Critical Access Hospital CoPs

Part 2 of 4

Physical Plant & Environment, Emergency Preparedness, Governing Board, Pharmacy and Dietary

Speaker

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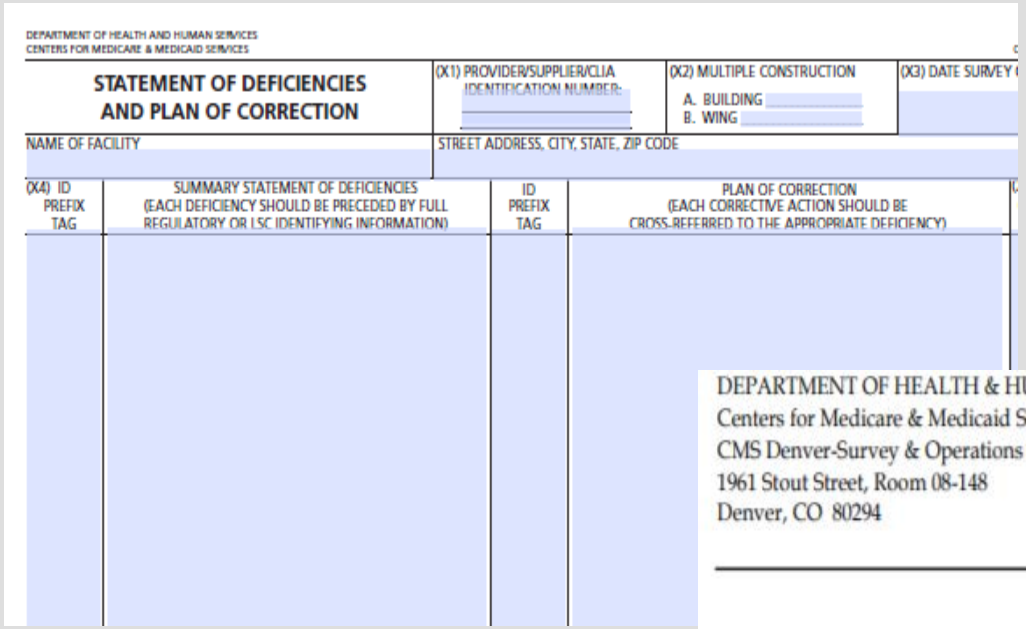
Why We are Here Today



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

A. BUILDING _____
B. WING _____

(X3) DATE SURVEY

NAME OF FACILITY

STREET ADDRESS, CITY, STATE, ZIP CODE

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-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.

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The Daily Journal of the United States Government

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

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Email Address *

SUBMIT CANCEL

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

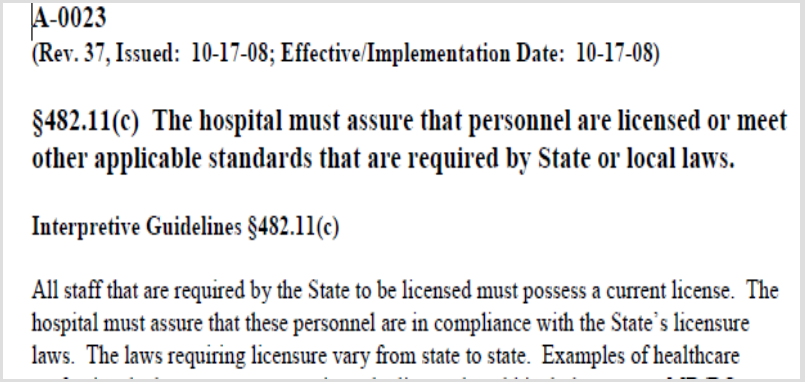
How to Keep Up with Changes

- Confirm current CoP [1].
- If new manual – check CMS transmittal page [2].
- Check the survey and certification website monthly [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/Transmittals
- 3 http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

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)

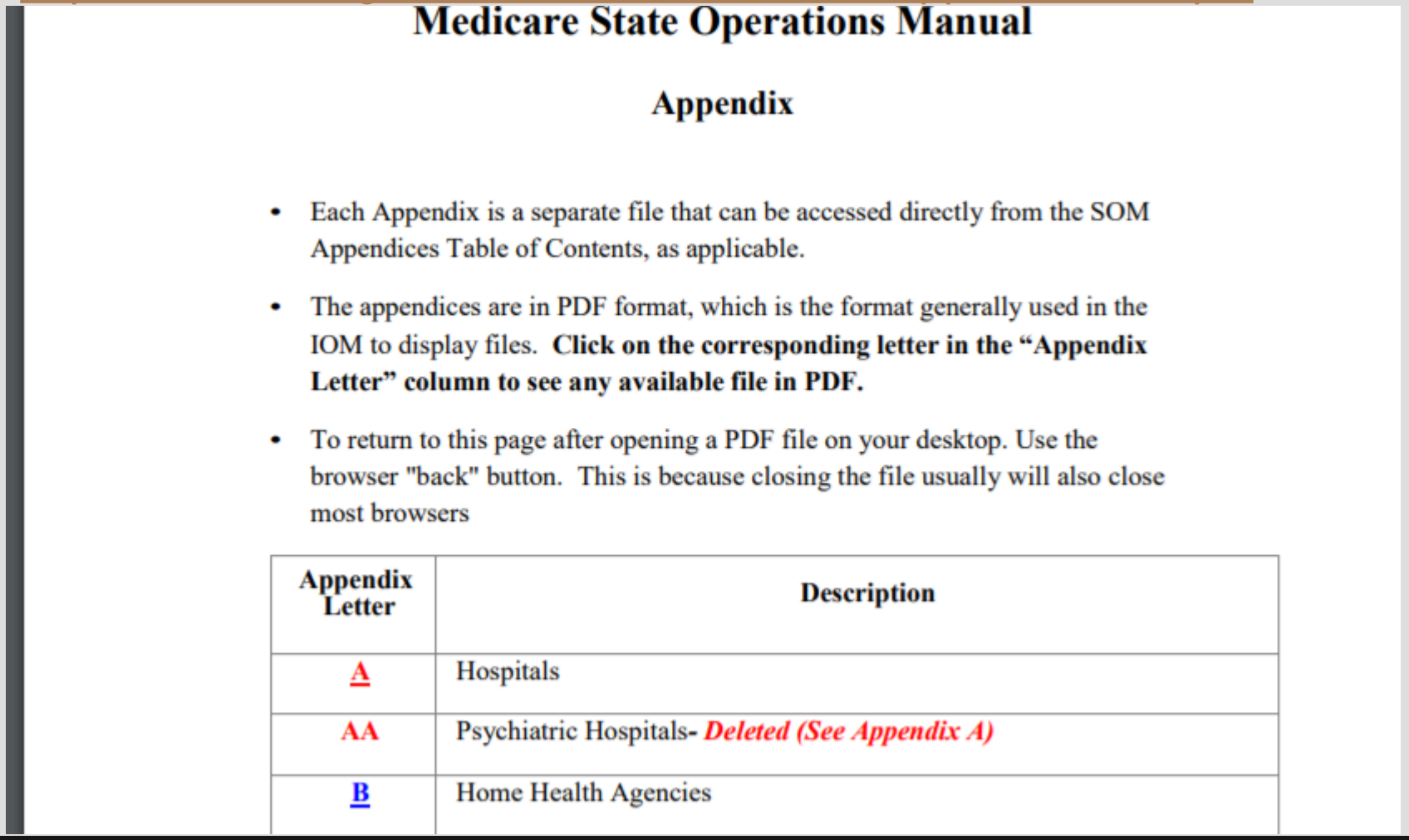
§482.11(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

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

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

CMS CoP Manual

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

State Operation Manual – Acute/PPS

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

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

State Operation Manual – Critical Access

State Operations Manual

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

(Rev. 200, 02-21-20)

Transmittals for Appendix W

INDEX

Survey Protocol

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 CRE and ERCP's

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

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

DATE: **April 3, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

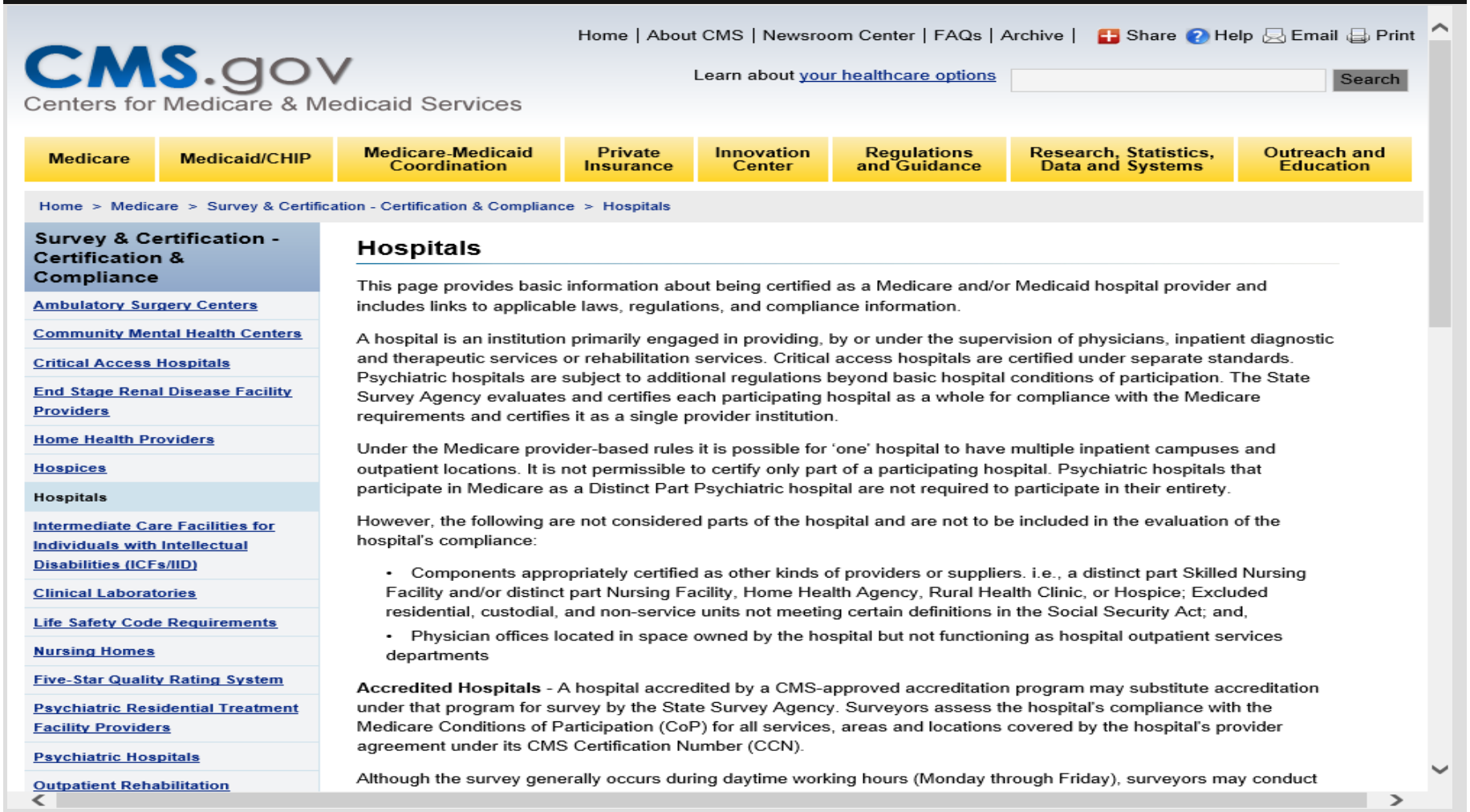
- *Situation:* Recent newspaper articles, medical publications, and adverse event reports associate multidrug-resistant bacterial infections caused by CRE with patients who have undergone ERCP. Duodenoscopes used to perform ERCP are difficult to clean and disinfect, even when manufacturer reprocessing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

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

Can Access 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

Updated Deficiency Data Reports



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

“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

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

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HospitalInspections.org
BRINGING TRANSPARENCY TO FEDERAL INSPECTIONS

Search hospital inspections

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

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

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

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

Last updated: May 2018

www.hospitalinspections.org/

Search your state

For all visitors

- A Q&A with CMS: Getting up to speed on inspection reports
- How to read inspection reports
- Sample inspection report
- Points to keep in mind about this data
- States that put hospital inspection reports online

For AHCJ members

- How to use 2567 forms in your reporting
- Having discussions with hospitals
- Beyond the 2567: Rounding out your story
- Reporter resources on covering hospital quality
- Resources page
- Download entire dataset

Search report text | All states | Search

Examples: abuse; "medication error"; Washington D.C.

