Critical Access Hospital CoPs

Part 2 of 4

What CAHs Need to Know

Pharmacy, Dietary, Maintenance, Board, ED, and Policies

Speaker

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- Email questions to CMS at qsog_CAH@cms.hhs.gov or cahscg@cms.hhsgov (Critical Access Hospitals)

The Conditions of Participation CoPs

- First, published in the Federal Register
- Next, CMS publishes **Interpretive Guidelines**
- Some include **survey procedures**
- When survey memos are final they are published in a transmittal and placed in the hospital CoP manual
- Best way to keep up with changes in the future is to have one or two people dedicated who can check for changes and for survey memos

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Location of CMS Hospital CoP Manual

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

Medicare State Operations Manual

Appendix

- Each Appendix is a separate file that can be accessed directly from the SC... Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the corresponding letter in the "Appendix Letter" column to see any available file in PDF.
- To return to this page after opening a PDF file on your desktop. use the browser "back" button. This is because closing the file usually will also close most browsers

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

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

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

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

and is critical access hospital CoP

CAH CoP or State Operations Manual

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

(Rev. 200, 02-21-20)

Transmittals for Appendix W

INDEX

Survey Protocol

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

Regulations and Interpretive Guidelines for CAHs

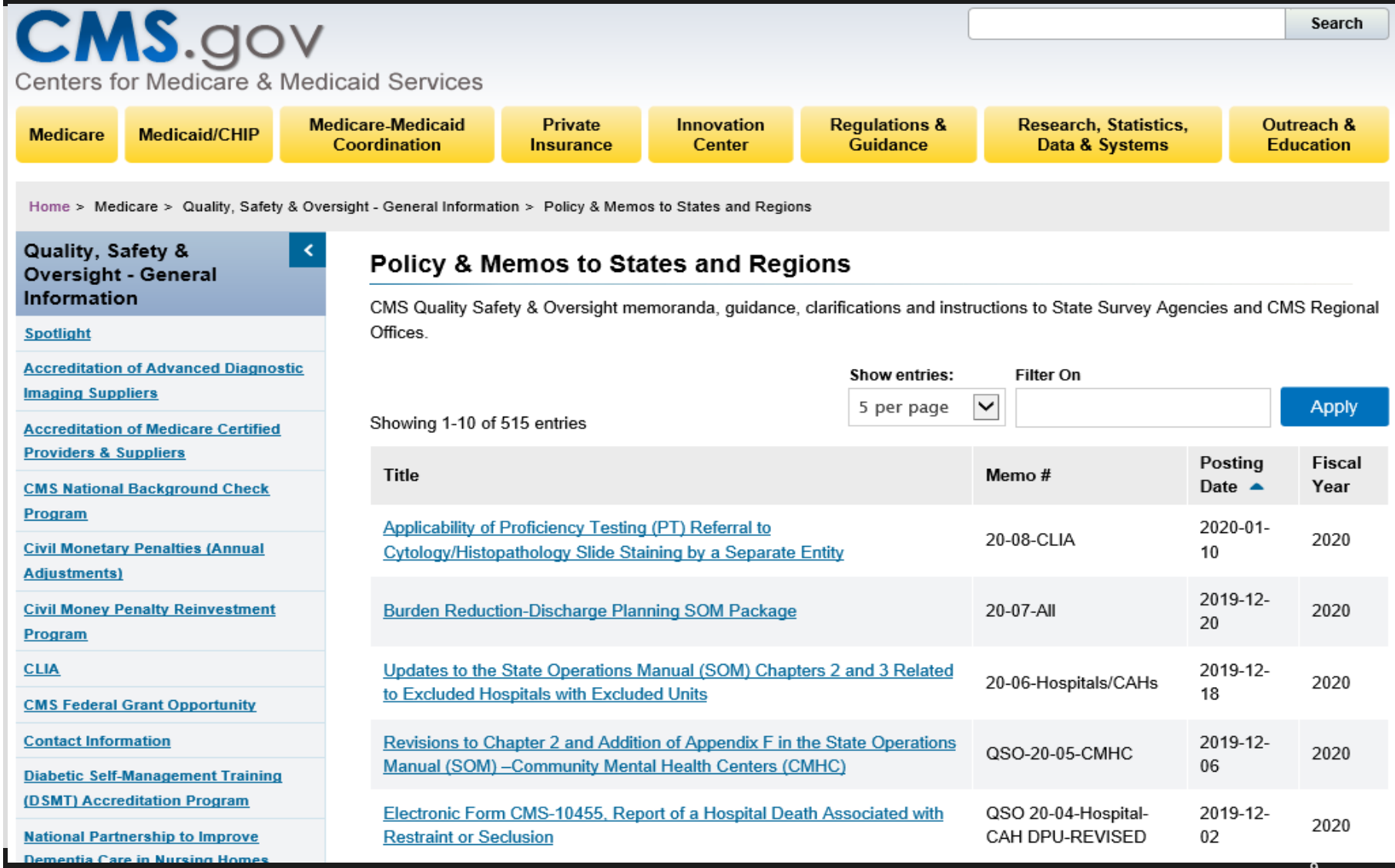
Questions to qsog_cah@cms.hhs.gov cahscg@cms.hhs.gov

CMS Survey and Certification Website

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

Click on Policy & Memo to States

CMS Survey Memos



New Tag Numbers in 2020

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: QSO-20-07-ALL

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

DATE: **December 20, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

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

Memorandum Summary

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

Background

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

The two final rules are as follows:

Crosswalk to New Tag Numbers

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

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

Construction 912

- **Standard**: CAH is constructed, arranged, and maintained to ensure access to and safety of patients
  - Additionally, it must provide adequate space to provide care to patients
- Must be constructed in accordance with state and federal law
- Will look to see if maintained in a manner to ensure safety of patients
  - Conditions of ceilings, walls, and floors
  - See Facility Guideline Institute (FGI)

Physical Environment 914

- Must have housekeeping (ES) and preventative maintenance (PM) programs,
- All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition
- This means facilities, supplies and **equipment** must be maintained
- How do you ensure your equipment is maintained properly

Maintenance 914

- This includes Boilers, elevators, air compressors, ventilators, X-ray equipment, IV pumps, stretchers, IV equipment, maintenance log, etc.
- Must identify equipment to meet patient needs in case of an emergency or disaster situation
- Could occur from mass trauma, disease outbreaks, internal disasters, etc.
- All equipment must be tested and inspected before initial use
- CMS has issued 2 survey memos on this

CMS Hospital Equipment Maintenance

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Baltimore, Maryland 21244-1850

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

Equipment Memo

- Discusses preventive maintenance (PM) and inspection of equipment
  - As recommended by the manufacturer or based on a risk-based assessment unless federal or state law of CoP specifies otherwise
- Discusses alternative equipment maintenance (AEM) program
- Must demonstrate that qualified personnel are performing risk based assessments, PM, or establishing the AEM program

