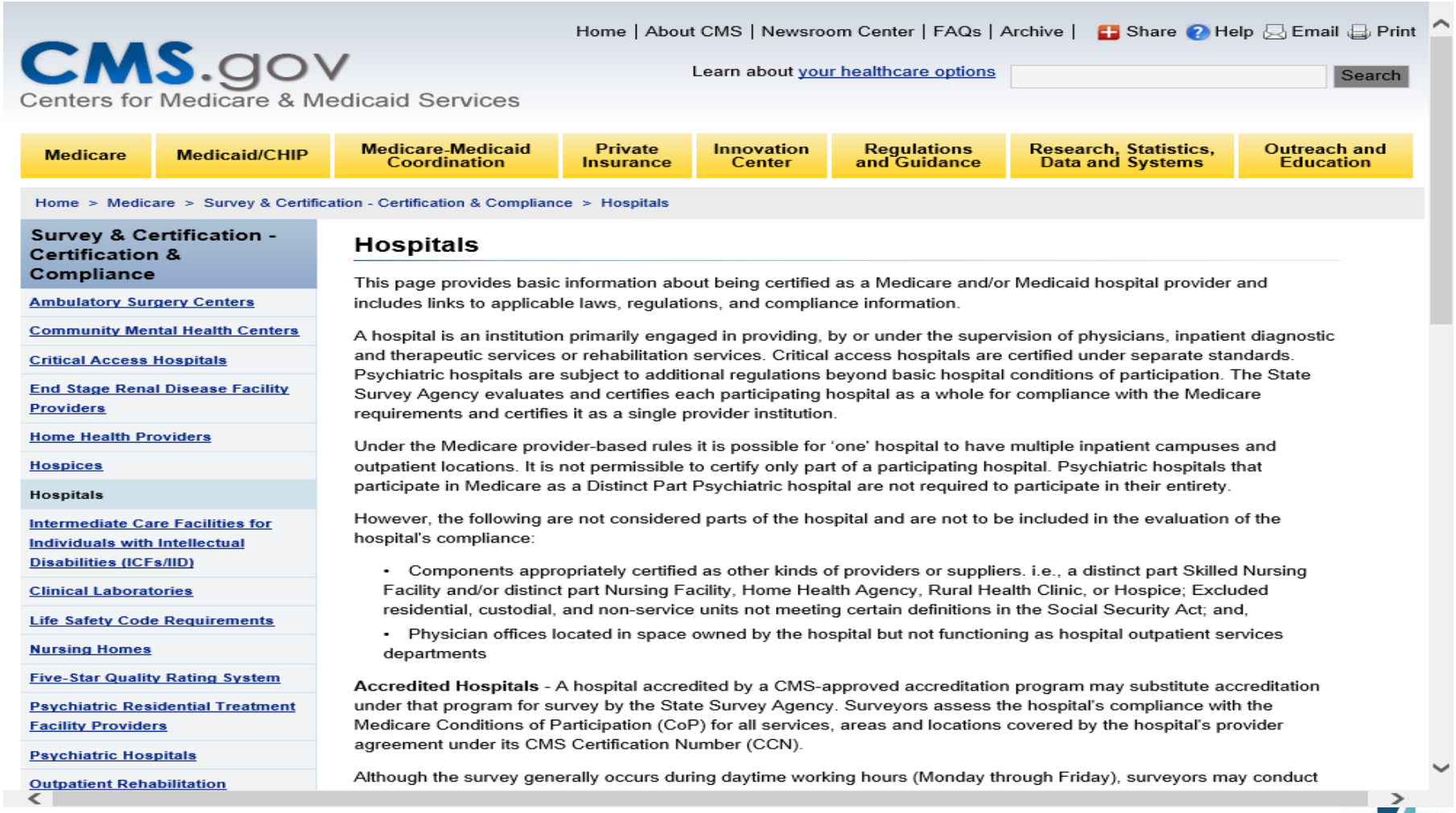
Updated Deficiency Data Reports



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

Survey & Certification - Certification & Compliance

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

Hospitals

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

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

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

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

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

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

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

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

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“Full Text Statements”

- Life Safety Code & Health Care Facilities Code Requirements
- Nursing Homes
- Five-Star Quality Rating System
- Psychiatric Residential Treatment Facility Providers
- Psychiatric Hospitals
- Outpatient Rehabilitation Providers
- Inpatient Rehabilitation Facilities
- Comprehensive Outpatient Rehabilitation Facilities
- Rural Health Clinics
- Religious Nonmedical Health Care Institutions
- Transplant

- 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 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)

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

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Count the Deficiencies by Tag Number

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

Sheet1

Lists by State and Names Hospitals

	A	B	C	D	E	F	G	H	I	J	
4041	GEISINGER - COMMUNITY MEDICAL CENTER	390	182	PA	18510	Short Term	A	0068	CARE OF PATIENTS - RESPONSIBILITY FOR CARE	6/14/2011	**NOTE- TERMS IN BRACKETS HA
4042	GEISINGER - COMMUNITY MEDICAL CENTER	390	182	PA	18510	Short Term	A	0115	PATIENT RIGHTS	6/14/2011	**NOTE- TERMS IN BRACKETS HA
4043	GEISINGER - COMMUNITY MEDICAL CENTER	390	182	PA	18510	Short Term	A	0048	MEDICAL STAFF - BYLAWS AND RULES	6/13/2012	Based on review of the governing
4044	GEISINGER - COMMUNITY MEDICAL CENTER	390	182	PA	18510	Short Term	A	0049	MEDICAL STAFF - ACCOUNTABILITY	6/13/2012	**NOTE- TERMS IN BRACKETS HA
4045	GEISINGER - COMMUNITY MEDICAL CENTER	390	182	PA	18510	Short Term	A	0115	PATIENT RIGHTS	6/13/2012	Based on review of Medical Staff
4046	GEISINGER - COMMUNITY MEDICAL CENTER	390	182	PA	18510	Short Term	A	0144	PATIENT RIGHTS: CARE IN SAFE SETTING	6/13/2012	Based on review of facility policy
4047	GEISINGER - COMMUNITY MEDICAL CENTER	390	182	PA	18510	Short Term	A	0405	ADMINISTRATION OF DRUGS	6/13/2012	**NOTE- TERMS IN BRACKETS HA
4048	GEISINGER - COMMUNITY MEDICAL CENTER	390	182	PA	18510	Short Term	A	0490	PHARMACEUTICAL SERVICES	6/13/2012	Based on review of facility policy,
4049	GEISINGER - COMMUNITY MEDICAL CENTER	390	182	PA	18510	Short Term	A	0492	PHARMACIST RESPONSIBILITIES	6/13/2012	Based on review of pharmacy poli
4050	HOLY SPIRIT HOSPITAL	390	503	PA	17011	Short Term	A	0438	FORM AND RETENTION OF RECORDS	5/10/2012	Based on a review of facility docu
4051	HOLY SPIRIT HOSPITAL	390	503	PA	17011	Short Term	A	0491	PHARMACY ADMINISTRATION	5/10/2012	**NOTE- TERMS IN BRACKETS HA
4052	HOLY SPIRIT HOSPITAL	390	503	PA	17011	Short Term	A	0115	PATIENT RIGHTS	4/27/2012	Based on review of facility docum
4053	HOLY SPIRIT HOSPITAL	390	503	PA	17011	Short Term	A	0263	QAPI	4/27/2012	Based on a review of facility docu
4054	HOLY SPIRIT HOSPITAL	390	503	PA	17011	Short Term	A	0392	STAFFING AND DELIVERY OF CARE	4/27/2012	Based on a review of facility polic
4055	HOLY SPIRIT HOSPITAL	390	503	PA	17011	Short Term	A	1100	EMERGENCY SERVICES	4/27/2012	**NOTE- TERMS IN BRACKETS HA
4056	GEISINGER MEDICAL CENTER	390	100	PA	17822	Short Term	A	0043	GOVERNING BODY	7/11/2011	Based on review of facility policie
4057	GEISINGER MEDICAL CENTER	390	100	PA	17822	Short Term	A	0057	CHIEF EXECUTIVE OFFICER	7/11/2011	Based on review of facility docum
4058	GEISINGER MEDICAL CENTER	390	100	PA	17822	Short Term	A	0115	PATIENT RIGHTS	7/11/2011	Based on review of facility policie
4059	GEISINGER MEDICAL CENTER	390	100	PA	17822	Short Term	A	0144	PATIENT RIGHTS: CARE IN SAFE SETTING	7/11/2011	Based on review of facility docum
4060	GEISINGER MEDICAL CENTER	390	100	PA	17822	Short Term	A	0164	PATIENT RIGHTS: RESTRAINT OR SECLUSION	7/11/2011	Based on review of facility docum
4061	GEISINGER MEDICAL CENTER	390	100	PA	17822	Short Term	A	0165	PATIENT RIGHTS: RESTRAINT OR SECLUSION	7/11/2011	Based on review of facility docum
4062	GEISINGER MEDICAL CENTER	390	100	PA	17822	Short Term	A	0174	PATIENT RIGHTS: RESTRAINT OR SECLUSION	7/11/2011	Based on review of facility docum
4063	GEISINGER MEDICAL CENTER	390	100	PA	17822	Short Term	A	0175	PATIENT RIGHTS: RESTRAINT OR SECLUSION	7/11/2011	Based on review of facility docum
4064	GEISINGER MEDICAL CENTER	390	100	PA	17822	Short Term	A	0186	PATIENT RIGHTS: RESTRAINT OR SECLUSION	7/11/2011	Based on review of facility docum
4065	JAMESON MEMORIAL HOSPITAL	390	121	PA	16105	Short Term	A	0701	MAINTENANCE OF PHYSICAL PLANT	2/2/2012	Based on review of facility docum
4066	JAMESON MEMORIAL HOSPITAL	390	121	PA	16105	Short Term	A	0144	PATIENT RIGHTS: CARE IN SAFE SETTING	4/20/2012	Based on review of medical recor
4067	CHESTNUT HILL HOSPITAL	390	883	PA	19118	Short Term	A	1104	EMERGENCY SERVICES POLICIES	3/15/2012	Based on review of facility policy
4068	CHESTNUT HILL HOSPITAL	390	883	PA	19118	Short Term	A	2406	MEDICAL SCREENING EXAM	3/15/2012	Based on review of facility Rules
4069	CHESTNUT HILL HOSPITAL	390	883	PA	19118	Short Term	A	2408	DELAY IN EXAMINATION OR TREATMENT	3/15/2012	Based on review of Chestnut Hill
4070	SCHUYLKILL MEDICAL CENTER - SOUTH JACKS	390	420	PA	17901	Short Term	A	0117	PATIENT RIGHTS: NOTICE OF RIGHTS	2/11/2011	Based review of facility document

Sheet1

NASH HEALTHCARE CONSULTING

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 (click for details)	Read full report
July 29, 2019	2 (click for details)	Read full report
May 8, 2019	4 (click for details)	Read full report
Oct. 19, 2016	1 (click for details)	Read full report
June 29, 2016	2 (click for details)	Read full report
March 24, 2016	2 (click for details)	Read full report
Nov. 4, 2015	1 (click for details)	Read full report
Aug. 7, 2015	2 (click for details)	Read full report
Nov. 15, 2012	3 (click for details)	Read full report

Read the Report

LUTHERAN MEDICAL CENTER	8300 W 38TH AVE WHEAT RIDGE, CO 80033	Nov. 7, 2019
VIOLATION: *PATIENT RIGHTS*		**Tag No:** A0115

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.