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

Topics To Be Covered

§485.623 Condition of Participation: Physical Plant and Environment

§485.625 Condition of Participation: Emergency Preparedness

§485.627 Condition of Participation: Organizational Structure

§485.631 Condition of Participation: Staffing and Staff Responsibilities

§485.635 Condition of Participation: Provision of Services

Physical Plant
&
Environment

Construction 910

- **Condition:** Applies to
  - All locations
  - All campuses
  - All satellites
  - All in-and out-patients
- Departments/services – responsible for building and equipment/maintenance – must be incorporated into QAPI

Construction 912

- **Standard**: Hospital constructed, arranged, and maintained
  - Ensure access
  - Safety of patients
  - Provide adequate space to provide care to patients
- Constructed per state and federal law
  - Will look to see if maintained to ensure safety of patients
    - Conditions of ceilings, walls, and floors
    - See Facility Guideline Institute (FGI)*

*See Appendix

Maintenance 914

- Required:
  - Housekeeping (ES)
  - Preventative maintenance (PM) programs
- All essential mechanical, electrical, and patient-care equipment maintained in safe operating condition
  - Facilities, supplies and **equipment** must be maintained

Equipment

- "Equipment" includes:
  - Boilers – elevators – air compressors – ventilators – x-ray equipment – IV pumps & equipment – stretchers – maintenance log, etc.
- Identify equipment to meet patient needs in case of an emergency/disaster situation
  - Mass trauma – disease outbreak – internal disasters, etc.
- All equipment must be tested and inspected before initial use and after major repairs/upgrades*

* See Appendix

Interpretive Guidelines

- All equipment must be
  - Inspected, testing and maintained
  - Ensure safety, availability and reliability
- Activities may be done by
  - Employees
  - Contractors
  - Combination

Interpretive Guidelines

- Individuals overseeing program must be qualified
  - Must maintain records to show individuals qualified
- Overall - must demonstrate that qualified personnel are performing risk-based assessments, PM, or establishing the AEM program

Interpretive Guidelines

- Must have policies, procedures and programs re:
  - Inventories
  - Activities
  - Schedules
- Follow manufacturer-recommended activities and schedules
  - Can do more frequently
  - But must use recommended activities
  - Maintain documentation

Question

- Our facility has an established alternate equipment management program.
  - Yes
  - No
  - Not sure

Alternate Equipment Management (AEM)

- Program – can use maintenance program differ from manufacturer recommendations
- Must develop, implement and maintain documentation
  - Minimize risk to patient and others with equipment use
  - Be based on generally accepted SOP
  - Example: American National Standards Institute for the Advancement of Medical Equipment Handbook

Equipment Placed in AEM

- Must verify qualified employees/contractors
  - Making the decision on placement
  - Performing risk-based assessments
  - Establishing AEM requirements
  - Managing the program
  - Performing maintenance per the AEM policies and procedures

Who Qualified for AEM Decision

- Medical equipment
  - Clinical or biomedical technician or engineer
  - Specialized/complex equipment – may need specially trained person
- Facility equipment
  - Healthcare Facility Management professional
  - Facility manager/director/VP facilities
- Must maintain records of qualifications
  - Demonstrated how assure contractors qualified

Equipment in the AEM Program

- Expected to identify critical equipment
  - Either biomedical or physical plan equipment
  - Where risk of serious injury or death if fails

Factors to Consider

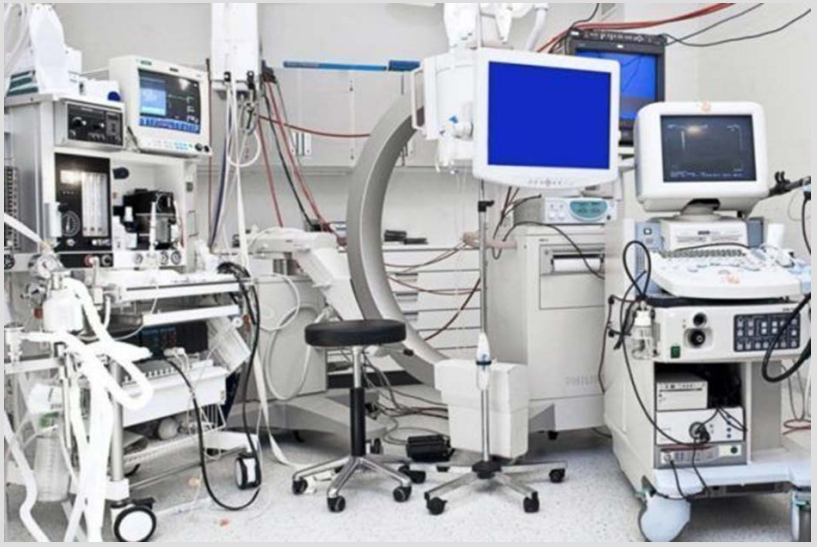
- How used and consequences of failure
  - Seriousness of harm if fails
  - How widespread the harm – one or many
  - Information on equipment maintenance recommendations
  - Maintenance requirements – simple to complex
- Timely availability of backup systems
- Incident history of same/similar euqipement

Equipment NOT Eligible for AEM

- Federal or State law require maintenance, inspection and testing done per manufacturer's recommendations
- Other CoPs require – National Fire Protection Association Life Safety Code
- Radiology/imaging equipment
- Medical laser
- New equipment with insufficient maintenance history

Frequency of PM

- Based on nature of equipment and risk to patients/staff health and safety
- Must follow manufacturer's recommendations
- Nationally recognized expert associations
- CAH's experience
- Must adhere strictly to AEM activities or strategies developed



Inventory

- Expected to have list of facility and medical equipment essential to operation of the CAH
- For low cost/risk essential equipment – housekeeping – can list the number under an item
  - Vacuum cleaners
- Other:
  - AEM equipment must be readily separately identified as such
  - Critical equipment must be readily identified as such

Survey Procedure

- Will interview personnel in charge of maintenance
  - Adequate provisions for availability
  - Equipment identified as essential
    - Regular
    - Emergency situation
- Determine if complete inventory of equipment to meet patient needs

Survey Procedure – continued

- Documentation of qualification of responsible personnel
- How assures contractors use qualified personnel
- If following manufacturer-recommended maintenance activities and frequency
- If using an AEM
  - Will look at a sample of equipment in AEM program
  - Maintenance strategies and how performed
    - Including critical equipment - ventilators

Disposal of Trash 920

- Standard: There is proper routine storage and prompt disposal of trash
  - Interpretive guidelines are pending
  - Reference only - previous interpretive guidelines
    - Includes biohazardous waste
    - Must be disposed of in accordance with standards (EPA, OSHA, CDC, environmental and safety)
    - Includes radioactive materials
  - Survey procedures pending

Storage of Drugs 922

- **Standard:** Drugs and biologicals must be appropriately stored
  - Properly locked in the storage area
  - Medication carts in C-section rooms locked
  - Drugs not left out in tube system/dumbwaiter ledge
- Surveyor will ask what
  - Standards
  - Guidelines
  - Law using

Physical Environment 924

- **Standard:** Premises clean and orderly
  - Uncluttered physical environment
  - Where patient/staff can function safety
  - Equipment/supplies properly stored
    - Not in corridors
  - Spill not left unattended
  - No floor obstructions
  - No evidence peeling paint, visible water leaks or plumbing problems

Ventilation, Lighting & Temperature 926

- **Standard:** There is proper ventilation, lighting and temperature control: (2020)
  - Pharmaceutical
  - Patient care
  - Food preparation
- Interpretive guidelines and Survey procedures pending

CMS Memo April 19, 2013

- AORN:
  - Temperature between 68-73 degrees
  - Humidity between 30-60% in the OR, PACU, cath lab, endoscopy rooms and instrument processing areas
- CMS: if no state law, hospital can write policy or procedure or process to implement the waiver
- Waiver allows RH between 20-60%
- In anesthetizing locations- see definition in memo*

* * See Slide 146

Impact of Lowering the Humidity

- Impacts some equipment and supplies
  - Shelf life and product integrity of some sterile supplies
    - EKG electrodes
  - Electro-medical equipment may be affected by electrostatic discharge
    - Especially older equipment
  - Erratic behavior of software and premature failure of the equipment
  - Calibration of the equipment
- Follow the manufacturers instructions for use that explains any RH requirements

Joint Commission and ASHRAE

- Joint effort with multiple organizations on humidity in OR
- RH lower than 30% can impact integrity and functionality of supplies and electro-medical equipment
- Was lowered to 20 – 30% upon request of multiple organizations
  - Upper limit 60%

https://www.aorn.org

Impact of Lowering the Humidity

American Hospital Association®

ASHE American Society for Healthcare Engineering

AHRMM Advancing the Healthcare Supply Chain

Quality Advisory

January 21, 2015

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

NEW GUIDANCE ON HUMIDITY LEVELS IN THE OPERATING ROOM

THE ISSUE

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

BACKGROUND

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

Life Safety From Fire 930 (2020)

- Follow LSC provisions
- Includes NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4
- Have positive latching hardware and no roller latches on doors where flammables/combustibles stored
- Interpretive guidelines are pending

LSC Provisions Waiver 2020

- LSC waiver – would cause unreasonable hardship (932)
  - Cannot affect the health or safety of patients
- Must maintain written evidence of regular inspections by the state fire control agencies (934)
- Can install alcohol-based hand rub dispensers if done in manner to protect against inappropriate access (936)
- Interpretive guidelines and Survey procedures pending for all three

Sprinkler System 938 (2020)

- If the system is shut down for more than 10 hours must:
  - Evacuate the building or portion of the building affected
    - Until the system is back up, or
  - Establish a fire watch until the system is back up
- Interpretive guidelines and Survey procedures pending

Sleeping Rooms - Windows 940 (2020)

- Every sleeping room must have an outside window or door
  - Constructed after 7-5-16:
    - Sill height can be higher than 36 inches about the floor
    - Does not apply to newborn nurseries for intended occupancy of less than 24 hours
    - Special nursing care area of new occupancies shall not exceed 60 inches
- Interpretive guidelines and Survey procedures pending

LSC Provisions 2020

- CMS can consider recommendation of state survey agency or accreditation organization for LSC waiver if would pose undue hardship (942)
- Must meet the Health Care Facility Code (944)
  - NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6
  - May grant waiver if unreasonable hardship and no does not affect health or safety of patients
- Interpretive guidelines and Survey procedures pending

Emergency Preparedness

Question

- We have reviewed and updated our Emergency Preparedness plan since the pandemic.
  - Yes
  - No
  - Not Sure

Emergency Preparedness

- In Appendix Z for interpretive guidelines and survey procedures
- Start at tag 950
- Changes in Hospital Improvement Rule 2019
  - Changed everything from yearly to every two years
  - EXCEPT - drills are still twice a year

Emergency Preparedness Appendix Z

- Requirements, final interpretive guidelines and survey procedures to Appendix Z
- Regulations start at tag 950
  - Questions: SCGEmergencyPrep@cms.hhs.gov

Emergency Preparedness 950 (2020)

- Standard: Must comply with all federal, state, and local emergency preparedness (EP) requirements
  - Have and maintain a comprehensive EP program
  - Utilize all-hazards approach – including emerging infections
- Program must include:
  - Plan >Policies & procedures
  - Communication plan >Training & testing
  - Emergency & standby power

Emergency Plan

- Reviewed and updated every 2 years
  - Based on and include documented facility & community-based risk assessment
    - Using all-hazard approach
  - Include strategies for addressing emergency events identified by the risk assessment
  - Address patient populations, persons at-risk, types of services that can be provided and succession plans
  - Include process for cooperation and collaboration with EP officials

Policies & Procedures

- Based on the plan, risk assessment and communication plan
  - Reviewed and updated every 2 years
- Address:
  - Provision of subsistence needs
    - Food-water-medical-pharmaceutical supplies
    - Alternate sources of energy – for services
  - System to track off-duty staff/sheltered patients in the hospital
  - Safe evacuation

Policies & Procedures (cont'd)

- Address – cont'd
  - Means to shelter in place
  - System of documentation – preserves confidentiality
  - Use of volunteers/other staffing strategies
  - Arrangement with other CAH/providers
  - Role of hospital under waiver - 1135

Communication Plan

- Plan that complies with all laws
  - Reviewed and updated every 2 years
- Must include
  - Names/contact information – patients/staff/physicians
  - Contact information – emergency preparedness staff
  - Primary and alternate means communication
    - Staff
    - Emergency management agencies

Communication Plan

- Must include (cont'd)
  - Method for sharing information/documentation for patients
  - In an evacuation – means to release patient information as permitted
  - Method to provide information about condition/location of patients
  - Means to provide information about occupancy/needs/ability to provide assistance

Training and Testing

- Must develop and maintain training and testing program
  - Based on emergency plan
  - Risk Assessment
  - P&P
  - Communication plan
  - Reviewed and updated every 2 years

Testing

- Conduct exercises twice a year
  - Participate in full-scale exercise community or facility based
  - If actual disaster – exempt from next full-scale exercise
  - Conduct annual additional exercise – full-scale, mock or table-top
  - Analyze and document all drills – revise as necessary

Power Systems

- Implement emergency & standby power systems
  - Emergency generator location – per Health Care Facilities code and Tentative Interim Amendments
  - Generator inspection and testing
  - Generator fuel
- If part of integrated healthcare system
  - Demonstrate each separately certified facility participates
  - Include a unified and integrated plan – based on risk assessment
  - Include integrated P&P

Organizational Structure Governing Body or Responsible Individual

Governing Body 960 & 962

- **Standard:** CAH has a governing body or individual that assumes legal responsibility for implementing and monitoring P&Ps
  - Must approve all policies
  - To provide quality care in safe environment
  - Determines categories of eligible practitioners with is written criteria for appointments
  - Must be written criteria for staff appointment

Appointment to Medical Staff

- Board appoints practitioners to medical staff
  - On advice of medical staff
  - Ensures and approves medical staff has bylaws
  - Ensures medical staff accountable to governing body

Criteria for Selection to Staff

- Character
- Competence
- Training
- Experience
- Judgment
- Surveyors – will look for/inquire
  - Written documentation of categories/staff
  - Verification appointment

Survey Procedure

- Verify have organized governing body/person
- Review documentation and verify – stated categories of eligible candidates
- Have policies been updated to reflect responsibilities
- Will ask for evidence showing board/person involved in day-to-day operations
- Will review records of staff appointees – board's involvement in appointments

Survey Procedure – continued

- Confirm board use established policies with appointments – scope of expertise, Federal and State law
- Verify written criteria for appointment
- Verify minimum criteria used for appointment
- Verify medical staff operates under bylaws