Equipment Memo PM

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

Equipment Memo

- Make sure the frequency is in accordance with manufacturers recommendation or with strategies of an alternate equipment maintenance (AEM) program
  - An example for medical equipment is the American National Standards Institute for the Advancement of Medical Equipment Handbook
- The frequency in testing, inspecting, and maintaining must be in accordance with manufacturers recommendation for the following: medical device **lasers**, **new** medical equipment with insufficient maintenance history to support use of AEM, **imaging and diagnostic equipment**, etc**.**

Disposal of Trash 920 2020

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

Storage of Drugs 922

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

Physical Environment 924

- **Standard**: Premises must be clean and orderly
- Means **uncluttered** and don't store equipment in corridors or hallways
- Area is neat and well kept
- Spills not left unattended
- No peeling paint or floor obstructions
- No visible water leaks or plumbing problems

Proper Ventilation 926 2020

- **Standard;** There must be proper ventilation, lighting, and temperature controls in pharmacy, patient care and food preparation areas
- Guidelines are pending and past ones include:
  - In pharmaceutical, patient care and food preparation areas
  - Proper ventilation in areas with nitrous oxide, glutaraldehyde, xylene, pentamidine, or other potentially hazardous substances
  - Isolation rooms comply with laws such as the CDC Isolation Guidelines, OSHA, NIH, etc.

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

Physical Environment Past Ones

- Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection,
- Including **anesthetizing locations** where inhalation anesthesia agents are used
- Excessive humidity in the operating room can cause bacterial growth and compromises the integrity of wrapped sterile instruments and supplies,
  - RH at 30% or greater unless waiver is used of 20% or greater
- Acceptable standards such as from AORN or the Facilities Guideline Institute (FGI) should be incorporated into CAH policy.

CMS Memo April 19, 2013

- CMS issues two memos related to the relative humidity (RH)
- AORN use to say temperature should be between 68-73 degrees and humidity between 30-60% in the OR, PACU, cath lab, endoscopy rooms and instrument processing areas
- CMS says 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

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.

Impact of Lowering the Humidity

- Lowering humidity can impact some equipment and supplies
- Can affect shelf life and product integrity of some sterile supplies including EKG electrodes
- Some electro-medical equipment may be affected by electrostatic discharge especially older equipment
  - Can cause erratic behavior of software and premature failure of the equipment
  - It can affect calibration of the equipment
- Follow the manufacturers instructions for use that explains any RH requirements

CMS Memo on Low Relative Humidity

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Baltimore, Maryland 21244-1850

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.

Impact of Lowering the Humidity

American Hospital Association®

ASHE American Society for Healthcare Engineering, A personal membership group of the American Hospital Association

AHRMM Association for Healthcare Resource & Materials Management, Advancing the Healthcare Supply Chain, A personal membership group of the American Hospital Association

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

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]

Life Safety From Fire 930 2020

- Must follow LSC provisions
- This includes NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4
- Must have positive latching hardware and no roller latches on doors
  - These are ones that swing both ways
- Interpretive guidelines are pending

LSC Provisions 2020

- CMS can issue a LSC waiver if result would cause unreasonable hardship (932)
  - But 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 are pending for all three

LSC Provisions 938 2020

- If the sprinkler system is shut down for more than 10 hours, the CAH must:
- Evacuate the building or portion of the building affected by the system outage until the system is back up, or
- Establish a fire watch until the system is back up
- Interpretive guidelines are pending

LSC Provisions 940 2020

- Every sleeping room must have an outside window or door
- If constructed after 7-5-16 the still height can be higher than 36 inches about the floor
- Sill height 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 are 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
- Both of these have interpretive guidelines

Physical Environment

- Must have adequate number of refrigerators where foods and meds are stored,
  - Monitor temperatures in refrigerators
  - Consider labeling refrigerator “Food, No Medications” or “Medications, No Food”
- Surveyor will verify these areas are well lit,
- Surveyor will verify compliance with ventilation in patients with TB or other airborne diseases,
- Surveyor will verify food products are stored under appropriate conditions (time, temperature, packaging) based on national sources like USDA and FDA,

Emergency Preparedness Appendix Z

- CMS has moved the emergency preparedness final interpretive guidelines and survey procedures to Appendix Z
- Regulations start at tag 950
  - September 16, 2016 the final rules were published
  - An advanced copy of the emergency preparedness final rule and survey process was published on June 2, 2017
  - Effective date was November 15, 2017 and amended February 2019
  - November 29, 2019 changes were in the hospital improvement rule and IGs in 2020 or 2021
  - Questions: SCGEmergencyPrep@cms.hhs.gov

Emergency Preparedness Appendix Z

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 17-29-ALL

DATE: **June 02, 2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

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

Memorandum Summary

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

Emergency Preparedness is Appendix Z

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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

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.

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.

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.

Emergence Preparedness 950 2020

- Standard: Must comply with all federal, state, and local emergency preparedness (EP) requirements
- Must have a comprehensive EP program
- Must include the following:
  - Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards 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

Emergence Preparedness 950 2020

- Must include the following: (continued)
  - Cooperate with the EP official's efforts to maintain an integrated response during an emergency or disaster
- Must have P&P based on the EP plan
- P&Ps must be reviewed every two years
- List of things that must be in the policy
  - Food, water, pharmacy supplies, alternative sources of energy to maintain temperature, emergency lighting, fire detection, extinguishing and alarm systems and sewage and waste disposal

Emergence Preparedness 950 2020

- Need a system to track location of on-duty staff and sheltered patients during an emergency
  - If they are relocated then must document the name and location of the receiving facility
- P&P must address safe evacuation from the CAH
  - This must include treatment needs of the evacuees, staff responsibilities, transportation and evacuation location
- P&P and a means to shelter in place for patients, staff, and volunteers who remain in the hospital
- A system of documentation to preserve patient information and confidentiality of information

Emergence Preparedness 950 2020

- P&P on use of volunteers in emergencies
- P&P on developing arrangements with other CAHs or providers to accept patients in a disaster
- CAH must have a communication plan
  - This must be reviewed every two years
- There is a list of things that must be in the communication plan
  - Like names and contact information for staff, physicians, and volunteers
  - Information on federal and state emergency management agencies

Emergence Preparedness 950 2020

- Communication Plan (continued):
- Method to share information and medical information to providers for continuity of care
- Means to release patient information in case of an evacuation
- To provide information on patient conditions and locations during a disaster
- Means to provide information about the CAH's occupancy, needs and its ability to provide assistance or the Incident Command Station

Emergence Preparedness 950 2020

- Training and testing must be done every 2 years
- There is a list of things required in the training program
  - Must be based on the emergency preparedness plan
  - Must document training
- Testing must be done at least twice per year
  - Participate in an annual full scale exercise that is community bases
  - Second one such as tabletop exercise or mock disaster drill
  - Analyze response and document

Emergence Preparedness 950 2020

- Section on emergency and standby power systems regarding emergency generators
- If CAH is part of a healthcare system can have a unified and integrated EP program
- List of requirement if elect a shared system program
  - Take into account each separate facility's unique circumstances, patient population and services provided
  - Show each hospital is in compliance
  - Document the community based risk assessments etc.
  - Include integrated or shared policies

Governing Body 960 & 962

- **Standard;** CAH has a board or individual that assumes legal responsibility **for implementing and monitoring P&Ps**
  - Board must approve all policies
- Must have a board or responsible person,
  - Board must determine what categories of practitioners are eligible for appointment and reappointment to MS (NP, PA, dentist, CRNA, podiatrist) and there is written criteria for staff appointments
- Done with advice of MS,

Board Must Approve All Policies

Ms. Dill- the answer to your question is yes. Please refer to the regulation and interpretive guideline excerpt below from Appendix W of the State Operations Manual (SOM).