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).

VIOLATION: *PATIENT RIGHTS: CARE IN SAFE SETTING*	**Tag No:** A0144

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).

Findings include:

Facility policy:

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.

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.

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

CMS Survey Memos

Recent Survey Memos of Interest

- Privacy and confidentiality
- **CRE and ERCPs, EBOLA**
- Luer misconnections
- IV and blood and blood products
- **Use of insulin pens issue**
- Immediate use steam sterilization
- **Texting orders**
- **Ligature risks**
- Three worksheets
- Glucose Monitoring
- **Single dose vials and safe injection practices**
- Humidity in the OR
- Reporting to internal PI program
- **Complaint manual and reporting to AO**
- Deficiencies of hospitals
- Equipment Maintenance
- OPO
- Medication and Safe Opioid Use
- **Legionella**

Memo on Ligature Risk

- TJC and CMS - safe environment vital to prevent patients hanging themselves or strangulation
- Focuses on the care and safety of behavioral health patient and staff
- No waivers for ligature risk deficiencies
- Hospitals cited will be required to provide monthly progress reports *

* See Appendix for information on accessing memos

Memo on Texting

- Medical record sections – tags 438, 441, and 467
  - No amendments made except to CAHs CoPs
- Texting of orders **not** allowed
- Permitted with other patient information:
  - System secure, encrypted, and minimize the risks to privacy and confidentiality
  - Text consults, emergency notification etc.
- CPOE is the preferred way to enter an order

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

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

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

DATE: **December 28, 2017**

TO: State Survey Agency Directors

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.

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

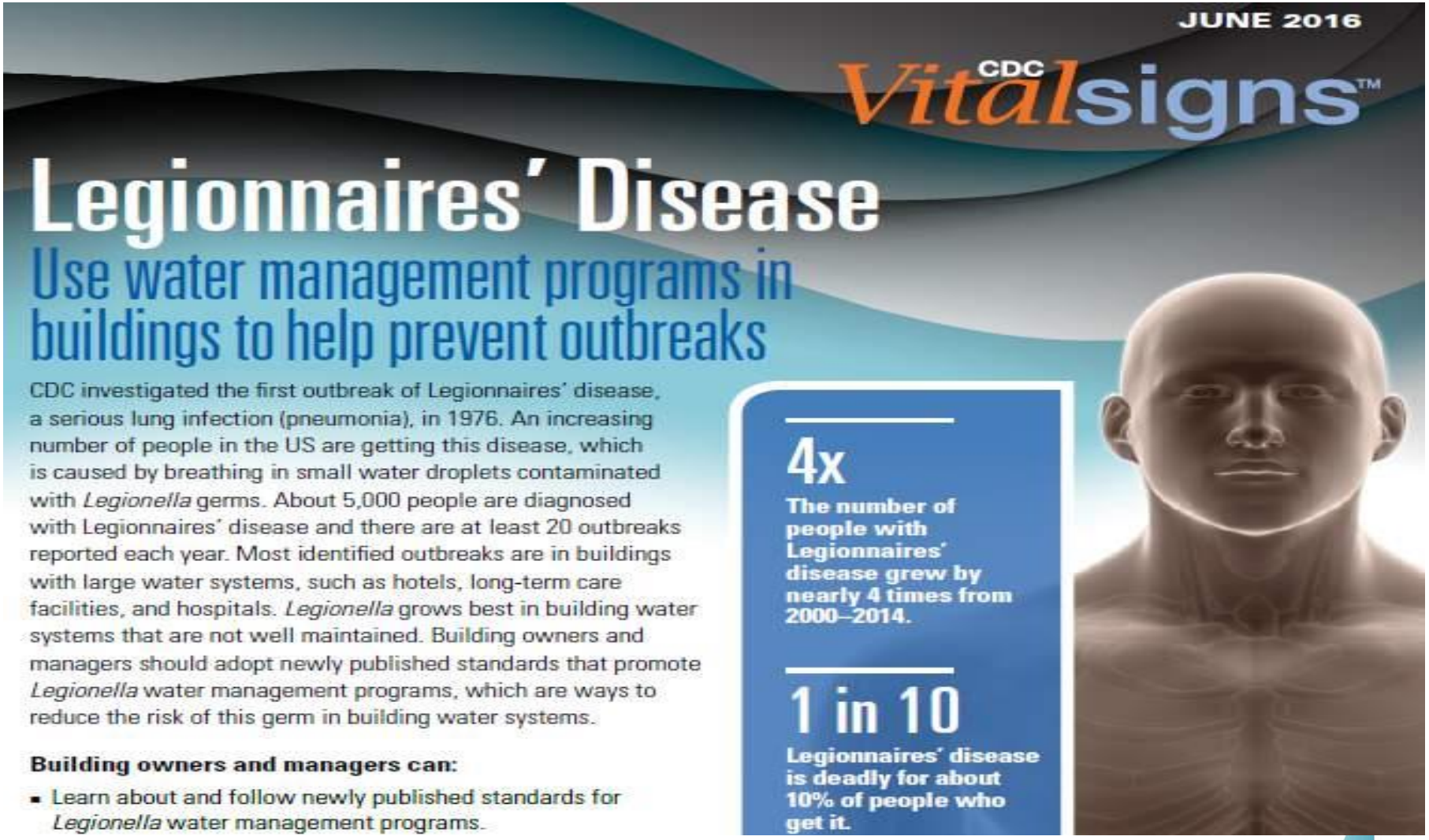
NASH HEALTHCARE CONSULTING

Memo on Legionnaires' Disease (LD)

- Grows water systems that are continuously wet
  - Water heaters and filters, fountains, water storage tanks, eyewash stations, ice machines, etc.
- 5,000 cases 2014
  - 15% of associated with hospitals
- Check waterborne pathogen compliance
- Conduct a facility risk assessment

* See appendix for memo

CDC Resources Legionnaires' Disease



NASH HEALTHCARE CONSULTING

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

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Memo re: Complaint Manual

- Updated compliance manual
  - 2-day visit if death from restraint or EMTALA Immediate Jeopardy
- If immediate jeopardy – could have full validation survey if the regional office requests
  - Regional office has discretion
  - Appendix Q
- GAO: share complaint information and survey findings with accreditation agency
  - TJC, DNV, HFAP, or CIHQ

Memo on Insulin Pens

- Regurgitation of blood into the cartridge can occur
- Need policy and procedure
- One insulin pen per patient
- Educate staff regarding the safe use of insulin pens
- CDC issues reminder on same and has free flier

CDC Reminder on Insulin Pens

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

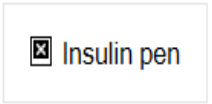
Format: Select One

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.

www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html

www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html

NASH HEALTHCARE CONSULTING

CDC Flier Insulin Pens

CDC CLINICAL REMINDER

Insulin Pens
Must Never Be Used for More than One Person

Summary

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Recommendations

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Insulin Pen Posters and Brochures Available

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

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

Insulin Pen Safety – One Insulin Pen, One Person

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)

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

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Memo on Four Infection Control Breaches

- Address breaches and when warrant referral to the public health authorities
- Includes a finding by the state agency (SA) or an accreditation organization
- CMS list breaches to be referred
- Referral is to the state authority:
  - State epidemiologist or State HAI Prevention Coordinator

Memo on Infection Control Breaches

- Same needle for more than one individual
- Same syringe, pen or injection device for more than one individual
- Re-using a needle or syringe subsequently entering a container then using contents for another individual
- Same lancing/fingerstick device on more than one individual

CRE and ERCP Scopes

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

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

DATE: **April 3, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

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

Memo on Safe Injection Practices

- Entries into a SDV for repackaging must be completed within 6 hours of initial puncture
  - Follow USP guidelines
  - Only time SDV can be used on multiple patients
- Any other use is a violation of CDC standards
- Will be cited under infection control standards
  - Also includes ASCs, hospice, LTC, home health, CAH, dialysis, etc.

Not All Vials Are Created Equal

SINGLE-DOSE OR MULTI-DOSE?

NOT ALL VIALS ARE CREATED EQUAL.

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

This information can literally save a life.

ONEANDONLYCAMPAIGN.ORG

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Memo on Safe Injection Practices

- Must follow nationally recognized standards of care
  - CDC guidelines
    - SDV typically lack an antimicrobial preservative
    - Once entered – can support the growth of microorganisms
- The vials must have:
  - Beyond use date (BUD)
  - Storage conditions on the label
- If made in a single dose vial – must buy it in a single dose
  - If only in multi-dose – use on one patient only

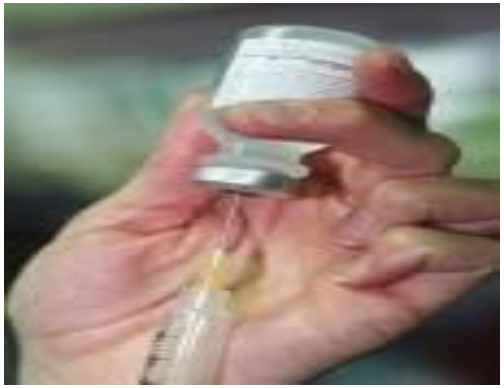
Memo on Safe Injection Practices – cont'd

- Mark multi-dose expired in 28 days
  - Less if manufacturer says
- Do not take multi-dose vials into the patient's room or operating room
- Clean the top for 10-15 seconds with alcohol
- If repackaged by off-site vendor or compounding facility - ask for evidence adhered to 797 standards

Question 1

- Our facility requires education on infection control practices regarding IV medication for:
- All Staff
- All providers and staff

ISMP IV Push 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)

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

NASH HEALTHCARE CONSULTING

IV Push Medications Guidelines

- Provide in a ready to administer form
- Use only commercially available or pharmacy prepared prefilled syringes of IV solutions to flush and lock vascular access devices
- Buy in single dose vial
- Aseptic technique used in preparation
  - Includes hand hygiene before and after administration

IV Push Medications Guidelines – cont'd

- Diaphragm disinfected – even new
  - Clean top with sterile approved antiseptic
  - Let dry for at least ten seconds
- Glass ampule - use filter needle
  - Unless specific drug precludes such
- Medication only diluted when recommended by the manufacturer
  - In per evidence-based practice or approved hospital policies

IV Push Medications Guidelines – cont'd

- If dilution/reconstitution required –
  - In clean, uncluttered, separate location
- Medication should not be withdrawn from a commercially available syringe into another syringe for administration
- Medication should not be drawn up into commercially prepared prefilled 0.9% saline flushes
  - These flush an IV line and are not approved to use to dilute medication

IV Push Medications Guidelines – cont'd

- Combining medications seldom necessary and may result in changes to the medication
- Never use IV solution or mini bags
  - As a common source to flush an IV
  - Dilutant for more than one patient
- Label syringes – unless prepared and immediately given
- Administer medication at rate recommended by manufacturer
  - Or per 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%)
  - Results from reliance on only sliding scale to control
    - Failure to increase to control blood sugar
    - Dosing errors
    - Omissions

ISMP's 2020 – 2021 Best Practices *

- #5 Purchase oral liquid dosing devices (oral syringes/cups/droppers) in metric scale such as ml
- #15 Verify and document patient's opioid status and type of pain before prescribing
- #16 Restrict overrides in ASC to emergently needed meds and monitor

* Information available at www.drugtopics.com/latest/ismp-unveils-2020-2021-best-safety-practice-updates-ashp-midyear

GUIDELINES

Targeted Medication Safety Best Practices for Hospitals

February 21, 2020

The ***ISMP Targeted Medication Safety Best Practices for Hospitals (TMSBP)*** were developed to identify, inspire, and mobilize widespread, national adoption of consensus-based Best Practices for specific medication safety issues that continue to cause fatal and harmful errors in patients, despite repeated warnings in ISMP publications.