Disclosure 964 & 966 (2020)

- **Standard:** person principally responsible for operation of CAH and medical direction
- Need policy or procedure - report changes of operating officials to state agency
  - i.e., – a new CEO or medical director
- Surveyor
  - Look for policy on reporting changes
  - Ensure hospital implements policy

Staffing and Responsibilities

Staffing 970 & 971

- **Standard:** CAH has professional staff that includes
  - One or more physicians
  - May include PAs, NPs, or CNS
- Need an organizational chart – shows names of all providers
- Surveyor will review work schedules

Staffing and Supervision

- **Standard:** All ancillary staff are supervised by professional staff (972)
  - Will look at organizational chart
- Sufficient staff to provide services essential to operation of the hospital (974)
  - Emergency services, nursing services, etc.
- Surveyor review schedules and daily census records

Provider Available 976

- MD, DO, NP, PA, or CNS must be available to furnish services at all times
  - Practitioner available and shows up when patient presents to the hospital
  - Does not mean they have to be there 24 hours a day
- Must provide diagnostic/therapeutic services/ supplies commonly furnished in a physician's office

Nurse on Duty 978

- **Standard**: Must have a RN, CNS, or LPN on duty whenever there is one or more inpatients
- Surveyor will review staff schedules

Physician Responsibilities 981

- **Standard:** MD/DO must provide medical directions and supervision of staff
  - Surveyor will make sure physician is available for consultation and supervision of staff
- PA/NP must participate in developing/reviewing written P&P (982)
  - Want evidence physician participated
  - Ensure physicians review the policies periodically

Physician Supervision 984 & 986

- Periodically review/ sign off all charts/orders of PA and NP
  - And as per state law
  - Surveyor will look for documentation of supervision (984)
- Plus – periodic review and sign off sample outpatient records
  - CMS recommends sample size of 25% all outpatient encounters managed by non-physician practitioners

Supervision – cont'd

- No specified time frame for periodic review
  - Time frame in the P&P
  - Maximum interval between inpatient reviews
- Consider volume and types of services provided in developing the P&P
  - 4 bed CAH would have different time frame than a 25 bed CAH
  - Does the CAH have EHRs that can be reviewed and signed off remotely?

Medical Direction 988

- MD/DO must
  - Be present sufficient period of time
  - To provide medical direction, supervision and consultation
  - Available via direct radio/telephone communication
  - Amount of time “present” – on-site – not specified

Other Requirements

- Biweekly visit might be burdensome – especially for a small CAH in a remote area with low patient volume
  - Remember the federal EMTALA law
- MD, DO, PA, CNS, or NP must be on call and available to provide emergency care
  - Must have list of on-call physicians

Standard: PA, NP, CNS Responsibilities

- Participate in development, execution and review of policies (991)
  - Be a member of the CAH staff
  - Surveyor: will interview mid level providers to determine participation and knowledge of policies
- Need to participate with MD/DO in review of the patient's medical records (993)

PA, NP, CNS – Duties

- Perform functions not being performed by the physicians (995)
- Refer patients if needed services cannot be provided at the CAH (997)
  - Make sure medical records are maintained
- Notify physician when patient is admitted by midlevel (998)
  - Document patient is under the care of the MD/DO

Transfer of Patients – Author's Notes

- Send a copy of the patient's medical records
  - Unless can access electronically
- EMTALA is a separate CoP
- Have a transfer policy – consistent with EMTALA
- Provide EMTALA training to staff, providers and on-call physicians

Question

- Our State law and hospital policy allows for non-physician provider to admit patients.
  - Yes
  - No
  - Do not know

Patient Admission

- CMS requires that Medicare and Medicaid patients be under the care of a MD/DO
  - **IF** the patient has a medical or psych problems that is outside of the scope of an advanced practice provider
- Admitting privileges must be consistent with what state law allows
- Surveyor will look to make sure a MD/DO monitors the care for any medical problem outside their scope of practice

Patient Admission 998

- Notify physician when Medicare/Medicaid patient admitted by midlevel
  - Patient with medical/psychiatric issue
  - Or – develops during inpatient stay
  - Outside the scope of NP/PA/CNS scope of practice
  - Document patient is under the care of the MD/DO
- If P&P allow mid-level to admit/care for patients
  - And per state law Scope of Practice
  - Must have P&P to ensure patient safety

Review of Care 999

- **Standard:** Periodic review of clinical privileges and performance
  - Quality and appropriateness of care
  - NP, CNS, PA – evaluated by MD/DO
- MD/DO
  - Hospital member of the network
  - QIO
  - Appropriate/quality entity in State rural healthcare plan
  - Telemedicine – by hospital member of the network
- Guidance pending

Provision of Services

Provision of Services

- **Condition:** establishes requirements related to:
- Patient care policies
- Required services
- Services via agreement/arrangements

Provision of Services

- **Scope of services (1010)**
- **Emergency medical services (1012)**
- **Referral, medical records & evaluation of services(1014)**
- **Drugs and biologicals (1016)**
- **Food and nutrition (1020)**
- Patient services(1024,1026)
- Laboratory(1028)
- Radiology (1030)
- **Emergency procedures (1032)**
- Services via Agreements/Arrangements (1034, 1036, 1038, 1040, 1042, 1044)
- Nursing (1046, 1048, 1049, 1050)
- Rehab (1052)
- Visitation rights (1054, 1056, 1058)

Patient Care Policies 1006

- **Standard:** Services are provided in accordance with appropriate P&P
  - Consistent with applicable state law
  - Requires services per written policies
- Surveyor will:
  - Review the policies on healthcare services that are provided in the CAH
  - Observe staff delivering care to the patient
  - If identify practices inconsistent with State law will refer to State authorities

Development of Policies 1008

- Developed with advice of professional staff
  - One or more: MD and PA – NP - CNS
- Reviewed every 2 years
  - Recommends changes if needed
- Final decision on content made by governing body
- If recommendations rejected
  - Governing body must include rationale

Scope of Services 1010

- **Standard:** P&P must include
  - Describes services provided directly or via contract
- Examples:
  - “Taking complete medical histories – providing complete H&P – laboratory testing – radiology testing –
  - “Arrangements made with Hospital X to provide (the following services)….”

Emergency Medical Services 1012

- Need P&P for emergency medical services
- Surveyor will verify policies:
  - How hospital provides 24/7 emergency care to patients
  - Equipment, supplies, medications, and blood available on site
  - How CAH coordinate with local EMS
  - Type of staff are available to provide care

Guidelines for Medical Management 1014

- When medical consultation or referral is needed
- Maintaining medical records
- Procedure for periodic review and evaluation of the services provided at the CAH
  - General instructions/protocols to medically manage problems commonly seen

PA, NP, CNS & Medical Management

- As mid-levels play large role in patient care at CAH policies must address:
  - Scope of medical acts/procedures may be done by PA, CNS, or NP
  - When the physician is consulted
  - When to refer patient to physician or outside the CAH

OIG Report on Surveyor Training
ISMP Guidelines
ASHP Resources

Surveyor Training on Compounding

- OIG report: CMS to ensure surveyors trained on nationally recognized compounding practices
  - Recommended addition to interpretive guidelines
    - Address hospital contracts with stand-alone compounding pharmacies
- OIG: lack of training prevented effective evaluation of hospital's use compounded sterile preparations

Guidelines on Sterile Compounding

- ISMP Guidelines published in 2013*
  - Safe preparation of CSP or compounded sterile preparations (Revised in 2016)
  - Goal: provide procedures and safe practices for reducing errors in CSP preparation
  - Addressed drug storage, compounding, labeling, and staff management
- ASHP issued guidelines* on contracting for sterile compounding services
  - Suggested contract language

* See appendix for resources

Drugs and Biologicals CoPs

USP Standards

- USP 797 – to be effective December 1, 2019
  - Delayed due to an appeal until March 2020
    - Chapter remanded to the compounding expert committee regarding the BUD
  - Many of the USP standards were changing
- CMS removed all references to USP
  - Now: follow all standards of care and evidenced based practices

Drugs and Biologicals P&P 1016

- Policies must include rules:
  - For storage – handling – dispensing - administration
  - Storage area administered per acceptable standards of practice
  - Rules that current and accurate records kept for Scheduled drugs
    - Receipt
    - Disposition
  - Outdated, mislabeled, or otherwise unusable drugs are not available for patient use

Policies & Procedures Requirements

- Consistent with standards or guidelines for pharmaceutical services and medication administration
  - I.e., USP, ASHP, ISMP, Infusion Nurses Society, IHI, and National Coordinating Council
- Consistent with state and federal law
- Others include:
  - ASHP Foundation (American Society of Healthcare System Pharmacist Foundation) – American Nurses Association (ANA) – American Pharmacy Association (APA), APIC, CDC, etc.

ISMP Institute for Safe Medication Practices

www.ismp.org

Upcoming Events

WEBINARS 09/26/2018
Global Drug Safety Issues with Packaging and Labeling

CO-SPONSORED 10/05/2018
Exhibitor Theater in conjunction with CSHP's Seminar 2018

CO-SPONSORED 10/07/2018
An Ancillary Event conducted at ASHRM's Annual Meeting

CO-SPONSORED 10/24/2018
Promotional Theater at ANCC National Magnet Conference

Responsibility for Pharmacy Services

- P&Ps must identify the qualifications for and designation of pharmacy director
- Duties:
  - Ensure adherence to State laws
    - Who can perform pharmacy services
    - Supervision of the pharmacy staff
  - Ensure adherence to acceptable standards used in developing P&P
    - Note: Can cite as references in the P&Ps

Storage and Environmental Conditions

- Storage of drugs/biologicals including location of:
  - Storage areas
  - Medication carts
  - Dispensing machines

- Proper environmental conditions
  - Follow manufacturer's recommendations
    - I.e.: keep refrigerated – room temperature – out of light, etc.

Security

- Security
  - P&P must be consistent with State and Federal law re: who authorized to access pharmacy or drug storage areas
    - Housekeeping, security or maintenance are usually not given unsupervised access
  - If kept in private office - patients and visitors not allowed in without supervision

“Secure Area”

- “Secure area” restricted to authorized personnel
  - Given flexibility in non-controlled drugs
    - Not required to be locked when setting up for a procedure
  - Lock when area not staffed – evenings, weekends
  - Covers controlled and non-controlled substances

Security & Monitoring of Carts

- Carts must be secure when not in use
  - Medication carts
  - Anesthesia carts
  - Epidural carts
  - Non-automated medication carts with medications
- Must have P&P
  - Whether locked or unlocked
  - If unlocked- staff must be close by and directly monitoring the cart as when passing medications

Medications in the OR ASA Statement

American Society of Anesthesiologists™

www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

Statement on Security of Medications in the Operating Room

Committee of Oversight: Quality Management and Departmental Administration

(Approved by the ASA Executive Committee in October 2003, and last amended by the ASA House of Delegates on October 17, 2018)

Preamble

A secure environment of care is necessary for medication safety. Medication safety includes the security of oral, sublingual, parenteral, and inhaled pharmaceutical agents used for elective and emergency patient care. A secure physical area ensures the integrity of anesthesia machines as well as other equipment and materials. Security of medications in the operating room suite is essential for patient safety.

Recommended Policies

1. Access to operating room suites must be strictly limited to authorized persons.
2. All Schedule II through V medications must be kept in locked enclosed areas when not under the direct control of an anesthesia professional.
3. Anesthesia professionals must have immediate access to drugs and equipment required for emergency patient care. Procedures designed to prevent unauthorized access to such drugs must not impede this imperative for patient safety.
4. Anesthesia carts and anesthesia machines may remain unlocked, and non-controlled* medications may be left in or on top of unlocked anesthesia carts or anesthesia machines immediately prior to, during, and immediately following surgical cases in an operating room, so long as there are authorized operating room personnel in the OR suite.

Rationale

Handling Drugs & Biologicals

- "Handling" includes mixing or reconstituting
  - Done per manufacturer's recommendations
  - Includes compounding or admixing of sterile IVs or other drugs
- Only pharmacy can reconstitute, mix, or compound a drug except:
  - In an emergency
  - If not feasible – i.e., product's stability is short

Compounding

- Compounded drugs used or dispensed
  - Must be prepared in a manner consistent with acceptable principles
  - For sterile and non-sterile compounding
  - Prevent microbial contamination and bacterial toxins for compounds intended to be sterile

Pharmacy Responsibilities – Compounding

- Must demonstrate:
  - How it assures all sterile and non-sterile compounded drugs are prepared are pursuant to SOC
  - All compounded forms must be sterile
    - Wound irrigations – eye drops and ointments – injections – infusions – nasal inhalation – etc.