We hope this is helpful,

Division of Acute Care Services
Survey & Certification Group

The information provided in this email is only intended to be general summary information to the public. It is not intended to take the place of statute, regulations or official CMS policy.

§485.627 Condition of Participation: Organizational Structure
C-0241

§485.627(a) Standard: Governing Body or Responsible Individual
The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH'S total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

Governing Body 962

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

Board

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

Board Responsibility

- If the hospital is in a system, the board can decide if they want to do system wide QAPI or system wide infection control but **not** with a CAH
- This is if the board is over more than one hospital
- See the **QAPI** and **Infection control** section as there are many board responsibilities
- There are also board responsibilities for the antibiotic stewardship program (ASP)
- The board must also appoint the infection preventionist

Disclosure 964 & 966 2020

- Need policy to report changes to the state agency if you get a new CEO or medical director
- Surveyor will look for policy on reporting changes of ownership
- Surveyor will ensure hospital implements its policy
- Removed section about ownership since duplicative

Staffing 970 & 971

- **Standard:** CAH has professional staff that includes one or more physicians, and may include PAs, NPs, or CNSs
- May operate with a MD/DO on staff as well
- Need to have an organizational chart which shows the names of all MD/DO and mid-level providers
  - PA, NP, or CNS
- Surveyor will review work schedules

Staffing

- **Standard:** All ancillary staff must be supervised by professional staff (972)
- Have enough staff to take care of patients (974)
  - Emergency services, nursing services, etc.
- Will review staffing schedules and daily census records,
  - Make sure staff answer call lights promptly
  - Make sure staff address monitors that are alarming timely

Staffing 978

- MD, DO, NP, PA, or CNS must be available at all times to furnish care,
- Must show practitioner is available and shows up when patient presents to the hospital,
- Doesn’t mean they have to be there 24 hours a day,
- Must provide diagnostic and therapeutic services and supplies that are commonly furnished in a physician’s office
- May ask hours for outpatient services

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 to make sure you have a nurse on duty,

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 or NP need to participate in developing and reviewing written P&P (982)
  - Want physician input into policies also and be sure physicians review the policies periodically
- Physicians must periodically review charts and orders of PA and NP and surveyor will look for documentation of supervision (984),

Physician Supervision 988

- Must have a doctor on staff and must perform medical oversight,
  - Must be present for sufficient period of time
  - No longer says must be present at least once every two weeks
- Will want evidence that the physician provided oversight and is available for consultation or patient referral,
- Want evidence that there is periodic review of the patient records by the doctor

Physician Supervision 986

- Periodically reviews and signs records of all inpatients cared for by a PA, NP, or CNS
  - MD/DO signs records after review completed
  - If case is managed by doctor and care given by non-physician review is not required
- Periodically reviews and signs sample of outpatient records
  - Of NP, CNS, PA, or CNM
  - **ONLY** if state law requires review or co-signature or state requires collaborating physician to sign

Physician Supervision 986

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

Physician Present in the CAH 988

- MD or DO must be present in the CAH for sufficient periods of time
  - No longer says every two weeks
  - To provide medical direction, consultation and supervision
- And is available through radio, telephone, or electronic communication (telemedicine)
- Develop a P&P on this and document compliance
- CAH with busy ED and large outpatient unit would expect more frequent visits

Physician Present in the CAH 988

- Biweekly visit might be burdensome 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
- Must make sure MD or DO is available via phone, radio, video conferencing etc to handle patient emergencies and refer patients to other facilities

PA, NP, CNS

- Recommend mid-level providers be a member of the CAH staff (991)
  - Want midlevels to participate in the development and review of P&P,
  - Surveyor will interview mid level providers to determine their participation and knowledge of policies,
- Policies also need to be consistent with state standards of practice,
- Need to participate with MD/DO in review of the patient's medical records (993)

PA, NP, CNS

- Midlevel providers perform functions that are not being performed by the physicians (995)
  - Make sure services are provided as per policies
- Refer patients if needed services cannot be provided at the CAH (997)
  - Make sure medical records are maintained
- When patient is admitted by midlevel the physician is notified (998)
  - Document patient is under the care of the MD/DO in the medical record

Transfer of Patients

- Regarding arranging for transfer of patients who need services that can not available in the CAH,
- Must send a copy of the patient's medical records unless can access electronically,
- Remember EMTALA is a separate CoP that every CAH must follow,
- Make sure you have a transfer policy and it should be consistent with EMTALA,
- EMTALA training should be provided to staff and on-call physicians

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 a mid level 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,

Period Review 999 2020

- Standard: Must periodically review the midlevel provider's clinical privileges and performance
  - Must evaluate the appropriateness of their diagnosis and treatment
  - Must be evaluated by a MD/DO
  - Doctor can also be contracted
- Standard: The quality and appropriateness of the diagnosis and treatment of physicians must also be evaluated

Period Review 999 2020

- Can be evaluated by one of the following:
  - A hospital that is a member of the network, when applicable
  - Quality Improvement Organization (QIO) or equivalent entity
  - An other appropriate and qualified entity identified in the State rural health care plan
- Regarding distant-site physicians and those providing telemedicine one of the above can evaluate them
- Interpretive guidelines will be published

Patient Care Policies

- **Standard:** Services are provided in accordance with appropriate P&P (1006)
- Provision of Services: Must have P&Ps for services provided including through contract
- Need P&P governing the healthcare services that are available
- Must follow the P&Ps in delivering care
- Surveyor will review the policies on healthcare services that are provided in the CAH
- Surveyor will observe staff delivering care to the patient

Patient Care Policies 1008 2020

- P&Ps need to be developed by a group of professional staff and must include:
  - 1 MD/DO and 1 or more PA, NP, CNS if the CAH has these individuals on staff
  - **Removed** requirement for one member is who not a member of the staff
  - Removed section that said will interview CNO to determine role in policy development but moved to the nursing section
- Review **every two years** and as needed such as when there is a change in the law (no longer annually)

Patient Care Policies 1008

- Must maintain documentation of the P&P committee's activity
  - Must show evidence that all the P&Ps are reviewed at least **2 years**
  - Must reflect any changes made
- P&P committee must review existing and new P&Ps
- Final decision on P&Ps is made by the board
- If the P&P recommendations by the advisory group are rejected, then the board must include in the record and the rational for the change