The Best Practice recommendations presented in this guidance document are based on error reports received through the ISMP National Medication Errors Reporting Program (ISMP MERP) and have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. This initiative was first launched in 2014 and is updated with additional Best Practices, as needed, every two years.

RELATED

Frequently Asked Questions (FAQs)

TMSBP Worksheet

ISMP Top 10 Medication Errors & Hazards*

- Extended-release opioids
- Not using smart infusion pumps with dose-error software
- Errors with Oxytocin
- Infusion pump hazards – outside rooms
- COVID-19 vaccine errors
- "Syringe pull-back" still utilized
- Dangerous admixtures outside pharmacy
- Med loss with small-volume infusions
- Wrong-route errors with tranexamic acid (look-alike vials)
- Error-prone abbreviations, symbols,

https://www.ismp.org/resources/start-year-right-preventing-these-top-10-medication-errors-and-hazards-2020

Table 1. Top 10 Medication Errors and Hazards from 2020

1	Prescribing, dispensing, and administering extended-release (ER) opioids to opioid-naïve patients
2	Not using smart infusion pumps with dose error-reduction systems (DERS) in perioperative settings
3	Errors with oxytocin
4	Hazards associated with positioning infusion pumps outside of COVID-19 patients' rooms
5	Errors with the COVID-19 vaccines
6	Use of the retrospective, proxy "syringe pull-back" method of verification during pharmacy sterile compounding
7	Combining or manipulating commercially available sterile products outside the pharmacy
8	Medication loss in the tubing when administering small-volume infusions via a primary administration set
9	Wrong route (intraspinal injection) errors with tranexamic acid
10	Use of error-prone abbreviations, symbols, or dose designations

CMS Three Worksheets: Discharge Planning, Infection Control and QAPI

Hospital Worksheets

- 3 worksheets:*
  - Discharge planning
  - Infection control
  - QAPI (quality assurance performance improvement)
- Some questions asked not apparent by reading CoPs
  - Worksheets are a good communication device
- Consider a team - review and complete as a **self assessment**

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Discharge Planning Worksheet

Section 2 Discharge Planning – Policies and Procedures		
Elements to be assessed		**Surveyor Notes**
2.1 Implementation of discharge planning policies and procedures for inpatients:		
2.1a For every inpatient unit surveyed is there evidence of applicable discharge planning activities?	☐ Yes ☐ No	
2.1b Are staff members responsible for discharge planning activities correctly following the hospital's discharge planning policies and procedures?	☐ Yes ☐ 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?	☐ Yes ☐ No	
If yes, check all that apply: ☐ Same day surgery patients ☐ Observation patients who are not subsequently admitted ☐ ED patients who are not subsequently admitted ☐ Other		
2.3 Is a discharge plan prepared for each inpatient?	☐ Yes, skip to question 2.8 ☐ No, go to question 2.4	
NOTE: No citation risk related to responses to questions 2.2 and 2.3; for information only.		

Page **2** of **15**

Infection Control Worksheet

Module 1: Infection Prevention Program

Section 1.A. Infection Prevention Program and Resources

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

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.)	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ 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.	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO
2.1.c Is the method (e.g., chart reviews, monthly observations, etc.) and frequency of data collection specified?	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO

CDC Vaccine Storage and Handling

Vaccine Storage and Handling Toolkit *

- No dorm like refrigerators
  - Temperature revised: 36 and 46 degrees (previously 35-46 degrees F)
  - State may have specific requirements
- Use a medical (biological) refrigerator
  - Monitors temperature
  - Set at mid range (40 degrees)

* Toolkit - See appendix

Vaccine Storage and Handling Toolkit

- Educate staff on storage and handling P&Ps
  - Document training
  - In orientation and annually
  - When new vaccines added to inventory
- Keep standard operating procedures (SOP) for storage and handling near storage units *
  - Will help staff to ensure vaccines are properly managed
- E-mail specific questions to CDC: NIPInfo@cdc.gov

*At A Glance Resource in Appendix

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Non-Discrimination, Interpreters: Compliance with Section 1557

Introduction to OCR Section 1557

- Some provisions in OCR 1557 overlap with CoPs
- CMS proposed additional sections to the CoPs
  - Not added in final rules
- Surveyor can punt an issue directly to OCR if they observe a violation

OCR Section 1557

- Two separate signs required
  - Posted in places like the ED, OB, admitting, etc.
- Required:
  - Translation services available at no charge to patient
  - Person to handle any complaints and must be in their job description (2020 changes)
    - A policy on such
    - Staff educated on the policy
    - Staff are competent
- FYI – EMTALA has separate required sign

Nondiscrimination Provision

- Section 1557 is the part in the Affordable Care Act (ACA)
  - Addresses the non-discrimination law
- Prohibits discrimination based on race, color, national origin, sex, age, or disability in certain health programs and activities
- Builds on longstanding non-discrimination rights and adds new civil rights protections

Final Changes

- Judge: cannot force hospital to perform abortions if against religious beliefs
- OCR returned to previous position: “sex” in the federal law does not refer to gender identity
- Provision on termination of pregnancy conflicted with OCR 1557 so rewritten to follow the Judge’s ruling

Non-discrimination Law

- Enhanced language assistance for patients with limited English proficiency (LEP)
  - Interpreters must be qualified
- Must make sure patients have auxiliary aids

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Examples of Auxiliary Aids and Services

- Large print materials and copies of things such as patient rights, consent form, etc.
- TDD phones for the hearing impaired (text telephone)
- White boards for intubated patients to write on
- Lighted magnifying glasses for patients with impaired vision
- Closed captioned on the TV for hearing impaired
- Telephone handset with amplifier

Examples Aids and Services – cont'd

- Qualified interpreters both onsite and through high functioning video remote interpreting
- Braille materials and displays
- Optical readers and screen reader software
- Qualified readers
- HHS also mentioned other services:
  - Voice, text, and video-based telecommunication products
  - Accessible electronic and information technology
  - Computerized assisted transcription services

Compliance with Section 1557

- Must post a sign so patients come in places like admitting and the emergency they can see it
  - OCR has a sample notice
  - Train all staff
    - Make sure staff aware of policy and procedure
- Post a sign in 15 languages – taglines: interpreting services available at no charge
  - OCR has a list for each state of the 15 top languages
  - 4 states and DC have 17: CO, MD, RI, VA
- Have a person in charge to handle any grievances

List 15 Top Language Spoken in Every State

Resource for Entities Covered by Section 1557 of the Affordable Care Act
Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency for the 50 States, the District of Columbia, and the U.S. Territories.

Covered entities may use this information to implement the tagline requirement at § 92.8(d)(1)-(2) of the Section 1557 rule (45 C.F.R. pt. 92), although nothing in the rule requires a covered entity to use this particular resource. For more information about this resource and the data used, refer to the Frequently Asked Questions on these topics.

Rank	State	Language	Estimate
1	AL	Spanish	75,000
2	AL	Chinese	5,405
3	AL	Korean	4,554
4	AL	Vietnamese	3,708
5	AL	Arabic	1,440
6	AL	German	1,411
7	AL	French	1,278
8	AL	Gujarati	888
9	AL	Tagalog	856
10	AL	Hindi	818
11	AL	Laotian	681
12	AL	Russian	586
13	AL	Portuguese	516
14	AL	Turkish*	505
15	AL	Japanese	484
1	AK	Tagalog	7,021
2	AK	Spanish	5,975

www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/top15-languages/index.html

Question 2

Recently we have had difficulty finding qualified interpreters for our LEP patients. To substitute we:

- 1. Use only clinical staff who are fluent in the language
- 2. Use clinical staff only in an emergency then use an electronic/phone communication system
- 3. Use handwritten material the extent we can
- 4. Use the Language Line service

The CMS Hospital CoPs

Mandatory Compliance

- If participate in Medicare or Medicaid must meet the COPs for all patients
- Hospitals accredited by TJC, HFAP, CIHQ, or DNV Healthcare have deemed status
- Can get reimbursed without going through a state agency survey
  - States can still institute a survey and be more restrictive

Emergency Preparedness

- Now primarily Appendix Z
- E tag numbers
- Questions on Emergency Preparedness (EP): QSOG_EmergencyPrep@cms.hhs.gov

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Interpretive Guidelines

- A- Hospitals
- W-Critical Access Hospitals
- V-EMTALA
- Q-Determining Immediate Jeopardy
- C-Labs
- I-Life Safety Code Violations
- Z-Emergency Preparedness

CMS Required Education

- Restraint & seclusion (annual)
- Abuse, neglect and harassment (annual)
- Infection control
- Advance directive
- Timing of medications
- Safe opioid use and Medication P&P
- Radiology
- Ligature risks
- Medication errors
- Drug incompatibility and ADR
- Organ donation
- Standing orders & protocols
- IVs and blood and blood products P&P (competency)
- ED common emergencies
- IVs and blood and blood products for ED

Key Areas

- Life Safety Code Compliance
- Patient Rights especially R&S and grievances
- EMTALA
- Medication Management
- Medical record review
- Performance Improvement (QAPI)
- Dietary and cleanliness of dietary
- Emergency Preparedness

Key Areas – cont'd

- Infection control issues
- Verbal orders
- History and physicals
- Order for respiratory and rehab
- Order for diet, medications, and radiology
- Anesthesia
- Standing orders and protocols
- Medications within 3-time frames

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

§482.12 Condition of Participation: Governing Body

§482.13 Condition of Participation: Patient's Rights

§482.21 Condition of Participation: Quality Assessment and Performance Improvement Program

§482.22 Condition of Participation: Medical staff

§482.23 Condition of Participation: Nursing Services

§482.24 Condition of Participation: Medical Record Services

Survey Protocol

- Off-survey preparation
  - Entrance activities
  - Information gathering/investigation
  - Exit conference
  - Post survey activities