Drug Quality & Security Act

- Has sections related to compounding
- "Outsourcing facility"
  - Elected to register and comply with entire section 503B of the FDCA
  - Plus – other requirements such as the FDA's current good manufacturing practice (CGMP)
  - Will be inspected by the FDA according to risk-based schedule
  - Must meet certain other conditions including reporting adverse drug events to the FDA*

*See appendix for resources

Compounding Pharmacy

- If use compounding pharmacy vs manufacturer/ registered outsourcing facility – must
  - Demonstrate medicine received was prepared in accordance with acceptable principles
  - Contract with the vendor - ensure have access to their quality data verifying their compliance with USP standards
  - Document when you obtain and review this data

Dispensing Drugs and Biologicals

- Comply with state laws re: qualifications of staff
- Dispensed timely
- Sufficient staff – accurate/timely medication delivery
- System to ensure order
  - Get to the pharmacy promptly
  - Available when needed
- Concerns or questions should be clarified with the prescriber before dispensing

Question

- Our facility utilizes a unit dose system with strict access limitations.
  - Yes
  - No
  - Prefer not to answer

Dispensing

- Can use unit dose or floor stock system
  - Automated dispensing cabinets are secure option
- P&P re: who can access medications after hours (night cabinet standard)
- P&Ps: (“Blue Box”)
  - “Do not use” abbreviations
  - High alert list
  - Quantities dispensed to minimize diversion,
  - Limit overrides

For Information Only – Not Required/Not to be Cited

In addition to the required pharmacy policies and procedures above, a well-designed pharmacy service would have policies and procedures addressing medication safety practices such as:

- *Implementation of a do-not-use abbreviation list. CAHs may wish to refer to lists offered by the Institute for Safe Medication Practices (http://www.ismp.org/tools/errorproneabbreviations.pdf) or The Joint Commission (http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf) ;*

- *A high alert drug list. CAHs may wish to refer to a high alert drug list offered by the Institute for Safe Medication Practices (https://www.ismp.org/tools/institutionalhighAlert.asp);*

- *For specific high alert medications designated by the CAH, having two health professionals independently check doses CAHs may wish to refer to guidance from the Institute for Safe Medication Practices concerning appropriate use of double-checks (http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=51);*

- *Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;*

- *Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit doses that have been repackaged by the pharmacy;*

- *The CAH consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system; and*

Do Not Use Abbreviations ISMP

Institute for Safe Medication Practices

ISMP's List of *Error-Prone Abbreviations, Symbols,* and *Dose Designations*

The abbreviations, symbols, and dose designations found in this table have been reported to ISMP through the ISMP National Medication Errors Reporting Program (ISMP MERP) as being frequently misinterpreted and involved in harmful medication errors. They should **NEVER** be used when communicating medical information. This includes internal communications, telephone/verbal prescriptions, computer-generated labels, labels for drug storage bins, medication administration records, as well as pharmacy and prescriber computer order entry screens.

Abbreviations	Intended Meaning	Misinterpretation	Correction
µg	Microgram	Mistaken as "mg"	Use "mcg"
AD, AS, AU	Right ear, left ear, each ear	Mistaken as OD, OS, OU (right eye, left eye, each eye)	Use "right ear," "left ear," or "each ear"
OD, OS, OU	Right eye, left eye, each eye	Mistaken as AD, AS, AU (right ear, left ear, each ear)	Use "right eye," "left eye," or "each eye"
BT	Bedtime	Mistaken as "BID" (twice daily)	Use "bedtime"
cc	Cubic centimeters	Mistaken as "u" (units)	Use "mL"
D/C	Discharge or discontinue	Premature discontinuation of medications if D/C (intended to mean "discharge") has been misinterpreted as "discontinued" when followed by a list of discharge medications	Use "discharge" and "discontinue"
IJ	Injection	Mistaken as "IV" or "intrajugular"	Use "injection"
IN	Intranasal	Mistaken as "IM" or "IV"	Use "intranasal" or "NAS"
HS hs	Half-strength At bedtime, hours of sleep	Mistaken as bedtime Mistaken as half-strength	Use "half-strength" or "bedtime"
IU**	International unit	Mistaken as IV (intravenous) or 10 (ten)	Use "units"
o.d. or OD	Once daily	Mistaken as "right eye" (OD-oculus dexter), leading to oral liquid medications administered in the eye	Use "daily"
OJ	Orange juice	Mistaken as OD or OS (right or left eye); drugs meant to be diluted in orange juice may be given in the eye	Use "orange juice"
Per os	By mouth, orally	The "os" can be mistaken as "left eye" (OS-oculus sinister)	Use "PO," "by mouth," or "orally"

TJC's Do Not Use Abbreviation List

Facts about the Official "Do Not Use" List

In 2001, The Joint Commission issued a *Sentinel Event Alert* on the subject of medical abbreviations, and just one year later, its Board of Commissioners approved a National Patient Safety Goal requiring accredited organizations to develop and implement a list of abbreviations not to use. In 2004, The Joint Commission created its "do not use" list of abbreviations (see below) as part of the requirements for meeting that goal. In 2010, NPSG.02.02.01 was integrated into the Information Management standards as elements of performance 2 and 3 under IM.02.02.01.

Currently, this requirement does not apply to preprogrammed health information technology systems (for example, electronic medical records or CPOE systems), but this application remains under consideration for the future. Organizations contemplating introduction or upgrade of such systems should strive to eliminate the use of dangerous abbreviations, acronyms, symbols, and dose designations from the software.

Official "Do Not Use" List[1]

Do Not Use	*Potential Problem*	Use Instead
U, u (unit)	Mistaken for "0" (zero), the number "4" (four) or "cc"	Write "unit"
IU (International Unit)	Mistaken for IV (intravenous) or the number 10 (ten)	Write "International Unit"
Q.D., QD, q.d., qd (daily)	Mistaken for each other	Write "daily"
Q.O.D., QOD, q.o.d, qod (every other day)	Period after the Q mistaken for "I" and the "O" mistaken for "I	Write "every other day"
Trailing zero (X.0 mg)* Lack of leading zero (.X mg)	Decimal point is missed	Write X mg Write 0.X mg
MS	Can mean morphine sulfate or magnesium sulfate	Write "morphine sulfate" Write "magnesium sulfate"
MSO_4 and $MgSO_4$	Confused for one another	

Scheduled Medications

- Keep records – receipt, disposition and use
  - Five schedules of controlled substances – I to V
  - Locked storage when not in use
  - Reconcile any discrepancies in the counts
- Ensure outdated, mislabeled, unusable medication not used
- Must have pharmacy labeling, inspection, and inventory management
- Do not use past beyond use date
  - P&P to determine BUD date if not marked

Labeling

- Each individual drug must be labeled
  - Name
  - Strength of drug
  - Lot and control number
  - Expiration date
- Open multidose vial
  - Expiration date of 28 days on the label
  - Unless otherwise specified by manufacturer

Reporting Errors

- Must have a system to report ADEs and errors
  - Educate staff
- Pharmacy to assess
  - If problems in pharmacy caused or contribute to these
- Hospital must take action to address identified issues

Surveyor Questions & Actions

- Nursing
  - Medications dispensed in a timely manner
  - If late – surveyor will investigate
- Pharmacy
  - Professional principles pharmacy using
- Will ensure drugs are secure
- Will verify only pharmacist/authorized person compound, label and dispense
  - Some states prohibit pharmacy tech from completing

Surveyor Duties

- Ensure facility has a process to follow up on ADE and medication errors
- Will determine if CAH obtains compounded drugs from external source not FDA registered
  - Does the facility evaluate and monitor adherence to safe principles
  - Ask for example of when the BUD had to be determined for a compounded sterile medication based on P&P
- Long survey procedure for this tag number

Reporting ADR and Errors 1018

- Standard: Procedures for reporting adverse drug events (ADEs) and medication errors
- Staff must report events/errors
  - Attend to patient and report to QAPI
  - Need P&P and ensure staff aware
- Need definition of each
  - CMS mentions National Coordinating Council Medication Error Reporting and Prevention

Medication Administration Error

- Preventable event
- May cause/lead to inappropriate medication use or patient harm
- While in control of HCP, patient or consumer
- Related to
  - Professional practice
  - Healthcare products
  - Procedures
  - Systems including

Adverse Drug Reaction

- Unexpected, unintended, undesired or excessive response to a drug
  - D/C drug
  - Changing therapy
  - Modifying dose
  - Prolongs stay
  - Necessitates supporting treatment
  - Significantly complicates diagnosis
  - Negatively affects prognosis
  - Results in temporary/permanent harm, disability, death

Patient Care

- ADR/errors that reach the patient must be reported to the practitioner
  - Report made immediately if causes harm
  - If harm is not known – must report immediately
  - If no harm – can notify practitioner in the morning
- Document:
  - Error
  - Notification of practitioner

Quality Assurance/Improvement Reporting

- Reduction of errors/ADR may be facilitated by effective reporting
  - Assess vulnerabilities in process
  - Implement corrective actions
- Must educate staff on errors/ADRs to facilitate reporting & how to report
  - Near misses
  - I.e.,- incident report sent to pharmacy, nursing, risk management, and then into the QAPI program
  - Can do RCA, FMEA, or QAPI review

Other Actions

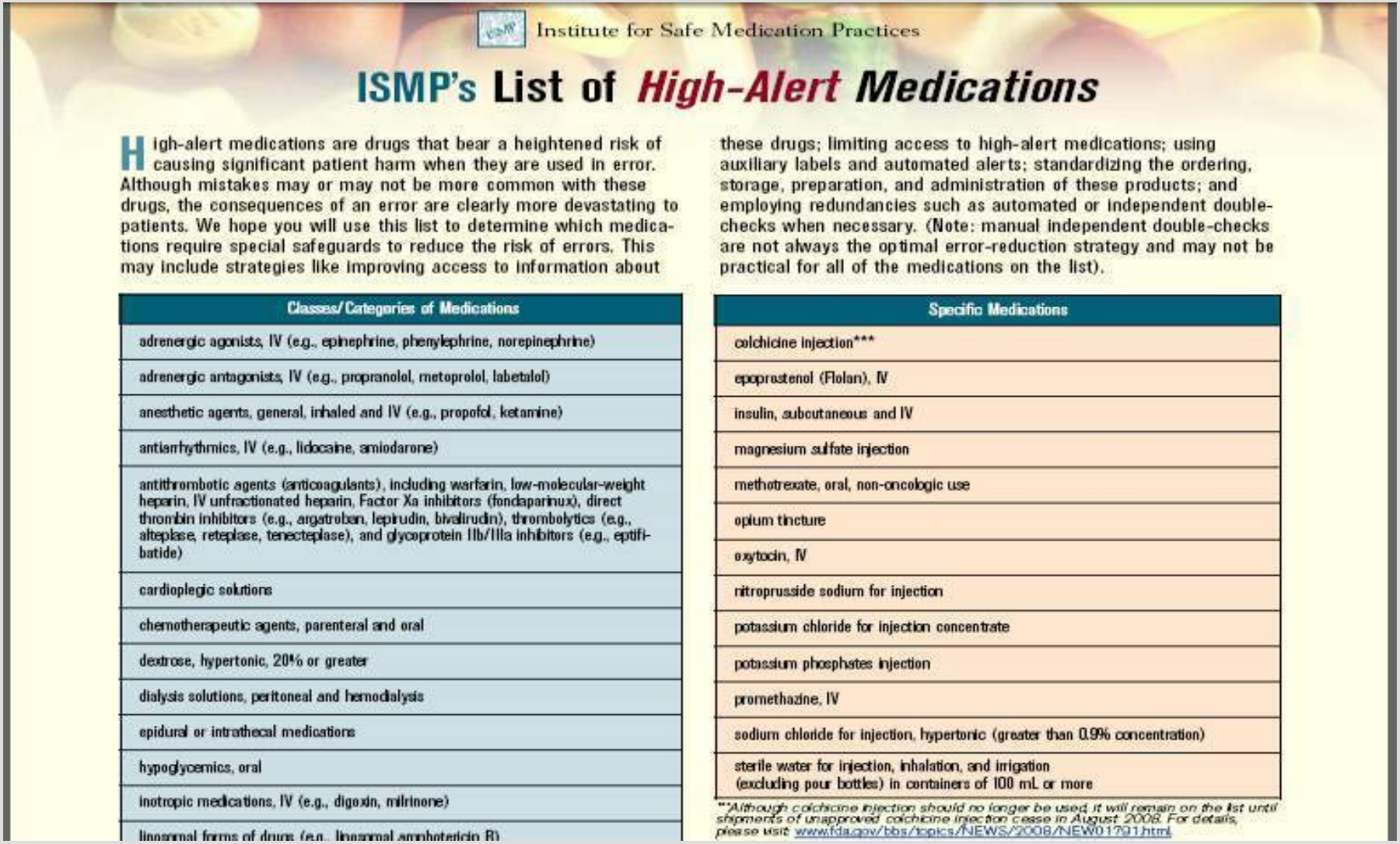
- Encourage non-punitive approach – focus on system issues
  - Do not rely on incident reports only
- Take other steps to identify errors and ADRs
  - Trigger drug analysis,
  - Observe medication passes,
  - Medication usage evaluations for **high alert drugs** etc.
- Encourages reporting to the FDA MedWatch Program and ISMP MER system*

*See appendix

Non-Punitive Environment

- Studies: punitive environment results in errors not being reported
  - Most of serious errors made by long term employees or physicians with unblemished records
  - System led to the error
- Need to change the environment or culture
- Important to have a non-punitive environment
- Balance with Just Culture

List of High Alert Medications



Institute for Safe Medication Practices

ISMP's List of *High-Alert* Medications

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies like improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; standardizing the ordering, storage, preparation, and administration of these products; and employing redundancies such as automated or independent double-checks when necessary. (Note: manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list).