Policies (Scope of Services) 1010

- **Standard:** Need P&P that describes the services provided by the CAH directly or through contract
  - Often called the scope of services or provision of care
- Should include statements like “taking complete medical histories, providing complete physical examinations, laboratory tests including” (with a list of tests provided) would satisfy this requirement,
- Should include arrangements made with Hospital X for providing the following services with a list of specialized diagnostic and lab testing,

Emergency Medical Services 1012

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

Guideline for Medical Management 1014

- Need guidelines on managing health problems that include when medical consultation or referral is needed
- Need written guidelines on maintaining medical records and procedure for periodic review and evaluation of the services provided at the CAH
  - Such as general instructions or protocols on how to medically manage the patient's health problems commonly seen in the CAH

Medical Management

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

OIG Report January 22, 2015
ISMP Guidelines
ASHP Resources

Surveyor Training on Compounding

- The OIG issued a report regarding a recommendation that which called on CMS to ensure hospital surveyors are trained on nationally recognized compounding practices
- Recommend that changes be made to the CoPs interpretive guidelines to address hospital contracts with stand-alone compounding pharmacies
- OIG said the lack of surveyor training prevented the oversight entities from effective evaluating the hospital's use of CSP or compounded sterile preparations

OIG Report on Oversight of Hospital Pharmacies

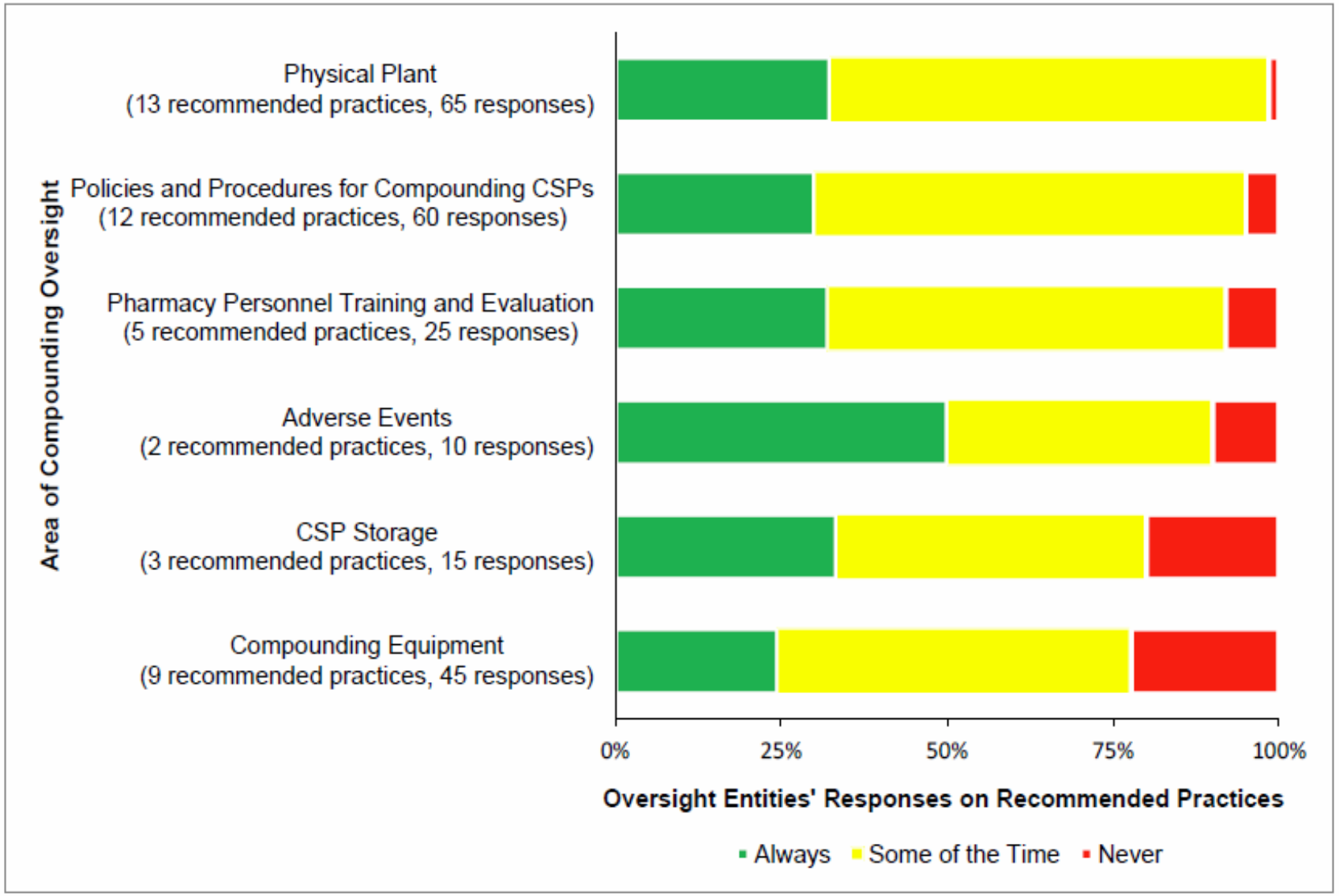
OFFICE OF
INSPECTOR GENERAL

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

ISMP Guidelines on Sterile Compounding

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

ISMP Revised 2016 22 Pages

Institute for Safe Medication Practices

ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations

Original Publication: 2013
Revised: 2016

www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.pdf

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

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]).

Pharmacy CoPs

No Reference to USP Standards

- USP 797 was suppose to go into effect December 1, 2019 but delayed due to an appeal until March 12, 2020 (chapter remanded to the compounding expert committee regarding the BUD)
  - Many of the USP standards were changing
- CMS removed all references to USP out of the CoPs
- Now says you have to follow all standards of care and evidenced based practices
- You still have to follow but when changes are made then CMS does not have to go back and change the Cops

Drugs and Biologicals P&P 1016

- CMS requires policies (rules) for the storage, handling, dispensing, and administration of drugs and biologicals,
- Need to store drugs in accordance with acceptable standards of practice,
- Keep accurate records of the receipt and disposition of all scheduled drugs,
- And all outdated, mislabeled, or otherwise unusable drugs are not available for patient use,

Drugs and Biologicals 1016

- Long section that pharmacy and nursing need to read
- Must make sure drugs are managed in a manner that is safe and appropriate
- Must have an order for the medication
- Must have written P&Ps to govern pharmacy services
- P&Ps must address storage, handling, dispensing, and administration
- Must follow acceptable standards of care

Drugs and Biologicals 1016

- CAH rules and P&P must be consistent with standards or guidelines for pharmaceutical services and medication administration
- Such as USP, ASHP, ISMP, Infusion Nurses Society, IHI, and National Coordinating Council
- The written P&Ps must also be 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

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.