Survey Protocol – cont'd

- Done through observation, interviews, and document review
- Federal law allows CMS or Department of Health access
  - Risk losing reimbursement under Medicare and Medicaid
- CAH 10 bed rehab or behavioral health distinct units surveyed under section A
- Size of team will vary
- Can find condition or standard level deficiency

Compliance with Laws 20

- Must comply with all federal, state, and local laws
  - Will interview CEO or other designated by hospital
- Refer non-compliance to proper agency with jurisdiction
  - OSHA: TB, blood borne pathogen, universal precautions
  - EPA: hazardous material or waste issues
- Will ask if cited for any violation since last visit

Compliance with Laws 22, 23

- Must be licensed or approved for licensure
  - Personnel must be licensed or certified if required by state (doctors, nurses, PT, PA, etc.)
- If telemedicine: must be licensed in state where patient is located
- Will verify staff and personnel meet all standards required by state law
- Will review sample of personnel files

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Board and Medical Staff

Governing Body (Board) 43

- Must have:
  - An effective governing body
  - Legally responsible for the conduct of the hospital
  - Can share a board in hospital system
  - Written documentation that identifies an individual as being responsible
- Board ensures MS requirements are met
  - Which categories of practitioners are eligible for appointment to medical staff
  - As allowed by your state law

Board Responsibilities

- Are in the QAPI and antibiotic stewardship sections
- Result of the changes in Hospital Improvement Rule
- Consider adding requirements in the board book
- Educate board members about their responsibility for QAPI and infection control

Governing Body – Systems

- No survey of hospital “systems”
- Cannot just have one policy for the system
  - Exception: system wide QAPI or infection control
- Individual hospital can use a system’s policy
  - But must individually adopt it
  - Such as hospital A adopts the policy of XX Health System
- Must be clear – hospital elected to adopt a specific policy
  - Minutes need to be clear of one board for two hospitals

Governing Body – Systems – continued

- Each hospital must have their own CNO
- Cannot have one integrated nursing service department
  - Can have one CNO to run two hospitals
- System may choose to operate QAPI program at the system level
  - Each certified hospital must have its own PI data with adverse events and standardized indicators

Medical Staff and Board 44

- Board determines categories of practitioners eligible for appointment to the MS
  - Physicians, dentists, podiatrists, chiropractors, optometrists
  - Grant privileges and be appointed to the MS
  - Non-physicians include PA, NP, CNS, CNM, CRNA, CSW, clinical psychologist, AA, clinical pharmacist, RD or nutrition specialist
  - Others may be eligible for privileges depending on state law and MS bylaws and R/R

Medical Staff and Board – continued

- Board
  - Appoints individuals to the MS with the advice and recommendation of the MS (Tag 46)
  - Ensures MS has bylaws which complies with the CoPs (Tag 47)
  - Ensure approval of MS bylaws and rules and regulations (Tag 48) and any changes
  - Ensure MS is accountable to the board for the quality of care provided to patients (49)

Medical Staff and Board – continued

- All care given to patients must be by or in accordance with the **order** of practitioner who is operating within privileges granted by the Board
  - Need order for any medications
  - Need to document the order – even if protocol
    - ED nurse starts IV on patient with chest pain and documents it in the order sheet

Board and Medical Staff – continued

- Board ensures criteria for selection of MS members is based on: (Tag 50)
  - MS privileges describe privileging process and ensure there is written criteria for appt to MS
  - Individual character, competence, training, experience and judgment
  - Make sure under no circumstances staff membership/ privileges based solely on certification, fellowship, or membership in a specialty society (Tag 51)

Medical Staff

- Hospitals can more fully utilize other practitioners' skills
  - NP, PharmD, or RD
- Podiatrist could serve as president of the MS
- Others C&P must follow the MS bylaws and R/R
- Can have categories in Medical Staff (MS) but MS must still examine credentials

Medical Staff

- Medical staff must
  - Conduct appraisals of practitioners at least every 24 months
  - Examine each practitioner's qualifications and competencies to perform each task, activity, or privilege
  - Includes current work, specialized training, patient outcomes, education, currency of compliance with licensure requirements

Board and the Medical Staff

- Must consult directly with the individual assigned the responsibility for the organization and conduct of the Medical Staff or designee
  - Usually chief medical officer (CMO) or President of the MS
- Must occur periodically throughout the year
  - CMS recommends at least twice a year
- Must include matters related to quality of the medical care provided
  - If multi-hospital system must consult directly with each CMO

Unified and Integrated Medical Staff

- Must be allowed by state law and established P&P
  - Consistent with MS bylaws
- MS must have voted and passed by a majority vote
- Can occur if part of a hospital system consisting of separately certified hospitals
  - Must describe the process for self governance, peer review, appointment, C&P, oversight, due process etc.

Telemedicine 52

- Medical staff makes a recommendation to use a distant site to C&P physicians
- Board agrees and must enter into agreement with distant site hospital (DSH) or distant site telemedicine entity (DSTE)
  - Must be licensed in that state
  - Provide evidence of C&P and copy of privileges

Telemedicine – continued

- Hospital can rely on the C&P decision of the DSH or DSTE
- The hospital must report to the distant site any complaints or adverse events
- Can have one file with all telemedicine physicians or separate files
- Surveyor will look at documentation:
  - Granted privileges to each telemedicine physician or
  - Relied on the distant site entity to do this

CEO 57

- Board must appoint
  - Responsible for managing the hospital
- Surveyor will verify
  - CEO is responsible for managing entire hospital
  - Board has appointed a CEO
- TJC in the leadership standard has more detailed information on the role of the CEO

Care of Patients 63-68

- Board must make sure every patient under the care of a doctor
  - Or: dentist, podiatrist, chiropractor, psychologist, et. al.
  - Practitioners must be licensed and a member of MS
- LIPs (now LPs) can admit
  - Still need to see evidence of being under care of MD/DO
  - If state law allows
    - Needs policies and bylaws to ensure compliance
  - Exception: separate federal law where no supervision required by midwives for Medicaid patients

Care of Patients – continued

- Evidence of being under care of MD/DO must be in the medical record
- Board and MS establish P&P and bylaws to ensure compliance
- Board must always ensure doctor on duty or on call
  - Doctor of medicine or osteopathy is responsible for monitoring care M/M patient
- Will interview nurses:
  - Able to call the on-call MD/DO and they come to the hospital when needed

Care of Patients – continued

- Must have policies to ensure Medicare patient
  - Monitored by MD/DO who is responsible for any care
  - Outside the scope of practice of the admitting practitioner
- Patient admitted by:
  - Dentist/Dental Surgeon
  - Chiropractor – limited to manipulations
  - Podiatrist
  - Optometrist
  - Clinical Psychologist
  - As allowed by state law

Institutional Plan and Budget 73-77

- Annual operating budget with all anticipated income and expenses
- Provide for capital expenditures for 3-year period
- Identify sources of financing
  - For acquisition/ improvement of land, buildings and equipment
- Must be submitted for review
  - TJC has similar standards in its leadership chapter

Institutional Plan and Budget – continued

- Include acquisition of land and improvement to land and building
- Reviewed and updated annually
- Be prepared under direction of board and a committee of representatives from the Board administrative staff, and MS (Tag 77)
  - Verify that all 3 participated in the plan and budget

Contracted Services – Board Responsibilities

- Board responsible for services provided in hospital (Tag 83)
  - Whether provided by hospital employees or under contract
- Must act under hospital's QAPI program to assess services
  - By employees and under contract
- Identify quality problems and ensure monitoring and correction of any problems

Contracted Services – continued

- Ensure contracted services performed in a safe and efficient manner
  - Increased scrutiny on contracted services
- Review QAPI plan to ensure that every contracted service is evaluated
- Maintain a list of all contracted services (85)
- Contractor services must comply with CoPs
  - Consider adding section to all contracts to address CoP requirements

Emergency Services

Emergency Services

- EMTALA a separate CoP – Appendix V
  - Consider yearly education on **EMTALA**
- If have an Emergency Department (ED) must comply with this section
- If no ED services – Board must ensure hospital has written P&P for emergency services

Emergency Services

- Qualified RN able to assess patients
- MS P&P on how to address emergency procedures
- P&P when patient's needs exceed hospital's capacity
- P&P on appropriate transport
- Train staff on what to do in case of an emergency
- Should not rely on 911
  - Need trained staff to respond to the code or emergency

Emergency Services

- If emergency services are provided at the hospital but not at off-campus department(s)
  - Need P&P on what to do when have an emergency
  - Stabilize and treat patient etc.
  - Call 911 (off campus only!)
  - Provide care consistent with ability
  - Includes visitors, staff and patients
  - Ensure staff are oriented to the policy

Medical Records: Patient Rights & Access

Patient Rights

- In discharge planning standards 2019 and IGs 2020
- Section that emphasizes patient's right of access
  - In timely manner
- OCR fining hospitals for access violations
- Covers difference between a patient request for records and when need a HIPAA compliant authorization form
- CMS reminds hospitals to follow the OCR documents and notes many hospitals are not aware

OCR Rights of Patients

- OCR issued a FAQ on cost and access
- Patients who do not get their records timely can file a complaint with OCR
  - One in every 10 complaints related to not getting records or not getting them timely
- OCR is now fining hospitals and providers who fail to provide records timely

OCR Settles First Case in HIPAA Right of Access Initiative

www.hhs.gov/about/news/2019/09/09/ocr-settles-first-case-hipaa-right-access-initiative.html

Today, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services is announcing its first enforcement action and settlement in its Right of Access Initiative. Earlier this year, OCR announced this initiative promising to vigorously enforce the rights of patients to receive copies of their medical records promptly and without being overcharged.

Bayfront Health St. Petersburg (Bayfront) has paid $85,000 to OCR and has adopted a corrective action plan to settle a potential violation of the right of access provision of the Health Insurance Portability and Accountability Act (HIPAA) Rules after Bayfront failed to provide a mother timely access to records about her unborn child. Bayfront, based in St. Petersburg, Florida, is a Level II trauma and tertiary care center licensed as a 480-bed hospital with over 550 affiliated physicians.

OCR initiated its investigation based on a complaint from the mother. As a result, Bayfront directly provided the individual with the requested health information more than nine months after the initial request. The HIPAA Rules generally require covered health care providers to provide medical records within 30 days of the request and providers can only charge a reasonable cost-based fee. This right to patient records extends to parents who seek medical information about their minor children, and in this case, a mother who sought prenatal health records about her child.

"Providing patients with their health information not only lowers costs and leads to better health outcomes, it's the law," said OCR Director Roger Severino. "We aim to hold the health care industry accountable for ignoring peoples' rights to access their medical records and those of their kids."

In addition to the monetary settlement, Bayfront will undertake a corrective action plan that includes one year of monitoring by OCR. The resolution agreement and corrective action plan may be found at: https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/bayfront/index.html

2nd OCR Fine On Access to Medical Records

FOR IMMEDIATE RELEASE
December 12, 2019

Contact: HHS Press Office
202-690-6343
media@hhs.gov

OCR Settles Second Case in HIPAA Right of Access Initiative

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services is announcing its second enforcement action and settlement under its HIPAA [1] Right of Access Initiative. OCR announced this initiative earlier this year promising to vigorously enforce the rights of patients to get access to their medical records promptly, without being overcharged, and in the readily producible format of their choice. Korunda Medical, LLC (Korunda) has agreed to take corrective actions and pay $85,000 to settle a potential violation of HIPAA's right of access provision. Korunda is a Florida-based company that provides comprehensive primary care and interventional pain management to approximately 2,000 patients annually.