Classes/Categories of Medications
adrenergic agonists, IV (e.g., epinephrine, phenylephrine, norepinephrine)
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)
antiarrhythmics, IV (e.g., lidocaine, amiodarone)
antithrombotic agents (anticoagulants), including warfarin, low-molecular-weight heparin, IV unfractionated heparin, Factor Xa inhibitors (fondaparinux), direct thrombin inhibitors (e.g., argatroban, lepirudin, bivalirudin), thrombolytics (e.g., alteplase, reteplase, tenecteplase), and glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)
cardioplegic solutions
chemotherapeutic agents, parenteral and oral
dextrose, hypertonic, 20% or greater
dialysis solutions, peritoneal and hemodialysis
epidural or intrathecal medications
hypoglycemics, oral
inotropic medications, IV (e.g., digoxin, milrinone)
liposomal forms of drugs (e.g., liposomal amphotericin B)

Specific Medications
colchicine injection***
epoprostenol (Flolan), IV
insulin, subcutaneous and IV
magnesium sulfate injection
methotrexate, oral, non-oncologic use
opium tincture
oxytocin, IV
nitroprusside sodium for injection
potassium chloride for injection concentrate
potassium phosphates injection
promethazine, IV
sodium chloride for injection, hypertonic (greater than 0.9% concentration)
sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more

****Although colchicine injection should no longer be used, it will remain on the list until shipments of unapproved colchicine injection cease in August 2008. For details, please visit www.fda.gov/bbs/topics/NEWS/2008/NEW01791.html*

Survey Procedure 1018

- Ensure nursing staff know what to do if there is a medication error or ADR
- Ask nursing to provide an example of what they would do if error or ADR
- Review records of errors/ADR – immediately reported & documented
- Ensure hospital has system for reporting to QAPI
- Make sure staff trained in reporting expectations

Dietary Standards

Dietary 1020 (2020)

- Standard: Nutritional needs of inpatients met per recognized dietary practices
- All diets ordered by practitioner responsible for care or:
  - Qualified dietitian (new) OR
  - Qualified nutrition professional (new)
  - Authorized by medical staff and per state law (new)
- The survey procedure and interpretive guidelines are pending

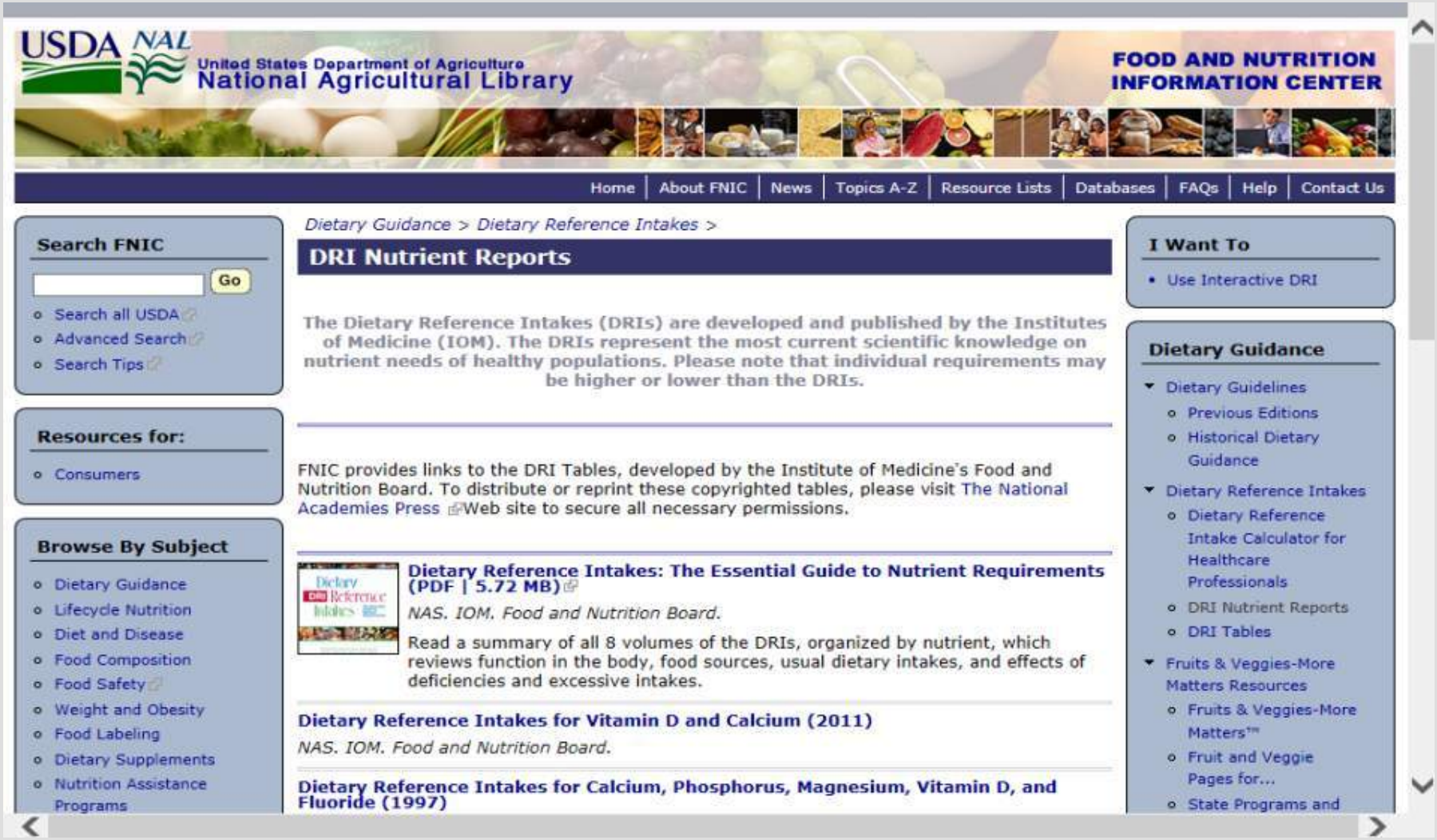
Previous Interpretive Guidelines

- Provided in the appendix as reference only
  - Final interpretive guidelines pending
- A CAH is not required to prepare meals itself
- Can obtain meals under contract
- Infection control issues in dietary hit hard
- Must be staffed to ensure that the nutritional needs of the patients are met

Policies Reviewed 1022 (2020)

- Policies are reviewed at least biennially
  - By a group of professional personal – NP, PA, CNS, MD/DO
- Interpretive guidelines and survey procedure pending

IOM DRI or Dietary Reference Intake



http://fnic.nal.usda.gov/dietary-guidance/dietary-reference-intakes/dri-nutrient-reports

Dietary Reference Intakes (DRIs): Estimated Average Requirements

Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage Group	Calcium (mg/d)	CHO (g/kg/d)	Protein (g/d)	Vit A (μg/d)[a]	Vit C (mg/d)	Vit D (μg/d)	Vit E (mg/d)[b]	Thiamin (mg/d)	Ribo-flavin (mg/d)	Niacin (mg/d)[c]	Vit B_6 (mg/d)	Folate (μg/d)[d]	Vit B_{12} (μg/d)	Copper (μg/d)	Iodine (μg/d)	Iron (mg/d)	Magnes-ium (mg/d)	Molyb-denum (μg/d)	Phos-phorus (mg/d)	Sele-nium (μg/d)	Zinc (mg/
Infants																					
0 to 6 mo																					
6 to 12 mo			1.0													6.9					2.5
Children																					
1–3 y	500	100	0.87	210	13	10	5	0.4	0.4	5	0.4	120	0.7	260	65	3.0	65	13	380	17	2.5
4–8 y	800	100	0.76	275	22	10	6	0.5	0.5	6	0.5	160	1.0	340	65	4.1	110	17	405	23	4.0
Males																					
9–13 y	1,100	100	0.76	445	39	10	9	0.7	0.8	9	0.8	250	1.5	540	73	5.9	200	26	1,055	35	7.0
14–18 y	1,100	100	0.73	630	63	10	12	1.0	1.1	12	1.1	330	2.0	685	95	7.7	340	33	1,055	45	8.5
19–30 y	800	100	0.66	625	75	10	12	1.0	1.1	12	1.1	320	2.0	700	95	6	330	34	580	45	9.4
31–50 y	800	100	0.66	625	75	10	12	1.0	1.1	12	1.1	320	2.0	700	95	6	350	34	580	45	9.4
51–70 y	800	100	0.66	625	75	10	12	1.0	1.1	12	1.4	320	2.0	700	95	6	350	34	580	45	9.4
> 70 y	1,000	100	0.66	625	75	10	12	1.0	1.1	12	1.4	320	2.0	700	95	6	350	34	580	45	9.4
Females																					
9–13 y	1,100	100	0.76	420	39	10	9	0.7	0.8	9	0.8	250	1.5	540	73	5.7	200	26	1,055	35	7.0
14–18 y	1,100	100	0.71	485	56	10	12	0.9	0.9	11	1.0	330	2.0	685	95	7.9	300	33	1,055	45	7.3
19–30 y	800	100	0.66	500	60	10	12	0.9	0.9	11	1.1	320	2.0	700	95	8.1	255	34	580	45	6.8
31–50 y	800	100	0.66	500	60	10	12	0.9	0.9	11	1.1	320	2.0	700	95	8.1	265	34	580	45	6.8
51–70 y	1,000	100	0.66	500	60	10	12	0.9	0.9	11	1.3	320	2.0	700	95	5	265	34	580	45	6.8
> 70 y	1,000	100	0.66	500	60	10	12	0.9	0.9	11	1.3	320	2.0	700	95	5	265	34	580	45	6.8
Pregnancy																					
14–18 y	1,000	135	0.88	530	66	10	12	1.2	1.2	14	1.6	520	2.2	785	160	23	335	40	1,055	49	10.5
19–30 y	800	135	0.88	550	70	10	12	1.2	1.2	14	1.6	520	2.2	800	160	22	290	40	580	49	9.5
31–50 y	800	135	0.88	550	70	10	12	1.2	1.2	14	1.6	520	2.2	800	160	22	300	40	580	49	9.5
Lactation																					
14–18 y	1,000	160	1.05	885	96	10	16	1.2	1.3	13	1.7	450	2.4	985	209	7	300	35	1,055	59	10.9
19–30 y	800	160	1.05	900	100	10	16	1.2	1.3	13	1.7	450	2.4	1,000	209	6.5	255	36	580	59	10.4
31–50 y	800	160	1.05	900	100	10	16	1.2	1.3	13	1.7	450	2.4	1,000	209	6.5	265	36	580	59	10.4

NOTE: An Estimated Average Requirement (EAR) is the average daily nutrient intake level estimated to meet the requirements of half of the healthy individuals in a group. EARs have not been established for vitamin K, pantothenic acid, biotin, choline, chromium, fluoride, manganese, or other nutrients not yet evaluated via the DRI process.

Emergency Procedures 1032

- Hospital provides medical services as a first response to common life-threatening injuries and acute illness
  - Must be on site
  - By employed staff or contractors
  - Person providing services must be able to recognize patients need for emergency care
    - At all times
  - Must provide appropriate initial interventions, treatment and stabilization

Summation Event

CAH utilizes contracted services, including Pharmacy, Anesthesia and Maintenance. Emma is 85 years-old, in good health. She has been admitted for surgical repair/pinning of a fractured left hip due a fall at home. Pre-op admitting orders call for bedrest, up with assist only.

Postop plan is transfer Emma to Swing Bed status and then to LTC rehab. Medication orders included her home meds and MS for pain. Emma weighs 44.45kg (98 lbs.). Emma is alert and oriented when admitted.

Summation Event – (cont.)

Prior to surgery the CRNA notices the anesthesia cart to be unlocked – unusual for the OR and some of the vials appear to have been opened. Does not notify anyone.

During surgery, Emma's vitals spike more than expected but surgery proceeds without further incidence. It was subsequently discovered the anesthesia cart had not been secured. The previous surgery occurred 2 days prior.

Q – If, during a survey, what would the hospital be cited for, if anything? (Options on next slide)

Possible Citations

- None
- Pharmacy Controls – security of medications, carts and reporting events
- Pharmacy, using open medications without confirming BUD/expiration and Reporting ADR/errors
- Pharmacy, use of unlabeled and undated medications, not reporting medication events, not notifying surgeon of concerns

The End Questions???

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APPENDIX & RESOURCES

New Tag Numbers in 2020

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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

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

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

Memorandum Summary

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

Background

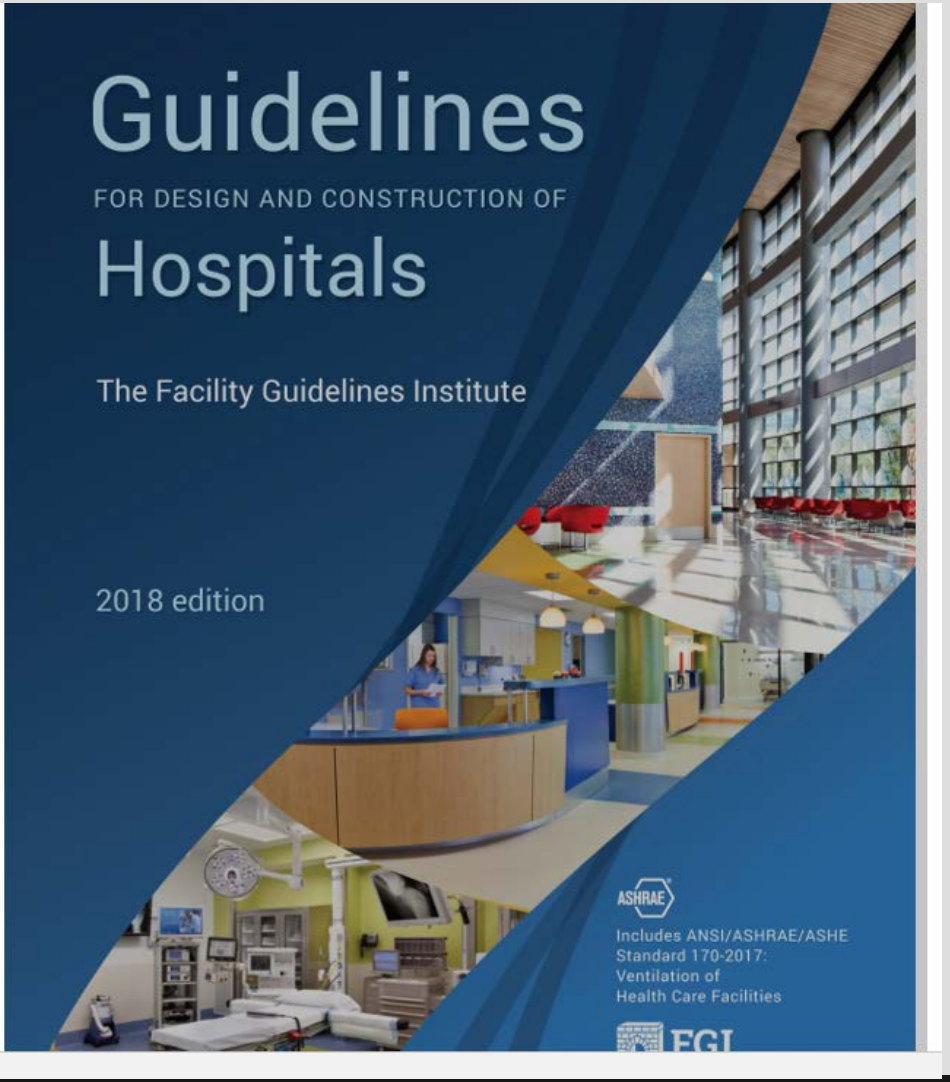
On September 30, 2019, CMS published two final rules which revised regulatory requirements for the various certified provider and supplier types.