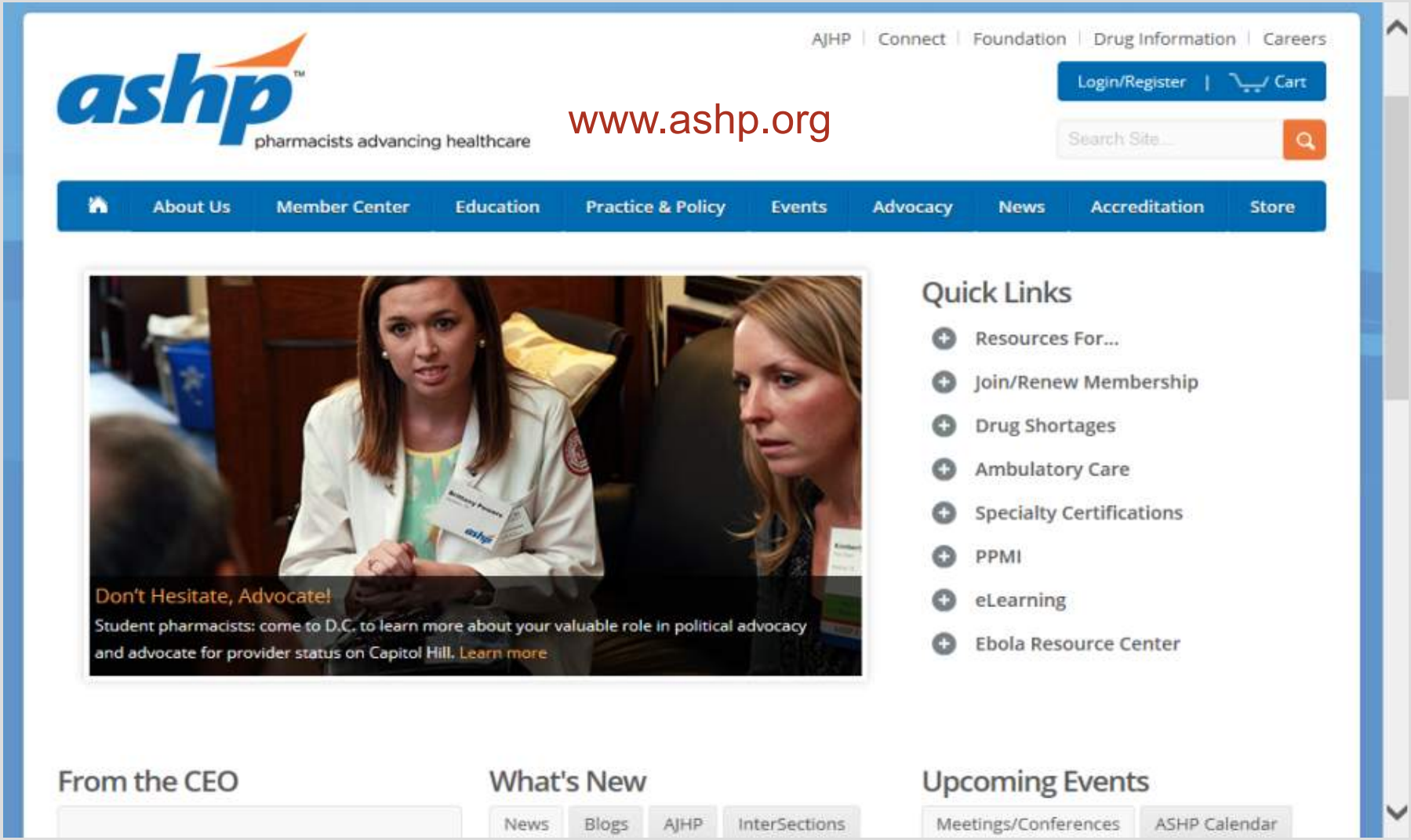
Best Practices for Hospitals

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

American Society of Health System Pharmacists or ASHP



Infusion Nurses Society INS

www.ins1.org

National Coordinating Council

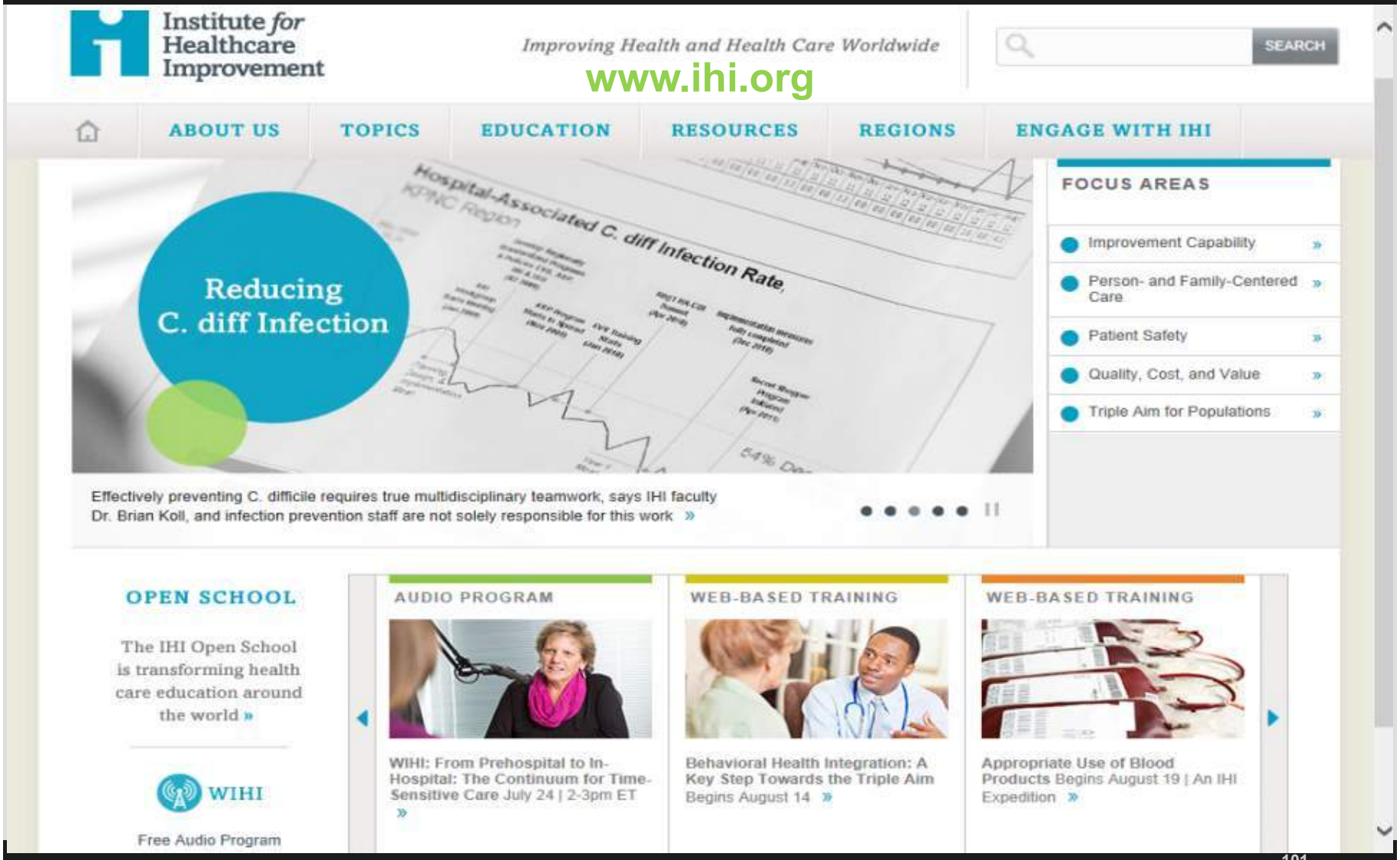
NAN Alert Archive

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

USP U.S. Pharmacopeial

Institute for Healthcare Improvement IHI



Drug Rules Must Include 1016

- P&Ps must identify the qualifications of pharmacy director
  - Person must make sure state laws are followed including who can perform pharmacy services
  - Including supervision of the pharmacy staff
  - Must be able to identify standards used in developing P&P
  - Note: Can cite as references in the P&Ps
- Storage including location of storage areas, medication carts, and dispensing machines