In March of 2019, OCR received a complaint concerning a Korunda patient alleging that, despite repeatedly asking, Korunda failed to forward a patient's medical records in electronic format to a third party. Not only did Korunda fail to timely provide the records to the third party, but Korunda also failed to provide them in the requested electronic format, and charged more than the reasonably cost-based fees allowed under HIPAA. OCR provided Korunda with technical assistance on how to correct these matters and closed the complaint. Despite OCR's assistance, Korunda continued to fail to provide the requested records, resulting in another complaint to OCR. As a result of OCR's second intervention, the requested records were provided for free in May 2019, and in the format requested.

"For too long, healthcare providers have slow-walked their duty to provide patients their medical records out of a sleepy bureaucratic inertia. We hope our shift to the imposition of corrective actions

14th Fine/ Investigation for Access Violation

HHS Office for Civil Rights in Action

January 12, 2021

OCR Settles Fourteenth Investigation in HIPAA Right of Access Initiative

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services announces its fourteenth settlement of an enforcement action in its HIPAA Right of Access Initiative. OCR announced this initiative as an enforcement priority in 2019 to support individuals' right to timely access their health records at a reasonable cost under the HIPAA Privacy Rule.

Banner Health, on behalf of the Banner Health affiliated covered entities (Banner Health ACE), has agreed to take corrective actions and pay $200,000 to settle potential violations of the HIPAA Privacy Rule's right of access standard. Banner Health is a non-profit health system based in Phoenix, Arizona. Banner Health operates 30 hospitals and numerous primary care, urgent care, and specialty care facilities and is one of the largest health care systems in the United States.

OCR received two complaints filed against Banner Health ACE entities alleging violations of the HIPAA Right of Access standard. The first complaint alleged that the individual requested access to her medical records in December 2017, and did not receive the records until May 2018. The second complaint alleged that the individual requested access to an electronic copy of his records in September 2019, and the records were not sent until February 2020. OCR's investigations determined that Banner Health ACE's failure to provide timely access to the requested medical records were potential violations of the HIPAA right of access standard.

"This first resolution of the year signals that our Right of Access Initiative is still going strong and that providers of all sizes need to respect the right of patients to have timely access to their medical records," said OCR Director Roger Severino.

In addition to the monetary settlement, Banner Health will undertake a corrective action plan that includes two years of monitoring. A copy of the resolution agreement and corrective action plan may be found at https://www.hhs.gov/sites/default/files/banner-racap.pdf.

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Question 3

Our medical records department gets frequent requests from patients who are still inpatients but want to see their medical records daily. We do not give them access to the entire record – only select portions. Is this a concern?

- Yes
- No
- Not sure

The CMS Hospital CoPs on Medical Records

Medical Record Services 431

- Standard: must have a MR service
  - Administrative responsibility for MR
- A medical record must be maintained for every individual treated or evaluated
  - One unified MR service responsible for all MR, both inpatient and outpatient
  - An administrator responsible
  - Surveyors will sample 10% of daily census and at least 30 records

Medical Record Services – continued

- MR on every patient – cont'd
  - Even if request not to bill, hospital must still maintain a medical record on the patient
  - If leaves AMA or before being seen – still need medical record
- Chapter standards apply to radiology films and scans, pathology slides, computerized information, etc.
- HIM department structured to meet the needs of the hospital and patients

Staffing of Medical Records 432

- Organization must be appropriate for size
- Must employ adequate personnel to ensure prompt completion, filing, and retrieval
- Must have proper education, skills, qualifications and experience to meet state and federal law
- Ensure proper coding and indexing of records
- Surveyor will look at job descriptions and staffing schedules

Retention of Record 438

- For each patient
  - Both inpatients and outpatients
- Must be accurate, complete, retained and accessible
  - Accessible 24 hours a day
- Use a system of author identification
  - Protect security of all records
- Protected from fire, water damage and other threats

Medical Records

- Completed promptly – within 30 days
- Kept at least 5 years (439)
  - Original, microfilm, computer memory or other electronic storage
  - CAH is 6 years
- Certain medical records may be longer
  - Required by state or federal law (OSHA, EPA, FDA)
  - Will request records from 48-60 months ago

Retrieval 440

- System of coding and indexing
  - Allows timely retrieval of MR
- Be able to retrieve by diagnosis and procedure
  - Support medical care studies
- Be accessible for departments when needed
  - Ex. – emergency department

Confidentiality 441

- Standard: procedure for ensuring confidentiality
  - Ensure unauthorized individuals cannot gain access or alter the medical records
- Copies only released to authorized individuals and written authorization by proper person
  - DPOA, guardian, etc.
  - Original – released only per court orders, subpoenas
    - Usually, will take a certified copy
- Need policy to ensure confidentiality
- Surveyor will ask for policy

Permitted Disclosures

- May use for payment or healthcare operations without the patient's authorization
  - Financial – legal – PI – activities of hospital to conduct business & support of core functions – case management – audit – medical reviews, fraud & abuse detection, etc.
- P&P must limit disclosure – minimum necessary
- Surveyor will observe to make sure MR protected

Content of Records 449

- Contain records, notes, reports assessment to justify:
  - Admission
  - Continued hospitalization
  - Support the diagnosis
  - Describe the patient's progress
  - Describe response to medications and to interventions, care, and treatment
- Records must be promptly filed in chart

Legible and Authenticated 450

- Entries legible, complete, dated and **timed**
- Authenticated by the person responsible for service
- Specify in MS or hospital policy who can make entries
- Need method to identify author
  - Plus – list of written signatures must be available

Legible and Authenticated – continued

- P&P for electronic medical records
- MS R&R address countersignature when required
- Section on standing orders (preprinted order sets)
  - Sign, date, and time the last page
  - Include total number of pages – i.e., page 3 of 3
  - Initial any changes, additions, or deletions

Medical Records

- Rubber stamp – signed statement only that individual will use it
  - CMS issued in a separate Program Integrity manual April 2010: stamps not allowed
- Electronic MR – must demonstrate how alterations prevented
- Cannot use auto authentication that says “not able to review as not yet transcribed”

Verbal Orders 454

- Any physician can sign a VO for another physician
  - On the case or practitioner responsible for care
  - If within scope and state law
- Person who takes VO:
  - Read back
  - Write it down with date and time
- When physician/LP authenticates and signs off
  - Must date and time

Verbal Orders – continued

- Sign off as required by state law
- If no state law
  - As required by your hospital P&P
    - Sign off ASAP
  - If state law designates 24 or 48 hours – must follow
  - Otherwise – no longer than 48 hours
  - Many hospitals sign off within 30 days
  - However – must still sign off, date and time the entry

Standing Orders 457

- Hospitals can use preprinted and electronic standing orders, order sets, and protocols only if:
- #1 Must be reviewed and approved by MS, nursing & pharmacy leadership before use in clinical setting
  - P&P address how it is developed, approved, monitored, initiated by staff and signed off or authenticated and orient new staff on standing orders
  - Must have specific criteria identified in the protocol for the order for a nurse or other staff to initiate
    - Such as a specific clinical situation, patient condition or diagnosis
- Must include process for authentication

Minimum Requirements – continued

- #2 Hospital must document standing order is consistent with nationally recognized and evidenced based guidelines
  - Burden is on the hospital to show there is sound basis for the standing order

POTENTIAL STANDING ORDERS

Immunizations	Influenza, pneumococcal, human papilloma virus
Screening tests	Mammograms, fecal occult stool cards, bone density scans
Routine labs for chronic disease monitoring	Diabetes, hypertension, hypothyroidism
Point of care testing	Rapid strep test, urine dip, urine pregnancy
Routine refills for chronic disease medications	Hypertension, cholesterol, hypothyroidism, contraceptives (if patient is up-to-date on pertinent labs and visits)
Referrals	Routine colonoscopy and diabetic eye exams

Minimum Requirements – continued

- #3 Must be subject to periodic and regular review by
  - Medical Staff
  - Nursing leadership
  - Pharmacy leadership
  - To determine the continued usefulness and safety
- At a minimum – annual
- P&P address how to correct it, revise or modify

Minimum Requirement – continued

- #4 Must be added to the record at time of initiation or as soon as possible after the fact
- Ensure are dated, timed, and authenticated promptly in the medical record
  - By the ordering practitioner or other practitioner on the case
  - By non-physician if allowed by hospital policy, state law, the person state law scope of practice, and medical staff bylaws or rules and regulations

No Standard Definition

- CMS uses standing orders to include
  - Pre-printed orders
  - Electronic standing orders
  - Order sets
  - Protocols
- Recognizes the lack of standard definition may result in confusion

Menu Options

- Not all preprinted and electronic order sets are considered a standing order covered by this regulation
  - Where solely menu options
  - Actions cannot be initiated by staff – not a standing order
  - Options do not create an “order set/standing order”

Standing Order- Nurse Initiation

- However - where a nurse can initiate without a prior specific order
  - Policy and practice must meet these regulations
    - Does not matter what it is called
  - Must meet certain pre-defined clinical situations
  - EX – emergency response or part of an evidenced-based treatment where it is NOT practical for a nurse to obtain a written order or verbal order
- Hybrids still require compliance with this section
  - Order set has a protocol for nurse initiated such as KCl

Other Requirements

- Must be well-defined clinical situations with evidence to support standardized treatments
  - Appropriate use can contribute to patient safety and quality care
- Can be initiated as emergency response
- Can be initiated as part of an evidenced based treatment regime where not practicable to get a written or verbal order
- Must be medically appropriate – such as RRT

Examples

- Triage and initialing screening to stabilize ED patients presenting with symptoms of MI, stroke, asthma
- Post-operative recovery areas like PACU
- Timely provisions of immunizations

- HOWEVER – cannot be used when prohibited by state or federal law
  - EX: no standing orders on R&S

Order Menus

- Example:
  - Doctor or qualified practitioner picks from an order set menu
  - If treatment choices cannot be initiated by nurses or other non-practitioner staff
  - Then menus are not standing orders covered by this regulation
- Menu options does not create an order set subject to these regulations
- The physician has the choice not to use this menu and could create orders from scratch or modify it

1135 Waivers

- Authentication may occur later than 48-hours
- If for drugs – used infrequently
- Dated, timed and authenticated promptly
- Hospital may use pre-printed/electronic standing orders, etc.
- Requirement of completion within 30-days following discharge

CMS Changes to the Hospital H&P CoPs

Changes to H&Ps

- Changes in medical records, surgery and MS sections
- Changed H&P for healthy outpatients in hospitals and in ASCs (Not allowed in CAHs)
- Allows flexibility for pre-surgery or pre-procedure assessment vs. an H&P in selected surgeries and procedures
- Will amend the MR chapter, interpretive guidelines and survey procedures will be published