The two final rules are as follows:

Crosswalk to New Tag Numbers

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

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


Guidelines
FOR DESIGN AND CONSTRUCTION OF
Hospitals
The Facility Guidelines Institute
2018 edition
ASHRAE
Includes ANSI/ASHRAE/ASHE
Standard 170-2017:
Ventilation of
Health Care Facilities
FGI

CMS Hospital Equipment Maintenance

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

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 14-07-Hospital

DATE: **December 20, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Hospital Equipment Maintenance Requirements

Memorandum Summary

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

Equipment Memo

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 14-41-CAH

DATE: **August 8, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Critical Access Hospital (CAH) Equipment Maintenance Requirements

Memorandum Summary

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

CDC Isolation Guidelines

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

Jane D. Siegel, MD; Emily Rhinehart, RN MPH CIC; Marguerite Jackson, PhD; Linda Chiarello, RN MS; the Healthcare Infection Control Practices Advisory Committee

Acknowledgement: The authors and HICPAC gratefully acknowledge Dr. Larry Strausbaugh for his many contributions and valued guidance in the preparation of this guideline.

Suggested citation: Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf

Humidity in Anesthetizing Areas

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

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

DATE: **April 19, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

- ***RH of ≥20 Percent Permitted in Anesthetizing Locations:*** The Centers for Medicare & Medicaid Services (CMS) is issuing a categorical LSC waiver permitting new and existing ventilation systems supplying hospital and critical access hospital (CAH) anesthetizing locations to operate with a RH of ≥20 percent, instead of ≥35 percent. We are also recommending that RH not exceed 60 percent in these locations.
- ***This Waiver Does Not Apply:***
  - When more stringent RH control levels are required by State or local laws and regulations; or
  - Where reduction in RH would negatively affect ventilation system performance.

CMS Memo on Low Relative Humidity

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

Center for Clinical Standards and Quality /Survey & Certification Group

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

DATE: **February 20, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

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

Lowering Humidity Can Have Other Effects

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

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

Emergency Preparedness is Appendix Z

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

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

Ref: QSO19-06-ALL

DATE: **February 1, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

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

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

Amended November 29, 2019

Memorandum Summary

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

Please refer to Appendix Z of the State Operations Manual to cite the specific Emergency Preparedness E-Tags, interpretive guidelines, and survey procedures.

C-0950
(Rev.)

§485.625 Condition of Participation: Emergency Preparedness

The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness plan must include, but not be limited to, the following elements:

(a) Emergency plan. The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

Survey Memo on COVID-19 Reporting

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

Ref: QSO-21-03-Hospitals/CAHs

DATE: **October 6, 2020**

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

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

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

Memorandum Summary

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

Background

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

Hospital Improvement Final Rule

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

[Billing Code: 4120-01-P]

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

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

RIN 0938-AT23

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

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

ACTION: Final rule.

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

Emergency Preparedness Rule

Survey & Certification- Emergency Preparedness Regulation Guidance

Guidance for Surveyors, Providers and Suppliers Regarding the New Emergency Preparedness (EP) Rule

On September 8, 2016 the Federal Register posted the final rule *Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers*. The regulation goes into effect on November 16, 2016. Health care providers and suppliers affected by this rule must comply and implement all regulations one year after the effective date, on November 16, 2017.

Purpose: To establish national emergency preparedness requirements to ensure adequate planning for both natural and man-made disasters, and coordination with federal, state, tribal, regional and local emergency preparedness systems. The following information will apply upon publication of the final rule:

- Requirements will apply to all 17 provider and supplier types.
- Each provider and supplier will have its own set of Emergency Preparedness regulations incorporated into its set of conditions or requirements for certification.
- Must be in compliance with Emergency Preparedness regulations to participate in the Medicare or Medicaid program. The below downloadable sections will provide additional information, such as the background and overview of the final rule and related resources.

Additional information has been provided on the left side hyperlinks categorized by information from the EP Rule, such as the Emergency Preparedness Plan, Communication Plan, Policies and Procedures and Testing.

OIG Report on Oversight of Hospital Pharmacies

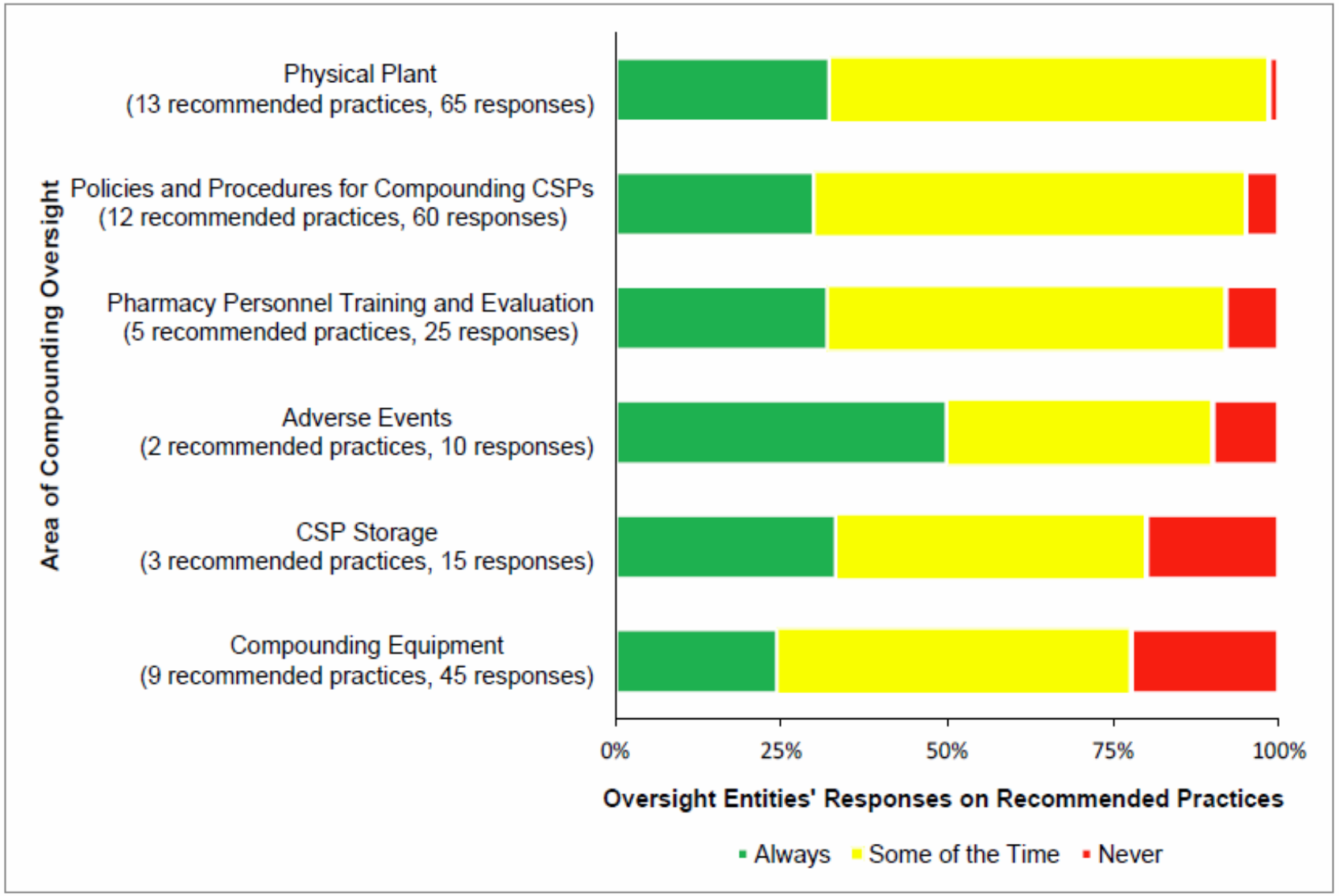
OFFICE OF
INSPECTOR GENERAL

http://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf

MEDICARE'S OVERSIGHT OF COMPOUNDED PHARMACEUTICALS USED IN HOSPITALS

Daniel R. Levinson
Inspector General

Figure 1: Extent to Which the Five Oversight Entities Incorporate Recommended Practices for Each Area of Compounding Oversight Into Surveys



Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

Table A1: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to the Hospital Physical Plant and Environmental Quality

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors request a copy of the hospital's pharmacy cleaning logs?	1	4	0
Do surveyors request a copy of the hospital's pharmacy environmental sampling logs?	0	5	0
If the hospital prepares CSPs onsite, do surveyors assess whether the area of preparation is appropriate for all CSP risk levels compounded at the hospital?	2	3	0
If the hospital prepares hazardous CSPs onsite, do surveyors assess the appropriateness of the physical area where hazardous CSPs are compounded?	3	2	0
If the hospital prepares CSPs onsite, do surveyors assess the environmental quality and control in the area of preparation?	3	2	0
If always or some of the time, do surveyors assess the adequacy of the environmental quality and control for each risk level of CSP prepared at the hospital?	2	3	0
If the hospital prepares CSPs onsite, do surveyors review the hospital's written procedures outlining the following:			
Cleaning and disinfecting of the compounding areas?	1	4	0
Personnel hand hygiene and garbing in compounding areas?	3	2	0
Employee aseptic technique in compounding areas?	2	3	0
Environmental sampling in compounding areas?	0	5	0
Facility and engineering control testing and certification in compounding areas?	0	4	1
If the hospital prepares CSPs onsite, do surveyors assess the adequacy of personnel protective equipment for compounding CSPs, including applicable	2	3	0

ASHP Guidelines on Outsourcing Sterile Compounding Services

Purpose

Health care organizations considering outsourcing sterile compounding services should have a clear understanding of what they want to accomplish. Consideration should include, at the least, an internal needs assessment, a cost analysis, and a careful review of prospective compounding pharmacies. The organization should examine the potential long-term consequences of outsourcing as well as the short-term outcomes expected during a contract's performance period.

The purpose of these guidelines is to provide an overview of factors and processes for health care organizations to consider when exploring outsourcing of pharmacy sterile compounding. The ideas presented in this document could be used for strategic planning with the organization's decision-makers, for drafting contract provisions, for comparing prospective compounding pharmacies, for preparing for contract negotiations, or for evaluating a compounding pharmacy's performance.

This document includes ideas about reasons for outsourcing and reasons for not outsourcing, services available from compounding pharmacies, the outsourcing process and outsourcing arrangements, and evaluation of a compounding pharmacy's performance. The appendix provides a topical list of contract provisions, some of which relate to practices that are the subject of other American Society of Health-System Pharmacy (ASHP) guidelines. Organizations should refer to pertinent ASHP guidelines for additional information on which to base their contract provisions, agreements, and deci-

- Shortage of pharmacy personnel with specific experience and capabilities.

Financial and Cost Control

- Restricted budgets.
- Increased operating costs.
- Increased drug costs.
- Increased emphasis on measuring performance in terms of staffing and costs.

Quality Assurance

- Increased expectations of and pressures from payers, accreditation organizations, and consumer groups to improve the quality of patient care, reduce the incidence of hospital infections, and demonstrate compliance with applicable standards and regulations.

Governmental and Regulatory

- Reductions of federal, state, and local government reimbursement for health care.
- Increased numbers of individuals dependent on federal, state, and local governments for health care.
- Increased federal and state interest in standards for sterile compounding (i.e., *United States Pharmacopeia* [*USP*] chapter 797[4]).

ASHP Guidelines on Outsourcing

www.ashp.org/DocLibrary/BestPractices/MgmtGdlOutsourcingSterileComp.aspx

ASHP Guidelines on Outsourcing Sterile Compounding Services

Purpose

The purpose of these guidelines is to provide an overview of factors and processes for healthcare organizations to consider when contracting with compounding pharmacies or outsourcing facilities to obtain sterile compounding services. These guidelines describe services available from compounding pharmacies or outsourcing facilities, reasons for outsourcing and reasons for not outsourcing, the outsourcing process and outsourcing arrangements, and recommendations for evaluating a contractor's performance. The guidelines also provide a topical list of contract provisions, some of which relate to practices that are the subject of other ASHP guidelines. Organizations should refer to pertinent ASHP guidelines for additional information on which to base their contract provisions, agreements, and decisions.[1-3] The concepts presented in this document could be used for strategic planning with the organization's decision-makers, assisting in assessing the quality of compounded sterile preparations or products, drafting contract provisions, comparing prospective contractors, preparing for contract negotiations, and evaluating contractor performance.