Drug Rules Must Include 1016

- Proper environmental conditions
  - Follow manufacturer's recommendations such as keep refrigerated, room temperature, out of light, etc.
- Security
  - P&P must be consistent with state and federal law as who can access pharmacy or drug storage areas
    - Housekeeping, security or maintenance are usually not given unsupervised access
  - If kept in private office then patients and visitors are not allowed in the area without supervision

Drug Rules Must Include 1016

- Secure area is restricted to personnel
  - Given flexibility in non-controlled drugs such as don't have to be locked up when setting up for a procedure
  - Example would be the OR
  - Would lock up when area not staffed such as in evenings and weekends
- Medication carts, anesthesia carts, epidural carts and non-automated medication carts with medications must be secure when not in use

Medications in the OR ASA Position

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

American Society of Anesthesiologists®

STATEMENT ON SECURITY OF MEDICATIONS IN THE OPERATING ROOM

(Approved by the ASA Executive Committee in October 2003, and last amended by the ASA House of Delegates on October 16, 2013)

Preamble

A secure environment of care is needed for medication safety. Medication safety includes the security of oral, sublingual, parenteral, and inhaled drugs used for elective and emergency patient care. A secure 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

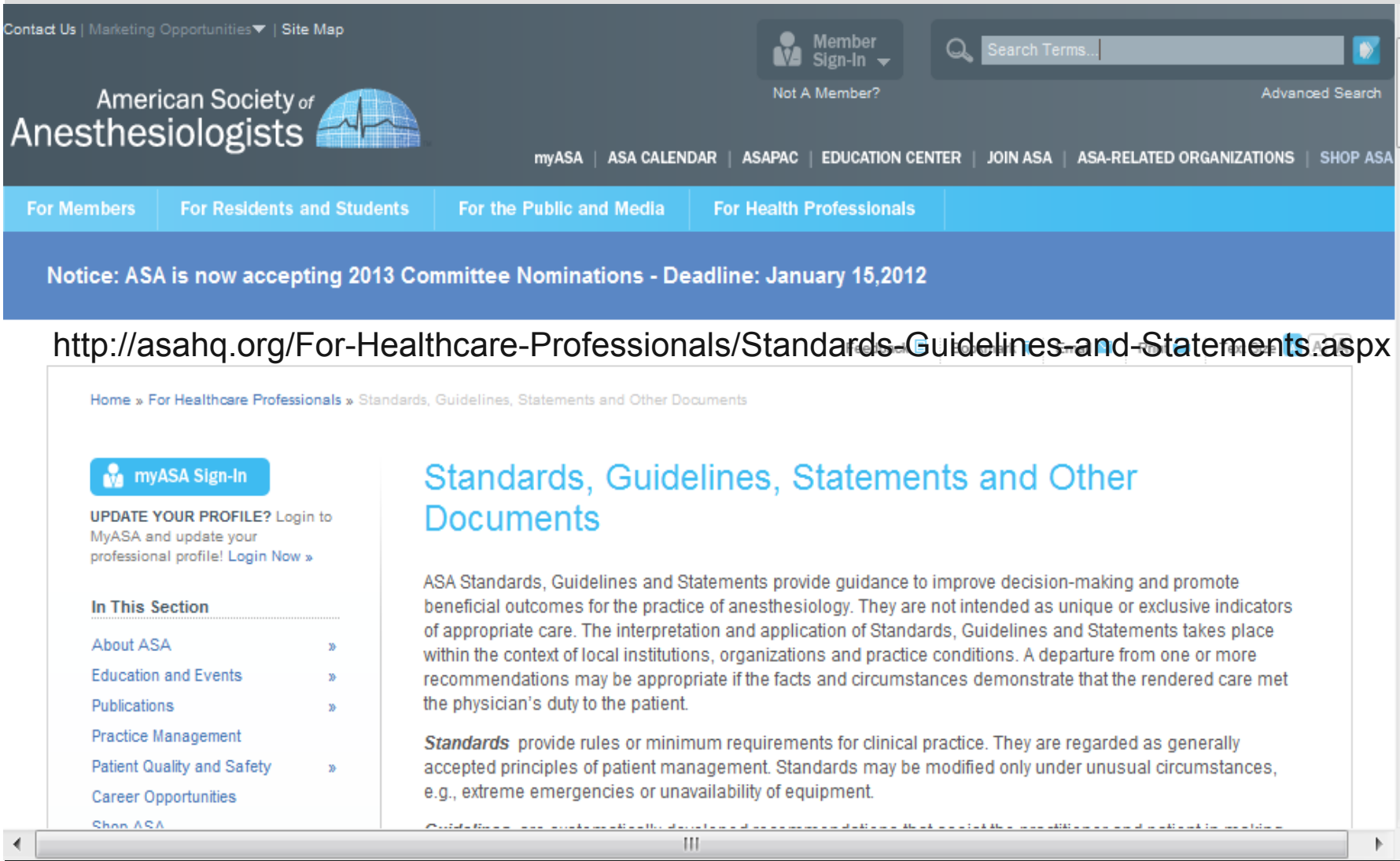
1. Access to operating room suites must be strictly limited to authorized persons.
2. All Schedule 3 and 4 narcotic medications must be kept in locked enclosed areas when not under the direct control of an anesthesia professional.
3. Anesthesia professionals must have immediate access to drugs required for emergency patient care. Procedures designed to prevent unauthorized access to such drugs must be consistent with 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

A. Because the operating room suite is a limited-access secure location, it is safe practice for anesthesia professionals to leave non-controlled* medications on the top of their anesthesia carts or anesthesia machines for brief periods (e.g., while going to a nearby holding area to bring a patient into the operating room).