H&P Changes

- Medical Staff policy required
- Applies to **outpatient** surgery and procedures only
- The **pre-procedure or pre-surgery assessment** would still need to be documented in the chart
  - Examples: appropriate minor things like cataract surgery, YAG laser, or capsulotomy which involves minor sedation and is done under a local
  - Not required but an option for hospitals

H&P Changes – continued

- Policy must consider the following:
  - Age and diagnosis
  - Type and number of surgeries and procedures to be scheduled
  - Co-morbidities
  - Level of anesthesia required
  - National guidelines
  - Standards of practice for assessment of specific types of patients
  - Any applicable state laws

H&P Changes – continued

- The assessment completed and documented after registration but prior to the surgery or procedure
  - If assessment is done before registration, would need to be updated before the outpatient surgery or procedure
- Procedures are the ones the MS have decided do not need a H&P and need a policy on this
- Policy needs to indicate consideration of age, diagnosis, comorbidities, level of anesthesia etc.
  - Even if procedure on the list can still decide to do a H&P

H&P Changes – continued

- Still need to document any
  - Pre-existing medical conditions and
  - Appropriate test results in the medical record
  - Allergies and current medications
- ASC section mentioned NEJM study:
  - Many routine tests do not add value or reduce adverse medical events (CBC, U/A, CXR, EKG, clotting studies or chemistry panels) in patients undergoing cataracts or hernias
- Studies found for other ambulatory surgeries

History and Physicals

HISTORY AND PHYSICAL

PATIENT: BLACK, BRENDA
MRN: 33333
DATE: 04/04/2000

CHIEF COMPLAINT
"There is a bulge between my legs when I stand."

HISTORY OF PRESENT ILLNESS
This is a 34-year-old woman who is para 1-1-0-2. The patient states that when she is on her feet, a bulge comes out of the vagina between her legs. She does not have any significant problem with urinary tract control.

PAST HISTORY
Medical: Her general health has been reasonably good. Surgical: Positive for C-section x1.

MEDICATIONS
She is on Ortho-Novum birth control pills.

ALLERGIES
She is allergic to penicillin.

FAMILY HISTORY
Positive for hypertension in mother and diabetes in father.

History and Physical 458 and 461

- Repeats same provisions as in medical staff section
  - Tag number 358 and 359
- H&P done within 24 hours
  - Not older than 30 days old
  - On chart before patient goes to surgery
- PA and NP can do
  - If allowed by hospital and all state laws allow
  - Physician reviews and authenticates with date, time, and signature

H&P Admission

- Must be an updated entry in the medical record to reflect any changes
- Person who does the H&P must be licensed and qualified
  - Ex. – family physician does H&P 2 weeks ago for patient having CABG today
  - Surgeon would review, update, and determine if any changes since it was done and authenticate document

History and Physicals

- Can include in progress notes, a stamp sticker, check box, or entry on H&P form
- Should say “H&P was reviewed, the patient examined, and no change has occurred in the patient’s condition since the H&P was completed”
- Must be a complete H&P in the chart for every patient
  - Except in emergencies and can make entry in progress notes

History and Physicals – continued

- New regulation expands the number of categories of people who can do a H&P
  - If state law and the hospital allows a PA or NP may perform
- Physician still responsible for the contents
  - Must sign off the H&P when done by one of these allied health professionals
- Do PI to make sure all H&P are on the chart especially when the patient goes to surgery

Documentation of Assessment 462

- For patients who are not required to have a H&P but an assessment
- Assessment
  - Must be documented in the medical record
  - After registration but before the surgery or a procedure requiring anesthesia
  - Consistent with the Medical Staff bylaws and P&Ps
- Repeated in all five sections on H&P in medical records, medical staff, and surgery section

MR Must Contain 463 – 465

- Admitting diagnosis in chart (463)
- All consults and findings documented (464)
- Information must be promptly filed in the medical record, so staff has access to it (464)
- Must document
  - Complications
  - Hospital associated infections (HAI)
  - Unfavorable reactions to drugs and anesthesia (465)
- All practitioners should be aware to document complications and how to do this correctly

Informed Consent 466

- Three separate sections related to informed consent in
  - Patient rights
  - Medical record
  - Surgical services

- Properly executed informed consent for procedures and treatments specified by MS
- Need list of all surgeries and procedures
  - As defined now by ACS and AMA
  - With “yes” or “no”

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Minimum Elements

- Name of hospital
- Name of procedure or treatment
- Name of responsible practitioner performing the procedure/treatment
- Statement that benefits, material risks and alternatives were explained
- Signature of patient
- Date and time form is signed

Medical Records Section

- CMS has list of optional elements:
  - Name of practitioner who conducted informed consent discussion
  - Date, time and signature of person witnessing the patient's signing the form
  - Indication/listing of material risk discussed with patient/representative
  - Statement physician other than operating practitioners (residents) will be performing important tasks
    - Per hospital policy
  - Statement qualified practitioners will perform important parts of surgery/anesthesia within SOP

Medical Records Section

- Medical record must contain an informed consent for procedures and treatments
  - Specified as requiring informed consent
  - MS by-laws should address this
- Consider state laws requiring informed consent for invasive procedures
- Federal laws for research

List of Procedures

Procedure Name	Requires Consent
Ablations	Yes
Amniocentesis	Yes
Angiogram	Yes
Angiography	Yes
Angioplasties	Yes
Arthrogram	Yes
Arterial Line insertion (performed alone)	Yes
Aspiration Cyst (simple/minor)	No

Informed Consent Forms

- Required for all surgeries
  - Exception: emergencies
- All inpatients and outpatients
- For all procedures specified
- Reflect a process
- Form must follow policies
- Include state or federal requirements
- Contain minimum requirements (mandatory)

Survey Procedure

- Verify hospital has assured MS has list of procedures and treatments that require consent
- Verify informed consent forms contain six mandatory elements
- Compare the hospital standard informed consent form to the P&Ps to make sure consistent
- Make sure any state law requirements are included

Record Must Contain 467

- All orders, nursing notes, reports, medication records, radiology, lab reports, and vital signs
- Orders must be authenticated/signed off
- All reports of treatment which includes complications
- Any other information used to monitor the patient's condition

Discharge Summary 468

- All medical records must have:
  - Discharge summary with outcome of hospitalization
  - Disposition of the patient
  - Provisions for follow up care

Discharge Summary – continued

- Follow-up care includes
  - Post hospital appointments
  - How care needs will be met, and
  - Plans for home health care, LTC, hospice or assisted living
- Can delegate to NP or PA
  - If allowed by state law
  - Physician must authenticate, date and time it

Final Diagnosis 469

- Every medical record must have a final diagnosis
- Medical records must be completed within 30 days* (same as TJC)
  - NQF 2010 34 Safe Practices recommends discharge summaries be dictated at discharge and sent promptly to PCP
  - CMS discharge planning worksheets says PCP needs to have before first post hospital visit
- Includes inpatient and outpatient charts

* * 1135 waiver

Interoperability NEW 470

- New standard – 482.24(d)
- If hospital utilizes ***electronic medical record*** system must demonstrate:
  - System notification capacity is
    - Fully operational and used according to all State and federal statues and regulations
    - Per hospital's exchange of patient health information
  - System sends notification that must include at least:
    - Patient name
    - Treating practitioner's name
    - Sending instituting name

Notification Requirements

- Standard – cont'd
  - To extent permissible under applicable federal and state law and regulation
    - And not inconsistent with patient's expressed privacy preferences
  - System send notification directly or via intermediary at time of
    - Registration in emergency department
    - Admission to hospital inpatient service

Notification Requirements – continued

- Standard – to extent permissible – cont'd
  - System sends notifications immediately prior to or at time of
    - Discharge or transfer from ED
    - Discharge or transfer from hospital's inpatient services
- Guidelines
  - Document patient's refusal
  - May be multiple notifications
    - ED
    - Then admitted

Reasonable Effort NEW 471

- If use an EHR conformant with exchange standards – must demonstrate
- Has made a reasonable effort to ensure
  - System sends notice to
    - All applicable post-acute care services providers/suppliers
    - Plus – any practitioners/entities which need to receive notice of the patient's status for treatment, care coordination or quality improvement activities
      - Patient's established PCP
      - Patient's established primary care practice group/entity
      - Other practitioner or other group/entity, identified by the patient as the practitioner, or group/entity, primarily responsible for his/her care

Information Blocking

- Definition – unless required by law or meets an exception:
- A practice - likely to interfere with access, exchange, or use of electronic health information
- If by a provider – the provider knows that
  - Such practice is unreasonable
  - Likely to interfere with, prevent or materially discourage
  - Access, exchange or use of electronic health information

Excluded from Access – Rule Not Apply

- 1. Psychotherapy notes separated from rest of individual's medical record
- Recorded by HCP who is mental health professional
- Documenting or analyzing content(s) of conversation during private counseling session, group, joint or family session

Excluded from Access – Rule Not Apply

- 2. Information complied in reasonable anticipation of or use in:
  - Civil, criminal or administrative action proceeding
- Overall – 3 exceptions applicable to health care providers where not considered “blocking”
  - Result – can “block” patient access to electronic information
  - Must meet all applicable requirements and conditions at all relevant times

1. Preventing Harm Exception

- Must meet BOTH:
  - A *reasonable belief* practice will substantially
    - Reduce a risk of harm to a patient
    - That would otherwise arise from the access, exchange or use of the information
  - The practice must be *no broader than necessary*
    - Substantially reduce the risk of harm the practice implemented to reduce

Type of Risk

- Must meet *one* of the following*:*
  - Risk of harm must be determined on individual basis
  - Arises from data that is known or reasonably suspected
    - Misidentified or mismatched
    - Corrupt due to technical failure
    - Erroneous for another reason

Type of Harm

- Practice likely to/does interfere with access, exchange or use of EHI
  - 1) Implemented pursuant to individualized determination of risk of harm
  - 2) Information that references another person
  - 3) Interferes with a legally permissible access, exchange or use of EHI not pursuant to determination of risk of harm

  - BUT -

  - Is consistent with risk determined by the professional or from corrupt information

2. Privacy Exception

- Practice is implemented in a consistent and non-discriminatory manner
  - Conforms to policies and procedures
    - In writing
    - Specify criteria used to determine when precondition satisfied
    - Implemented with training on P&P
    - Documented on case-by-case basis criteria used to determine when
      - Precondition satisfied
      - Criteria not met
      - Reason why not met

Privacy Exception - continued

- Precondition relied on a consent/authorization
  - If provider received authorization/consent that does not satisfy all elements of the precondition must:
    - Give the person a consent/authorization that satisfies all required elements of precondition or assistance to satisfy all elements
    - Not improperly encourage/induce individual to withhold consent/authorization
    - Provider adopted uniform privacy policies and procedures to address restrictive preconditions

Privacy Exception - continued

- Denial of access when request under right of access {45 CFR 164.524(a)(1)}
- Request not to share information – unless required by law – provider may elect not to provide access, exchange or use of EHI if:
  - Individual requests provider not to provide access, etc, without improper encouragement or inducement of the request by the provider
  - Provider documents request w/n reasonable time frame
  - Practice consistent and non-discriminatory