This document addresses representative outsourcing options and contract agreements and is not intended to cover all situations. Managers of pharmacy and healthcare organizations should use their professional judgment about applicability to their own needs and circumstances.

Compounding Pharmacies. Section 503A clarified the FD&C Act for activities described as traditional patient-specific compounding (sometimes now called "503A compounding"). Healthcare organization pharmacies fall into this category, as do other pharmacies that fill prescriptions or medication orders within a prescriber–pharmacist–patient professional relationship. All 503A compounding pharmacies, except those in federal facilities, are regulated by state boards of pharmacy; however, they may also be subject to Food and Drug Administration (FDA) inspection under the agency's authority to enforce section 503A of the FD&C Act. The agency's expectations for compliance are specified in the FDA *Compliance Policy Guide* (CPG) *on Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.*[5] In addition to current regulatory requirements, such as prescriptions or medication orders for compounded preparations and compliance with applicable *United States Pharmacopeia* (*USP*) chapters on compounding (i.e., *USP* chapters 795 and 797),[8,9] inspectors may look for implementation of additional CPG recommendations. The services provided by compounding pharmacies are limited by the existing requirement for individual prescriptions or medication orders and may be further limited by forthcoming regulation of distribution across state lines,[7] state and federal restrictions on office-use preparations, and other limitations of section 503A.

Outsourcing Facilities. Section 503B outsourcing facilities

ISMP
Institute for Safe Medication Practices

CHEERS ABOUT CONTACT NEWS SUPPORT

Information for consumers

Consulting and Education | Tools and Resources | Publications and Alerts | Error Reporting

ISMP Medication Safety Guidelines cover a variety of topics, including the safe use of technology, specific high-alert medications, and treating high-risk patient populations.

Most guidelines are driven by multi-disciplinary summits that include a review of the literature, assessment of reported errors, and input from experts. Final statements are developed by consensus decision making.

Best Practices for Hospitals

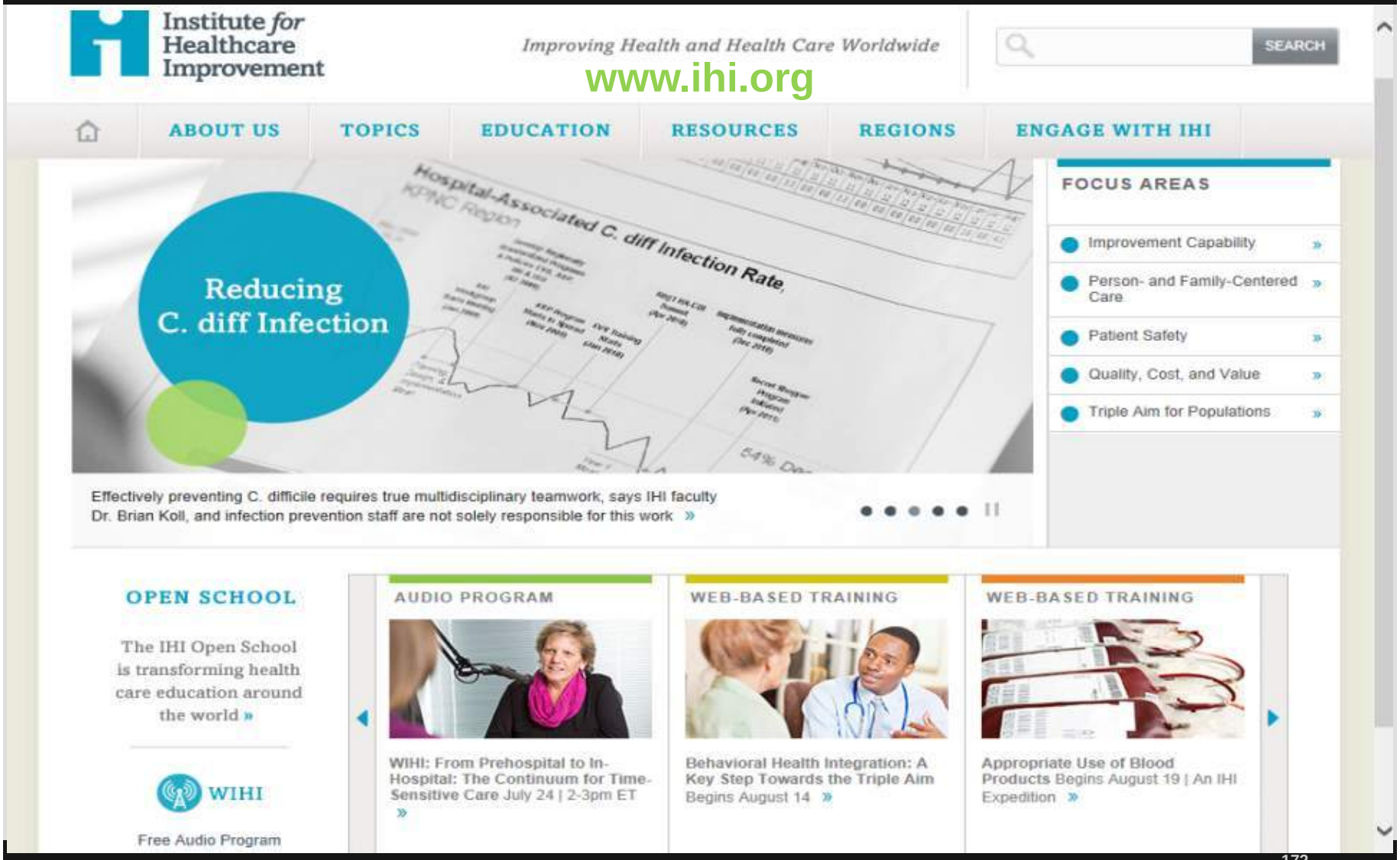
These guidelines provide consensus-based best practices for safety issues that continue to cause fatal

Guidelines for Safe Insulin Use

These guidelines address at-risk behaviors and unsafe practices associated with subcutaneous insulin use in

USP U.S. Pharmacopeial

Institute for Healthcare Improvement IHI



Recommendation on Medications in the OR

The Official Journal of the Anesthesia Patient Safety Foundation

apsf www.apsf.org **NEWSLETTER** Spring 2010

www.apsf.org/newsletters/html/2010/spring/01_conference.htm

In this issue:

APSF Hosts Medication Safety Conference

APSF Funds New Registry

Web Application to Track Patient Safety During Sedation

Dear SIRS—Why Do New Defaults Turn Off CO_2 and Apnea Alarms?

Q&A—Exposure to Ultraviolet Radiation in the Operating Room

Hospital Coalition Group Endorses APSF Recommendations for PCA Monitoring

Letters to the Editor:

Accidental Intrathecal Injection of Tranexamic Acid

APSF Hosts Medication Safety Conference

Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

Overview

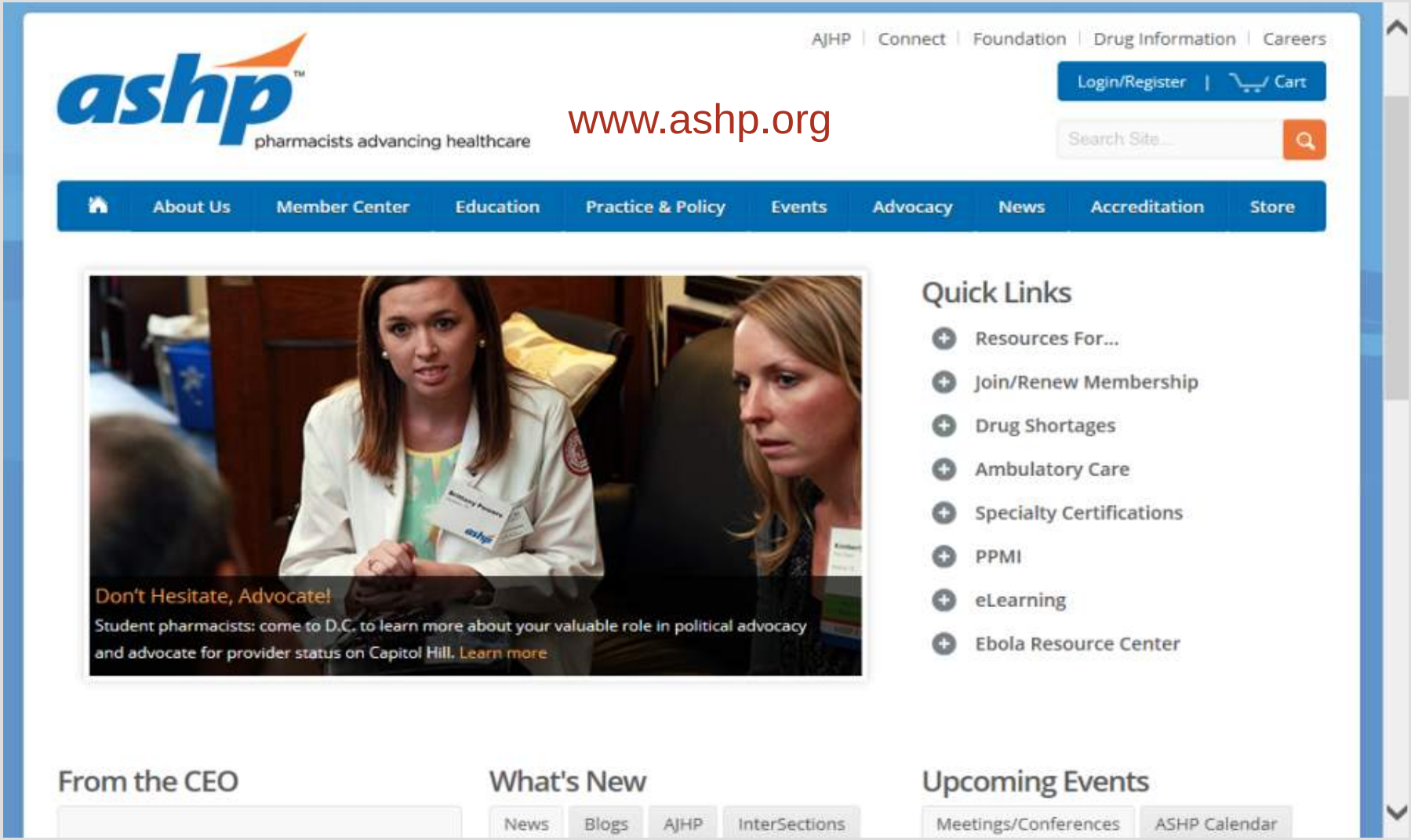
On January 26, 2010, the Anesthesia Patient Safety Foundation (APSF) convened a consensus conference of 100 stakeholders from many different backgrounds to develop new strategies for "predictable prompt improvement" of medication safety in the operating room. The proposed new paradigm to reduce medication errors causing harm to patients in the operating room is based on Standardization, Technology, Pharmacy/Prefilled/Premixed, and Culture (STPC). This new paradigm goes far beyond the important but traditional emphasis on medication label format and the admonition to "always read the label." Small group sessions on each of the 4 elements of the new paradigm (STPC) debated and formulated specific recommendations that were organized and prioritized by all the attendees.

The resulting consensus recommendations include:

Standardization

- High alert drugs (such as phenylephrine and epinephrine) should be available in