B. At the end of anesthesia cases, when patients are particularly vulnerable, anesthesia

ASA Guidelines and Statements



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:

Letters to the Editor:

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

Drugs Rules Must Include 1016

- Must have P&P on security and monitoring of all carts
  - Whether locked or unlocked
  - If unlocked staff must be close by and directly monitoring the cart as when passing medications
- Handling medications, which includes mixing or reconstituting, is done according to manufacturer's recommendations
  - Includes compounding or admixing of sterile IVs or other drugs

Drugs Rules Must Include

- Only pharmacy can reconstitute, mix, or compound a drug
  - Except in an emergency
  - Except if not feasible such as product's stability is short
- Compounding drugs used or dispensed must be prepared in a manner consistent with acceptable principles for sterile and non-sterile compounding
- Want to prevent microbial contamination and bacterial toxins for compounds intended to be sterile

Drugs and Biologicals 1016

- Pharmacy must demonstrate how it assures that all sterile and non-sterile compounded drugs are prepared are pursuant to SOC
- All compounded forms must be sterile including wound irrigations, eye drops and ointments, injections, infusions, nasal inhalation, etc.
- Remember in part one that the ASHP foundation has a free resource on outsourcing sterile products preparation: contractor assessment tool

Drugs Rules Must Include 1076

- The Drug Quality and Security Act (DQSA) has sections related to compounding
- Outsourcing facilities who compound drugs should register and must comply with section 503B of the FDCA and 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

FDA's Compounding Website

Use a Company that is Registered

Drug Rules Must Include 1016

- If CAH obtains compounded medications from compounding pharmacy rather than a manufacturer or a registered outsourcing facility then must demonstrate that medicine received have been prepared in accordance with acceptable principles
  - Contract with the vendor would want to ensure CAH access to their quality data verifying their compliance with USP standards
  - Should document you obtain and review this data

Drugs and Biologicals 1016

- Dispensing medications
  - Dispensed timely
  - Follow all state laws
  - Enough staff to provide accurate and timely medication delivery
  - System so medications orders get to pharmacy promptly and are available when needed by the patient
- Concerns or questions should be clarified with the prescriber before dispensing

Drugs and Biologicals 1016

- Can use unit dose or floor stock system
  - Automated dispensing cabinets are secure option
- Need P&P for who can access medications after hours (night cabinet standard)
- Suggest P&P on do not use abbreviations, high alert drug list, safety recommendation for high alert medications, quantities of medications dispensed to minimize diversion, limit overrides, return all meds in secure one-way return bin, etc.

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	

ISMP List of High Alert Medications

www.ismp.org

Institute for Safe Medication Practices (ISMP)

ISMP List of *High-Alert Medications in Acute Care Settings*

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 such as standardizing the ordering, storage, preparation, and administration of these products; improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; 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., **EPINEPH**rine, 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, including: ■ anticoagulants (e.g., warfarin, low molecular weight heparin, IV unfractionated heparin) ■ Factor Xa inhibitors (e.g., fondaparinux, apixaban, rivaroxaban) ■ direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran etexilate) ■ thrombolytics (e.g., alteplase, reteplase, tenecteplase) ■ glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)
cardioplegic solutions

Specific Medications
EPINEPHrine, subcutaneous
epoprostenol (Flolan), IV
insulin U-500 (special emphasis)*
magnesium sulfate injection
methotrexate, oral, non-oncologic use
opium tincture
oxytocin, IV
nitroprusside sodium for injection
potassium chloride for injection concentrate

Drugs and Biologicals 1016

- Administer meds by qualified staff in accordance with state law
  - So in one state, LPNs can not push certain IV medications or hang blood
  - Must follow acceptable standards of practice for medication administration
- Follow record keeping for receipt and disposition of scheduled drugs
  - DEA has five from schedule I to V substances
  - Schedule IV includes certain narcotics so must track them

Drugs and Biologicals 1016

- Want locked storage of scheduled drugs when not in use
  - Keep accurate counts to show use
  - Reconcile any discrepancies in the counts
- Ensure outdated, mislabeled, or unusable medication is not used
- Must have pharmacy labeling, inspection, and inventory management
- Do not use past the BUD or beyond use date
  - P&P to determine BUD date if not marked

Drugs and Biologicals 1016

- Each individual drug must be labeled with name, strength of drug, lot and control number and expiration date
- If multidose vial is opened, must have expiration date of 28 days on the label unless otherwise specified by the manufacturer
- Must have a system to report ADEs and medication errors
- Pharmacy needs to assess to see if problems in pharmacy caused or contribute to these

Drugs and Biologicals 1016

- Surveyor is to ask nursing if medications dispensed in a timely manner
- If late medications, the surveyor is to investigate
- Surveyor is to ask what professional pharmacy principles pharmacy is using
- Surveyor to make sure drugs are secure
- Will verify only pharmacist or authorized person compounds, labels, and dispenses
  - Some state laws state can not be done by pharmacy tech

Survey Procedure 1016

- Surveyor to make sure has a process to follow up on ADE and medication errors
- Surveyor to determine if CAH obtains compounded drugs from external source that is not FDA registered then does the facility evaluate and monitor adherence to safe principles
- Will 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 reactions (ADR) and medication errors
- Staff must report these
  - Take care of patient and report to QAPI
  - Need a policy and procedure and ensure staff are aware of the P&P
- Need a definition for both
- CMS mention National Coordinating Definition of Medication Error (NCCMER)
- Mentions ASHP definition of adverse event

Definition of Medication Error

- Medication administration error:

  The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use." A medication administration error is one that occurs in the phase of the medication process where the drug actually enters the patient by one of various possible routes, e.g., orally, intravenously, etc.

Definition of Adverse Drug Event ADR

- Adverse drug reaction:

The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as "Any unexpected, unintended, undesired, or excessive response to a drug that:

1. Requires discontinuing the drug (therapeutic or diagnostic)
2. Requires changing the drug therapy
3. Requires modifying the dose (except for minor dosage adjustments)
4. Necessitates admission to a hospital
5. Prolongs stay in a health care facility
6. Necessitates supportive treatment
7. Significantly complicates diagnosis
8. Negatively affects prognosis, or
9. Results in temporary or permanent harm, disability, or death.

Reporting ADR and Errors 1018

- ADR and medication errors that reach the patient must be reported to the practitioner
- The report must be made immediately, such as a phone call, if the error causes harm to the patient
  - If harm is not known then must report immediately
  - If no harm then can inform practitioner in the morning
- Documentation of the error and notification of the practitioner must be made in the MR

Reporting ADR and Errors 1018

- Must educate staff on medication errors and ADEs to facilitate reporting
  - Must include reporting of near misses
  - Must educate how they are to be reported
  - For example, on a medication incident report which is sent to pharmacy, nursing, risk management, and then into the QAPI program
- To help assess vulnerabilities and implement reoccurrences
  - Can do RCA, FMEA, or QAPI review

Reporting ADR and Errors 1018

- Encourages a non-punitive approach that focuses on system issues
- Can't just rely on incident reports
- Must take other steps to identify errors and ADRs
  - Trigger drug analysis, observe medication passes, computer assessment, concurrent and retrospective reviews, medication usage evaluations for **high alert drugs** etc.
- Encourages reporting to the FDA MedWatch Program and ISMP MER system

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.