Request Not To Share – continued

- Provider may terminate persons request for restriction to not provide access only if:
  - Person agrees to termination in writing or requests termination in writing
  - Person orally agrees to termination and agreement documented by provider
  - Provider informs person it is terminating agreement to not provide access to extent
    - Not prohibited by law
    - Only applicable to EHI create or received after provider informed person of termination

3. Security Exception

- Practice to interfere with access to EHI to protect security of the EHI is not blocking when:
  - Directly related to safeguarding confidentiality, integrity and availability of EHI
  - Tailored to specific security risk being addressed
  - Is implemented in a consistent, non-discriminatory manner
  - Organizational security policy has been implemented

4th Exception – Infeasibility Exception

- Is not blocking when not fulfilling a request to access EHI is due to infeasibility
- Conditions to be met:
  - Uncontrollable events – disasters, PHE, terrorists attack
  - Segmentation – cannot unambiguously segment the requested EHI from remaining electronic information
    - Cannot be made available due to individual's preference or by law
  - Infeasible under the circumstances (next slide)

Determination of Infeasibility

- In determining circumstances – does not consider whether manner requested would have
  - Facilitated competition with the provider
  - Prevented provider from charging fee/reduced fee

Infeasible Under Circumstances

- Type and purposes for which needed
- Cost to provider to comply in manner requested
- Financial/technical resources available to the actor
- Practice is non-discriminatory and provides same access, etc., to others with whom it has a business relationship
- Provider owns/has control over platform, exchange or network

Responding to Requests

- If provider does not fulfill a request for access, exchange or use of EHI for any reason must:
  - Provide written reason(s) why request infeasible
  - Within 10 *business days* of receipt of request

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Other Important Sections

- There are other important sections that pertain to health information management that are found in other sections of the CoP hospital manual
- There should be documentation in the medical record for the following;
  - Restraint and seclusion (50 pages of standards)
  - Medications
  - Pre- and post-anesthesia evaluations

Final Discussion

Coast Hospital requires an H&P be completed for all procedures, including pain management injections. Dr. Z is a long-standing member of the medical staff and performs limited services, such as trigger point injections. He has consistently refused to perform H&Ps in contradiction to hospital policy. Medical Staff has not taken steps to rectify with Dr. Z. Coast is up for state survey after complaints from 2 patients who had complications following injections. What, if any, citations might Coast receive?

- Informed Consent
- Medical Staff
- Medical Records

The End Questions???

- Lena Browning
- MHA, BSN, RNC-NIC, CSHA
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APPENDIX

- **Resources**
- **Internet Links**

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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

Admin Info: 20-05-Hospital/Psych

DATE: **January 13, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Informational Notice: Forthcoming Integration of the Psychiatric Hospital Program into the Hospital Program and State Operations Manual (SOM) Changes

Questions about Psych Hospitals: QSOG_PsychiatricHospital@cms.hhs.gov

Memorandum Summary

- **To improve the identification of quality issues, the Centers for Medicare & Medicaid Services (CMS) is in the process of integrating the psychiatric hospital program survey into the hospital program survey:** Currently the hospital and psychiatric hospital programs are reviewed separately for compliance with the Conditions of Participation. Our intent is to ensure psychiatric hospital services are evaluated in the context of the overall hospital program to better identify systemic quality issues.
- **Update and relocation of the Interpretive Guidelines for Psychiatric Hospitals:** The interpretive guidelines in SOM Appendix AA for the special psychiatric Conditions of Participation (CoPs) will be updated and relocated in the interpretive guidance for Hospitals in Appendix A. Appendix AA will be deleted.
- **Develop training to provide the necessary competencies for all State Survey Agency surveyors to evaluate compliance with the psychiatric hospital CoPs:** CMS is developing training to assist surveyors in identifying compliance with the special psychiatric hospital CoPs. Currently, the SA surveys the hospital requirements in all non-deemed psychiatric hospitals as well as during validation and complaint surveys of deemed psychiatric hospitals. Once the psychiatric program is moved to the hospital program, the hospital survey team will assess compliance with all requirements. All interpretive guidelines and survey procedures will be located in Appendix A.

New Regulations to Tag Numbers

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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

Ref: QSO-20-07-ALL

DATE: **December 20, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

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

Memorandum Summary

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

Background

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

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Hospital Improvement Rule

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

[Billing Code: 4120-01-P]

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

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

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Discharge Planning 201 Pages

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

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482, 484, and 485

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

RIN 0938-AS59

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

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

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CMS Memo on Texting #2

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

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

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

DATE: **December 28, 2017**

TO: State Survey Agency Directors

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.

Current Requirements

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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

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

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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.

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Legionnaires' Disease

Use water management programs in buildings to help prevent outbreaks

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

Language: English

Overview

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

Building owners and managers can:

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

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CDC Resource Slides

Centers for Disease Control and Prevention

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

Welcome

Office for State, Tribal, Local and Territorial Support

presents

CDC *Vital Signs* Town Hall

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

June 13, 2017

2:00–3:00 PM (ET)

Complaint Manual Update

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Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

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

DATE: **April 19, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

Post-Complaint Survey Procedure - Deemed Providers/Suppliers:

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

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

A. Full Survey After Complaint for Deemed Providers/Suppliers

Infection Control Breaches

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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

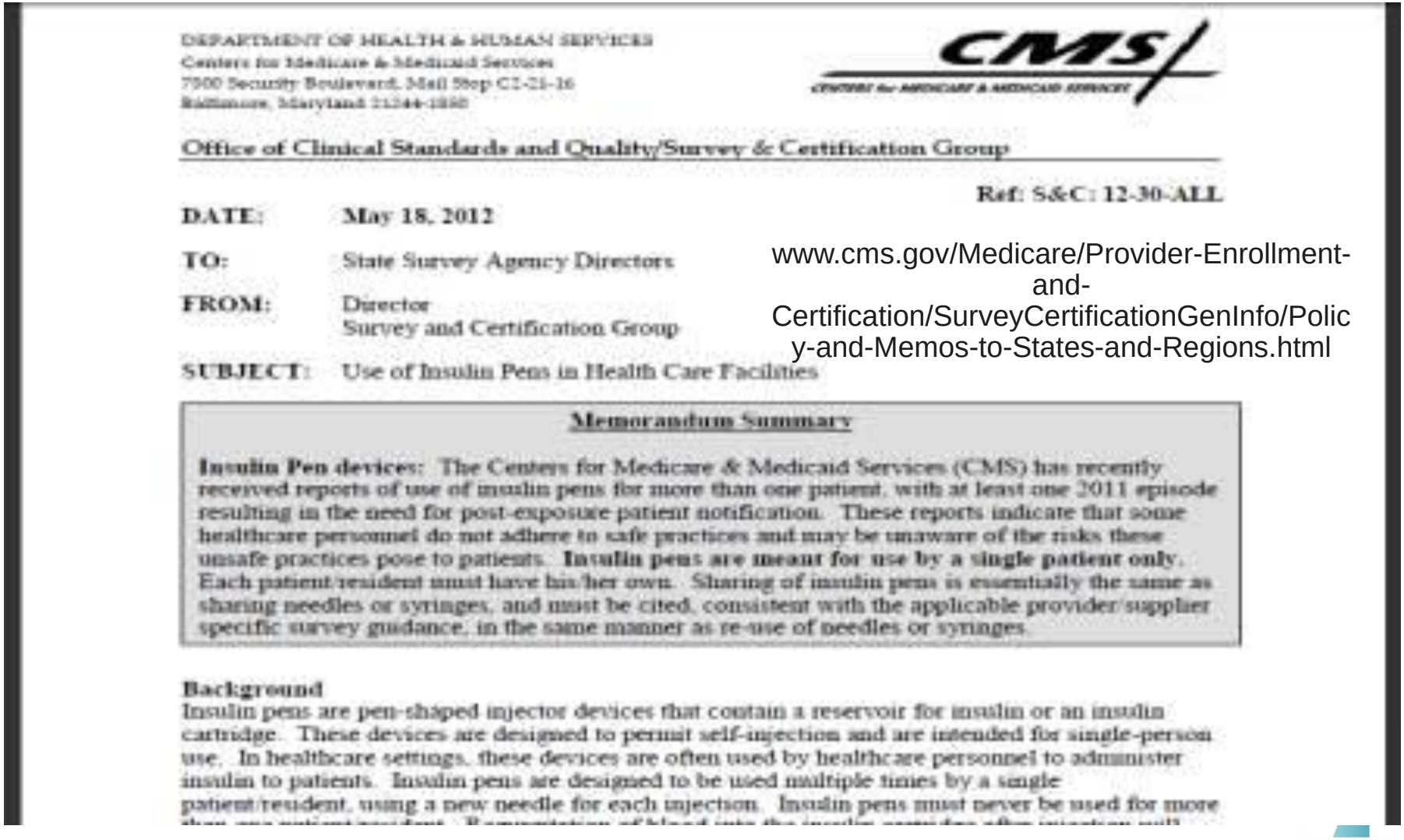
SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities

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

Insulin Pens



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Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-30-ALL

DATE: May 18, 2012

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Use of Insulin Pens in Health Care Facilities

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

Memorandum Summary

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

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

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

Insulin Pen Brochure

DON'T DO IT

Sharing Insulin Pens and Other Injection Equipment Jeopardizes Patients

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

A SIMPLE RULE

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

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

About the Safe Injection Practices Coalition

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

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

BE AWARE DON'T SHARE

ONE INSULIN PEN, ONLY ONE PERSON

What Every Healthcare Professional Needs To Know

ONE INSULIN PEN, ONLY ONE PERSON

Recommendations for Safe Insulin Pen Use

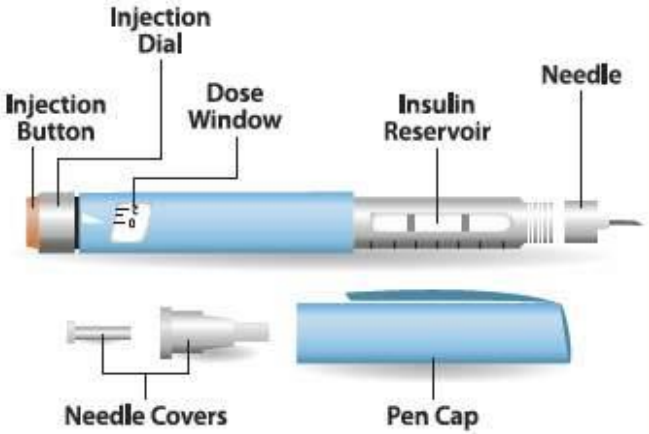
Protection from infection is a basic expectation anywhere healthcare is delivered. Use of insulin pens and other injection equipment for more than one person poses unacceptable risks and should be considered a "never" event.

- Insulin pens and other injection equipment containing multiple doses of medication are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens and other injection equipment should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

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

Insulin Administration

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection. They are intended for single-person use.