American Society of Health System Pharmacists or ASHP



Infusion Nurses Society INS

www.ins1.org

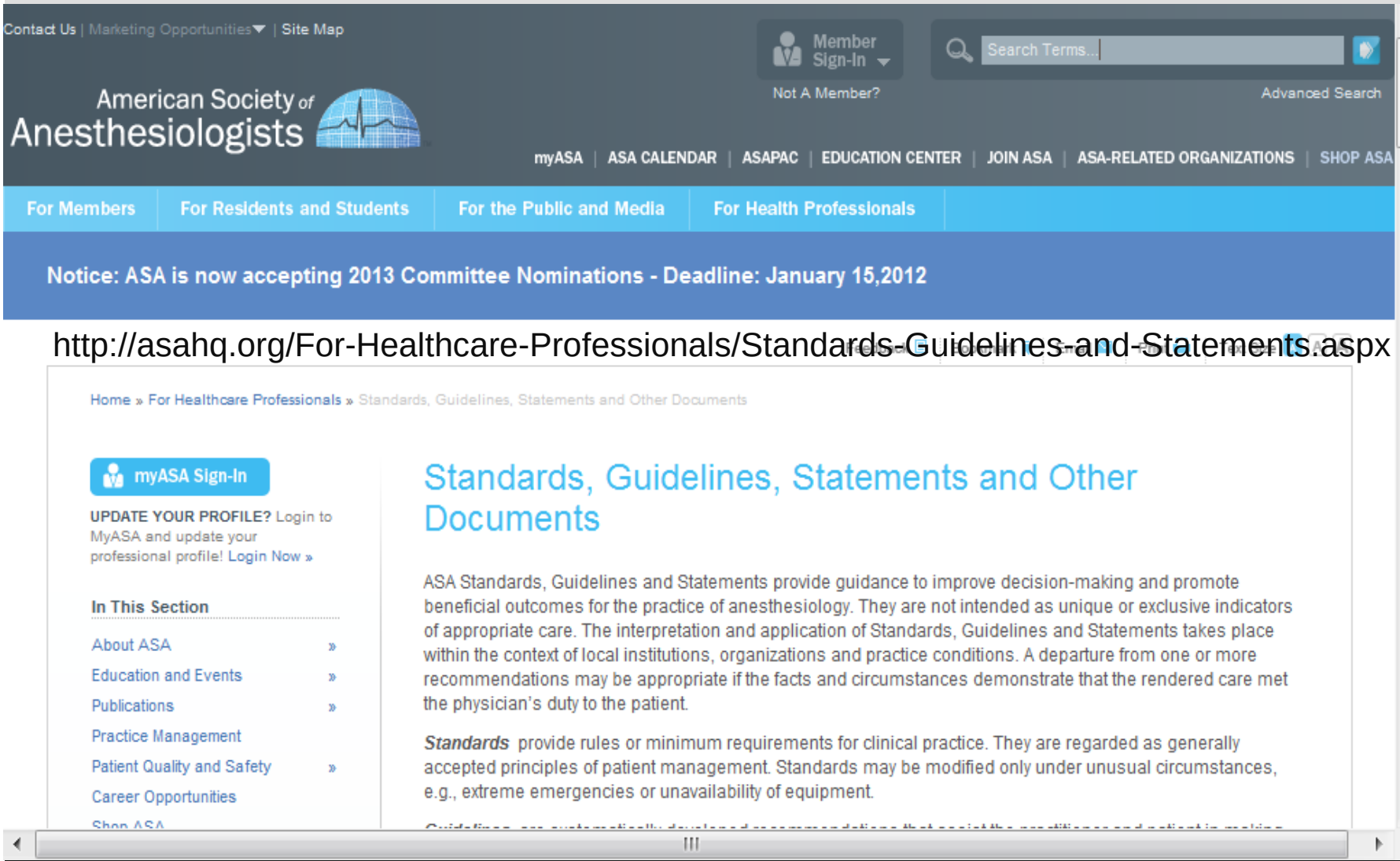
National Coordinating Council

NAN Alert Archive

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

September 15, 2016	Observe for possible fluid leakage when preparing parenteral syringes
June 30, 2015	Move toward full use of metric dosing: Eliminate dosage cups that measure liquids in fluid drams. Use cups that measure mL.
March 23, 2015	Bloxiverz and Vazculep potential for mix-ups
February 18, 2014	Potential inaccuracy of electronically transmitted medication history information used for medication reconciliation
June 10, 2013	Important Change with Heparin Labels
April 17, 2013	Confusion regarding the generic name of the HER2-targeted drug KADCYLA (ado-trastuzumab emtansine)
January 23, 2013	Severe burns and permanent scarring after glacial acetic acid (≥ 99.5%) mistakenly applied topically

ASA Guidelines and Statements



Use a Company that is Registered

FDA's Compounding Website

FDA MedWatch Form

Reset Form

U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page 1 of 3

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	_____ lb or _____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
   ☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Disability or Permanent Damage
   - ☐ Life-threatening
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Hospitalization - initial or prolonged
   - ☐ Other Serious (Important Medical Events)
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*

5. **Describe Event, Problem or Product Use Error**

2. Dose or Amount	Frequency	Route
#1		
#2		

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
   #1
   #2

4. **Diagnosis or Reason for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. Common Device Name	2b. Procode

INK

Programs
Topics
Improvement
Leading System Improvement
Chronic Conditions
Critical Care
Developing Countries
End Stage Renal Disease
Flow
Healthcare-Associated Infections
Health Professions Education
HIV/AIDS
Last Phase of Life
Medical-Surgical Care
Office Practices
Patient-Centered Care
Patient Safety
Safety: General
Measures
Changes
Improvement Stories
Tools
Resources
Literature
FAQs
Medication Systems
Reducing Harm from Falls
Surgical Site Infections
Perinatal Care
Reducing Mortality
Reliability
Community
Workspace
Results

Introduction to Trigger Tools for Identifying Adverse Events

The use of "triggers," or clues, to identify adverse events (AEs) is an effective method for measuring the overall level of harm from medical care in a health care organization. Traditional efforts to detect AEs have focused on voluntary reporting and tracking of errors. However, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients. Hospitals need a more effective way to identify events that do cause harm to patients, in order to select and test changes to reduce harm.

There are various Trigger Tools available on IHI.org, including:

- IHI Global Trigger Tool for Measuring Adverse Events
- Trigger Tool for Measuring Adverse Drug Events
- Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting
- Trigger Tool for Measuring Adverse Drug Events in the Nursing Home
- Surgical Trigger Tool for Measuring Peri-operative Adverse Events
- Intensive Care Unit Adverse Event Trigger Tool
- Pediatric Trigger Toolkit: Measuring Adverse Drug Events in the Children's Hospital
- Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit
- Outpatient Adverse Event Trigger Tool

These Trigger Tools provide an easy-to-use method for accurately identifying AEs (harm) and measuring the rate of AEs over time. Tracking AEs over time is a useful way to tell if changes being made are improving the safety of the care processes.

Choosing a Tool

There are two approaches to using the harm measures from the Trigger Tools:

1. To monitor an overall level of harm as a "dashboard" item
2. To track harm in a specific topic or area

The **IHI Global Trigger Tool** is designed specifically for the first approach. This is the tool to use for an organization-wide measure that can be reported to leadership. It is designed for use with the records of adult inpatients in acute care.

Related Information
- Measures
- Changes
- Tools
- Improvement Tip: Focus on Harm, Not Errors

Join the Discussion

Free Trigger Tools Listserv

Join a free listserv with other users of IHI Trigger Tools.

1. Send a completely blank email (no subject, signature, or text in message body) to: subscribe-triggertools@ls.ihi.org.

2. You will receive a confirmation message.

3. Post messages to the listserv by sending emails to triggertools@ls.ihi.org.

Featured Tool

Interactive Trigger Tool for Measuring ADEs

The interactive Trigger Tool makes tracking ADEs over time easier and more accurate, and

High Alert How to Guide IHI

v03
10/01/2008

PROTECTING 5 Million lives FROM HARM IHI.org

Getting Started Kit:
Prevent Harm from High-Alert Medications

How-to Guide

A national initiative led by IHI, the 5 Million Lives Campaign aims to dramatically improve the quality of American health care by protecting patients from five million incidents of medical harm between December 2006 and December 2008. The How-to

www.ihi.org/NR/rdonlyres/8B2475CD-56C7-4D9B-B359-801F3CC3A8D5/0/HighAlertMedicationsHowToGuide.doc

WISCONSIN PATIENT SAFETY INSTITUTE

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www.WPSI.org

MODEL HIGH-ALERT MEDICATIONS POLICY & PROCEDURES

PURPOSE

- To provide guidance to acute care organizations for the safe handling and administration of medications designated as High Alert Medications.
- To increase awareness of High Alert Medications, thereby improving patient safety.

DEFINITION

High Alert Medications are drugs that bear a higher risk of causing significant patient harm when they are used in error.[1]

POLICY

A. The following medications are appropriate for inclusion in a High Alert Medications policy.

- Epidural infusions
- Fentanyl
- Heparin (>100 units, flushes exempt)
- Insulin (including regular, aspart, NPH, and glargine)
- Lidocaine with epinephrine vials

B. The following medications may also be appropriate for inclusion in a High Alert Medication policy in addition to the medications above.

- Glycoprotein IIb/IIIa inhibitors (eptifibatide, abciximab, tirofiban)
- Iron Dextran
- Adrenergic antagonists agents (e.g., esmolol)
- Anticonvulsants

C. Concentrated electrolyte vials (e.g., potassium chloride) should not be stocked in patient care areas.

PROCEDURES

Safety procedures during the ordering, preparation, dispensing and administration of High Alert Medications include:

Prescribing

A. Verbal orders for High Alert Medications should

POLICY

A. The following medications are appropriate for inclusion in a High Alert Medications policy.

- Epidural infusions
- Fentanyl
- Heparin (>100 units, flushes exempt)
- Insulin (including regular, aspart, NPH, and glargine)
- Lidocaine with epinephrine vials
- Neuromuscular blocking agents (atracurium, cisatracurium, mivacurium, pancuronium, rapacuronium, rocuronium, succinylcholine, vecuronium, etc)
- Patient Controlled Analgesia (PCA) infusions of any medication
- Total Parenteral Nutrition (TPN) and Total Nutrient Admixture (TNA) solutions
- Oncologic agents
- Moderate sedation agents (e.g., midazolam)
- Anesthetic agents (e.g., propofol)
- Adrenergic agonists (phenylephrine)

C. Concentrated electrolyte vials (e.g., potassium chloride) should not be stocked in patient care areas.

PROCEDURES

Safety procedures during the ordering, preparation, dispensing and administration of High Alert Medications include:

Prescribing

A. Verbal orders for High Alert Medications should be discouraged.

B. If possible, prescribing for High Alert Medications should be standardized using preprinted orders.

Preparation and dispensing

A. All storage locations should be clearly labeled and separated from regular stock. If High Alert Medications must be kept in patient care areas, locked storage areas should be used with a distinct High Alert Medication warning label visibly placed on the storage bin.

ISMP Medication Error Reporting Program

FDA Reporting

PDF format Reporting Forms

These forms are fillable on your computer using the free Adobe Acrobat Reader, or just print the blank form and fill it out by hand. The Voluntary Form FDA 3500 features a postage-paid pre-addressed mailer.

www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

- **Form FDA 3500 - Voluntary Reporting**

  For use by healthcare professionals, consumers, and patients. Submit the completed form using built-in postage-paid mailer, or fax.
  Instructions for Completing Form FDA 3500

- **Form FDA 3500B - Voluntary Reporting for Consumers**

  A consumer-friendly version of the 3500 reporting form. Submit the completed form using address on page 3 of the form, or fax.

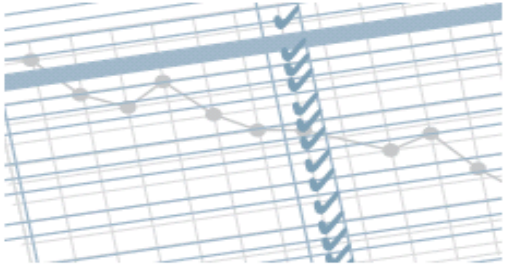
- **Form FDA 3500A - Mandatory Reporting**

  For use by IND reporters, manufacturers, distributors, importers, user facilities personnel
  Instructions for Completing Form FDA 3500A

Online Reporting Form (Voluntary Reporting)

Report serious adverse events online for human medical products, including potential and actual product use errors, product quality problems, and therapeutic inequivalence/failure. The introductory page features additional information and instructions.

INSTITUTE FOR HEALTHCARE IMPROVEMENT



Innovation Series 2009

IHI Global Trigger Tool

for Measuring Adverse Events

Second Edition

Medication Resources

- Governmental agencies may include;
  - Food and Drug Administration (FDA) at www.fda.gov
  - Med Watch Program at www.fda.gov/medwatch
  - Agency for Health Care Research and Quality (AHRQ) at www.ahrq.gov

Websites

- The Institute for Safe Medication Practices (ECRI) - www.ismp.org
- U.S. Pharmacopoeia (USP) www.usp.org
- Institute for Healthcare Improvement- www.ihi.org (NPSF combined),
- Sentinel event alerts at www.jointcommission.org,

Additional Resources

- American Pharmaceutical Association-www.aphanet.org
- American Society of Heath-System Pharmacists-www.ashp.org
- Enhancing Patient Safety and Errors in Healthcare-www.mederrors.com
- National Coordinating Council for Medication Error Reporting and Prevention-www.nccmerp.org,
- FDA's Recalls, Market Withdrawals and Safety Alerts Page: http://www.fda.gov/opacom/7alerts.html

Interactive DRI Tool and Tables

Search FNIC

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- Search all USDA
- Advanced Search
- Search Tips

Resources for:

- Consumers

Browse By Subject

- Dietary Guidance
- Lifecycle Nutrition
- Diet and Disease
- Food Composition
- Food Safety
- Weight and Obesity
- Food Labeling
- Dietary Supplements
- Nutrition Assistance Programs
- Surveys, Reports and Research

Dietary Guidance >

Dietary Reference Intakes

The Dietary Reference Intakes (DRIs) are developed and published by the Institutes of Medicine (IOM). The DRIs represent the most current scientific knowledge on nutrient needs of healthy populations. Please note that individual requirements may be higher or lower than the DRIs.

Dietary Reference Intake Calculator for Healthcare Professionals

Easily calculate daily nutrient recommendations for dietary planning based on the National Academy of Sciences' Institute of Medicine's DRI recommendations.

DRI Tables

Find downloadable tables and charts of DRIs for all nutrients categorized by age and sex.

DRI Reports

Find details on how the DRIs were set, including the application of statistically valid methods and the roles nutrients play in traditional deficiency and chronic diseases.

Resources on Individual Macronutrients, Phytonutrients, Vitamins and Minerals

- **Macronutrients** - including general and specific resources on carbohydrates, proteins, fiber, fats and cholesterol, water, as well as interactive tools.
- **Phytonutrients** - including general information, government-related sites, and resources on specific phytonutrients such as tea, lycopene, and

Dietary Guidance

- Dietary Guidelines
  - Previous Editions
  - Historical Dietary Guidance
- Dietary Reference Intakes
  - Dietary Reference Intake Calculator for Healthcare Professionals
  - DRI Nutrient Reports
  - DRI Tables
- Fruits & Veggies-More Matters Resources
  - Fruits & Veggies-More Matters™
  - Fruit and Veggie Pages for...
  - State Programs and Resources
  - Resources in Spanish
- Individual Dietary Assessment
- MyPlate and Historical Food Pyramid Resources