In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used for a single person multiple times, using a new needle for each injection.

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

The Safe Injection Practices Coalition created an easy to use check list for facilities. Similar to a risk assessment, the list contains the necessary components of injection safety for facilities to quickly assess their practices.

A copy of the checklist can be found at: www.cdc.gov/injectionsafety/Checklist

Single Dose Memo

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-35-ALL

DATE: **June 15, 2012**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

- *Under certain conditions, it is permissible to repackage single-dose vials or single use vials (collectively referred to in this memorandum as "SDVs") into smaller doses, each intended for a single patient:* The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, *Pharmaceutical Compounding - Sterile Preparations* ("USP <797>"). Under USP <797>, healthcare facilities may repackage SDVs into smaller doses, each intended for use with one patient. Among other things, these standards currently require that:
  - The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
  - All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process.
- *Administering drugs from one SDV to multiple patients without adhering to USP <797>*

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

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Advancing Practice

- Optimizing Antithrombotic Management: An Assessment Tool
- Bar Code Guide
- My Medicine List™
- Outsourcing Sterile Products Preparation: Contractor Assessment Tool
- Pharmacy Practice Model Initiative

Outsourcing Sterile Products Preparation: Contractor Assessment Tool

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Now available!

Preparation of sterile parenteral products is a critical component of health-system pharmacy practice. For departments that choose to outsource the preparation of parenteral medications, this web-based tool can be used to evaluate proposals during the selection of an external organization that would provide parenteral product preparation services.

The assessment tool helps you evaluate each of these areas:

- Regulatory compliance
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- Medication administration safety features
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www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx

NASH HEALTHCARE CONSULTING

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

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

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

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

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

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

www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit-2020.pdf

Vaccine Storage and Handling Toolkit

The toolkit has been updated for 2020 to clarify language including:

- Beyond use date (BUD)
- Routine maintenance for vaccine storage units
- New definition added to the glossary

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

January 2020

AT-A-GLANCE RESOURCE GUIDE

VACCINE ADMINISTRATION AND STORAGE AND HANDLING

IMMUNIZATION AND VACCINES (GENERAL)

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

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

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

"You Call the Shots" Online Training Modules

VACCINE STORAGE AND HANDLING

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

VACCINE ADMINISTRATION

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

Copy of OCR Final Changes Effective Aug 2020

This document is scheduled to be published in the Federal Register on 06/19/2020 and available online at **federalregister.gov/d/2020-11758**, and on **govinfo.gov**

4153-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 438, 440, and 460

Office of the Secretary

45 CFR Parts 86, 92, 147, 155, and 156

RIN 0945-AA11

Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority

AGENCY: Centers for Medicare & Medicaid Services (CMS); Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services ("the Department" or "HHS") is committed to ensuring the civil rights of all individuals who access or seek to access health programs or activities of covered entities under Section 1557 of the Patient Protection and Affordable Care Act ("ACA"). After considering public comments, in this

OCR has Sample Notice in English

Appendix A to Part 92—Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement:

Discrimination is Against the Law

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. [Name of covered entity] does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

www.hhs.gov/sites/default/files/sample-ce-notice-english.pdf

[Name of covered entity]:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

• Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact [Name of Civil Rights Coordinator]

If you believe that [Name of covered entity] has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: [Name and Title of Civil Rights Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email]. You can file a

grievance in person or by mail, fax, or email. If you need help filing a grievance, [Name and Title of Civil Rights Coordinator] is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services

200 Independence Avenue, SW

Room 509F, HHH Building

Washington, D.C. 20201

1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Appendix Z Emergency Preparedness

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 17-29-ALL

DATE: **June 02, 2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy- Appendix Z, Emergency Preparedness Final Rule Interpretive Guidelines and Survey Procedures

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

Memorandum Summary

- **Advanced Copy of Interpretive Guidelines:** The Centers for Medicare & Medicaid Services (CMS) is releasing a new Appendix Z of the State Operations Manual (SOM) which contains the interpretive guidelines and survey procedures for the Emergency Preparedness Final Rule.
- **Affects all 17 providers and suppliers:** Appendix Z applies to all 17 providers and suppliers included in the Final Rule.

Background

On September 16, 2016, the final rule on Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers was published (Federal Register Vol. 81, No. 180). This rule affects all 17 provider and supplier types eligible for participation in Medicare. The rule became effective on November 15, 2016 and will be implemented on November 15, 2017.

Updates to Emergency Preparedness

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: QSO19-06-ALL

DATE: **February 1, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

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

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

Memorandum Summary

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

Background

Regulations and Interpretive Guidelines

A-0001

New website for all manuals
www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.2 Provision of Emergency Services by Nonparticipating Hospitals

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if--

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e)(1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by non-participating hospitals are set forth in subpart G of part 424 of this chapter.

(b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

Interpretive Guidelines §482.2

The statutory requirements that a hospital must meet are:

OCR Issues

Individuals' Right under HIPAA to Access their Health Information 45 CFR § 164.524

Newly Released FAQs on Access Guidance

New Clarification – $6.50 Flat Rate Option is Not a Cap on Fees for Copies of PHI

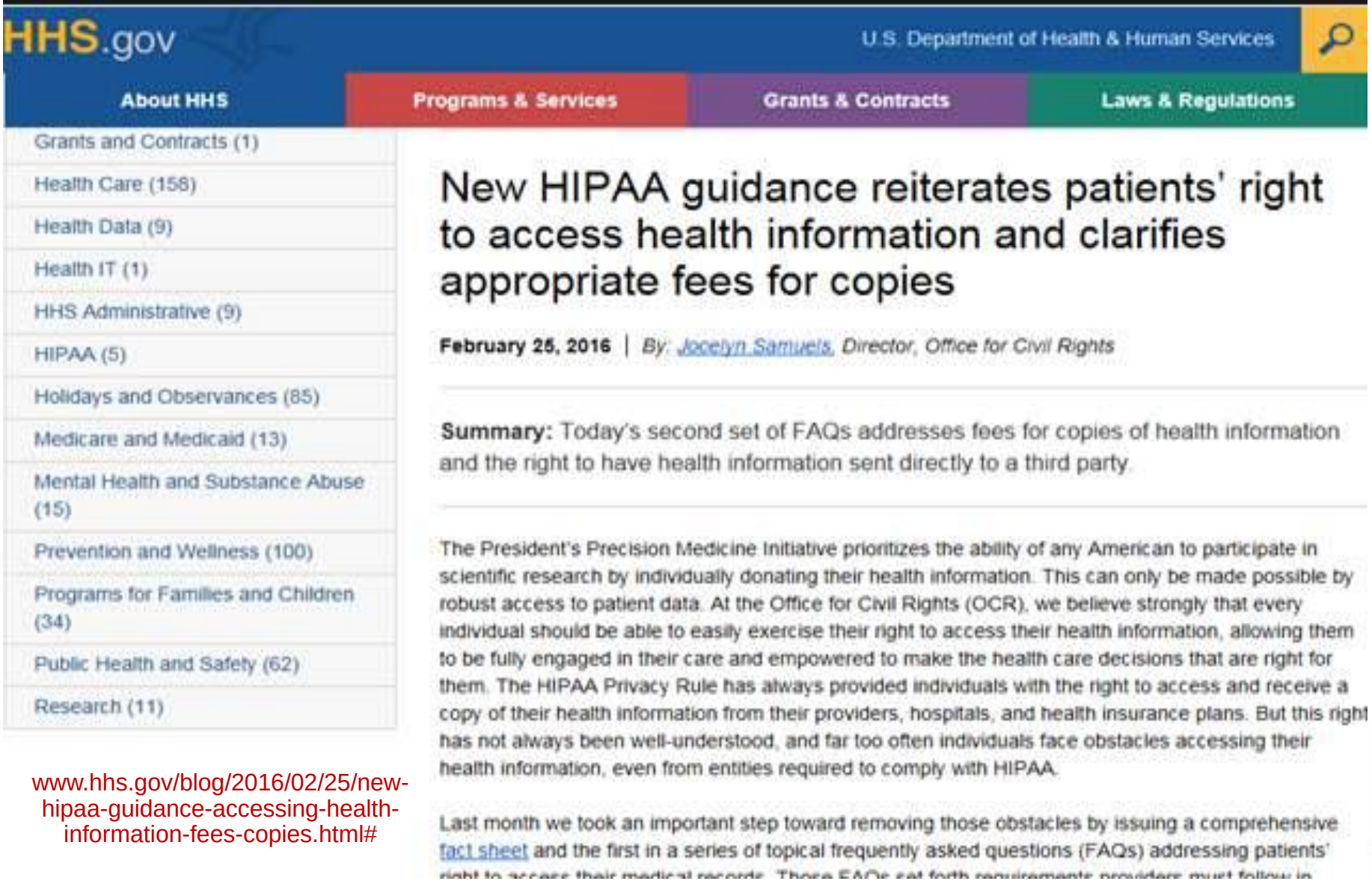
www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html#newlyreleasedfaqs

Introduction

Providing individuals with easy access to their health information empowers them to be more in control of decisions regarding their health and well-being. For example, individuals with access to their health information are better able to monitor chronic conditions, adhere to treatment plans, find and fix errors in their health records, track progress in wellness or disease management programs, and directly contribute their information to research. With the increasing use of and continued advances in health information technology, individuals have ever expanding and innovative opportunities to access their health information electronically, more quickly and easily, in real time and on demand. Putting individuals "in the driver's seat" with respect to their health also is a key component of health reform and the movement to a more patient-centered health care system.

The regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which protect the privacy and security of individuals' identifiable health information and establish an array of individual rights with respect to health information, have always recognized the importance of providing individuals with the ability to access and obtain a copy of their health information. With limited exceptions, the HIPAA Privacy Rule (the Privacy Rule) provides individuals with a legal, enforceable right to see and receive copies upon request of the information in their medical and other health records maintained by their health care providers and health plans.

Second FAQ Feb 2016 and Updated 2017



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New HIPAA guidance reiterates patients' right to access health information and clarifies appropriate fees for copies

February 25, 2016 | *By: Jocelyn Samuels, Director, Office for Civil Rights*

Summary: Today's second set of FAQs addresses fees for copies of health information and the right to have health information sent directly to a third party.

The President's Precision Medicine Initiative prioritizes the ability of any American to participate in scientific research by individually donating their health information. This can only be made possible by robust access to patient data. At the Office for Civil Rights (OCR), we believe strongly that every individual should be able to easily exercise their right to access their health information, allowing them to be fully engaged in their care and empowered to make the health care decisions that are right for them. The HIPAA Privacy Rule has always provided individuals with the right to access and receive a copy of their health information from their providers, hospitals, and health insurance plans. But this right has not always been well-understood, and far too often individuals face obstacles accessing their health information, even from entities required to comply with HIPAA.

Last month we took an important step toward removing those obstacles by issuing a comprehensive fact sheet and the first in a series of topical frequently asked questions (FAQs) addressing patients'

www.hhs.gov/blog/2016/02/25/new-hipaa-guidance-accessing-health-information-fees-copies.html#