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

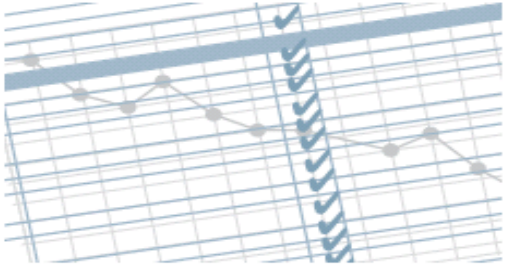
Non-Punitive Environment

- Studies showed that if you have punitive environment errors will not be reported,
- Most of serious errors are made by long term employees or physicians with unblemished records,
- It was the system that actually lead to the error,
- Need to change the environment or culture and this is called system analysis,
- Important to have a non-punitive environment,
  - We need to move beyond the culture of blame so we can find out what errors are occurring and how to prevent them,
- Balance this with Just Culture,

Indicator Drugs (Trigger Drugs)

- Monitor Digibind usage and develop protocol for appropriate use,
- Monitor use of reversals agents such as Romazicon and Narcan to look for unreported cases of adverse events during moderate sedation,
  - Narcan, antihistamines, Vitamin K,
  - IV glucose, glucagon,
  - Epinephrine, topical calamine,
  - Phentolamine, digibind, protamine, hyaluronidase,
  - Kayexalate, anti-emetics and anti-diarrheas,

INSTITUTE FOR HEALTHCARE IMPROVEMENT



Innovation Series 2009

IHI Global Trigger Tool

for Measuring Adverse Events

Second Edition

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.

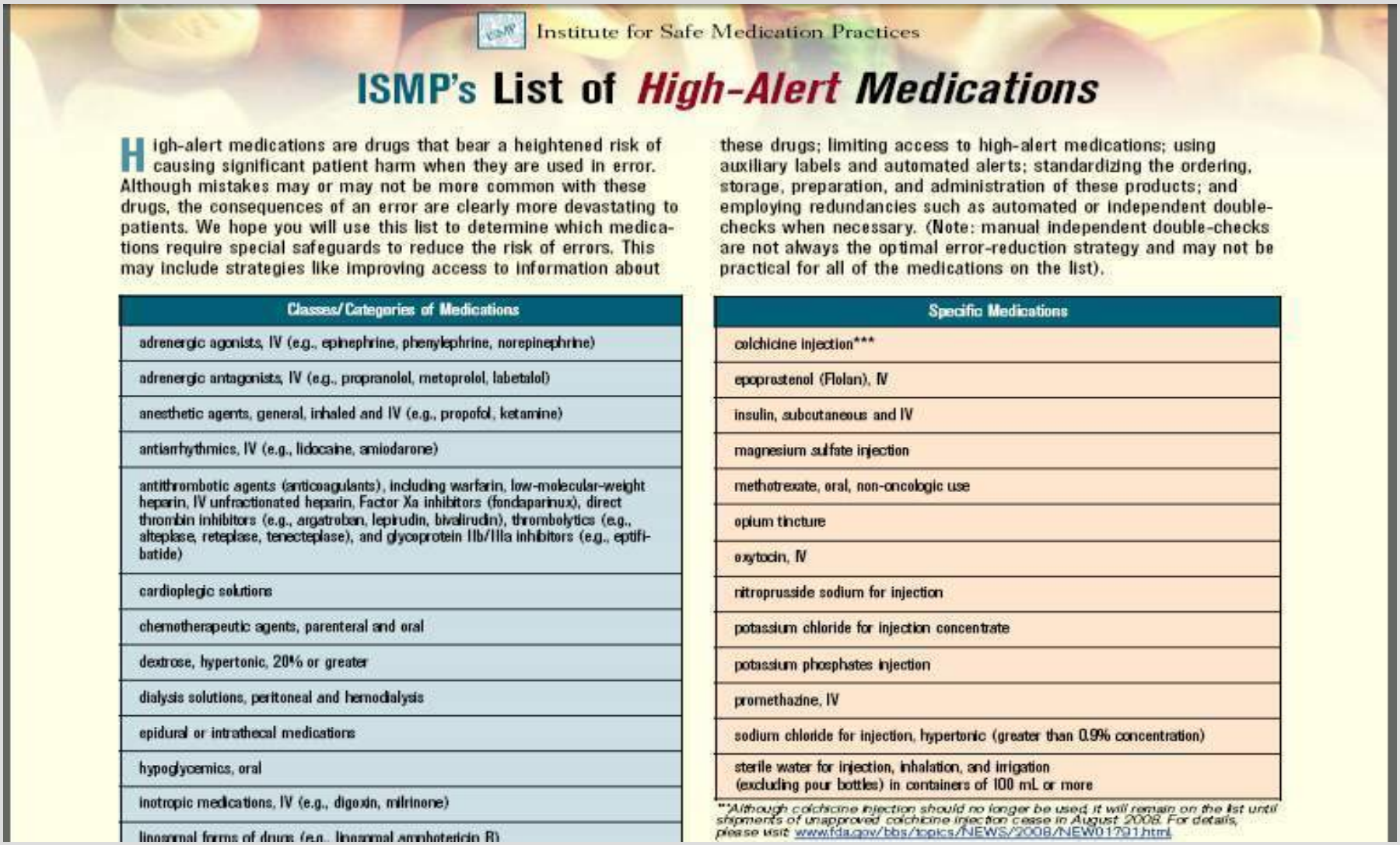
3. Post messages to the listserv by sending emails to triggertools@ls.ihi.org.

Featured Tool

Interactive Trigger Tool for Measuring ADEs

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

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*

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

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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.

Survey Procedure 1018

- Will make sure nursing staff knows what to do if there is a medication error (ME) or ADE
  - Will ask nursing to provide an example of what they would do if ME or ADE
- Surveyor will review records of MEs and ADEs to make sure immediately reported and documented in the medical record
- Will ensure hospital has system for reporting into QAPI
  - Will make sure staff trained in reporting expectations

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

The CMS Dietary Standards

Dietary 1020 2020

- Standard: If the CAH furnishes inpatient services, including swing bed patients
- Procedures must be in place that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices
- And need the **order** of a practitioner
  - Can C&P dietician to order diet if state allows
  - Includes swing beds
- The survey procedure and interpretive guidelines are pending

Previous Interpretive Guidelines

- These are the previous interpretive guidelines and are here for reference only
- Due out in late spring or early summer 2020
- 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

Dietary Services Previous Guidelines

- Must have a qualified director
  - Based on education, experience, specialized training and license, certified, or registered if required by the state
- If swing beds must comply with following:
  - Make sure resident maintains acceptable parameters of nutritional status such as body weight and proteins
  - Receives a therapeutic diet

Policies Reviewed 1020 2020

- Standard: The policies have to reviewed at least biennially
- Policies on meeting the nutritional needs of inpatients
- Need to be reviewed by a group of professional personal
- The interpretive guidelines and survey procedure are pending
- The remaining slides will not be discussed and are the old interpretive guidelines

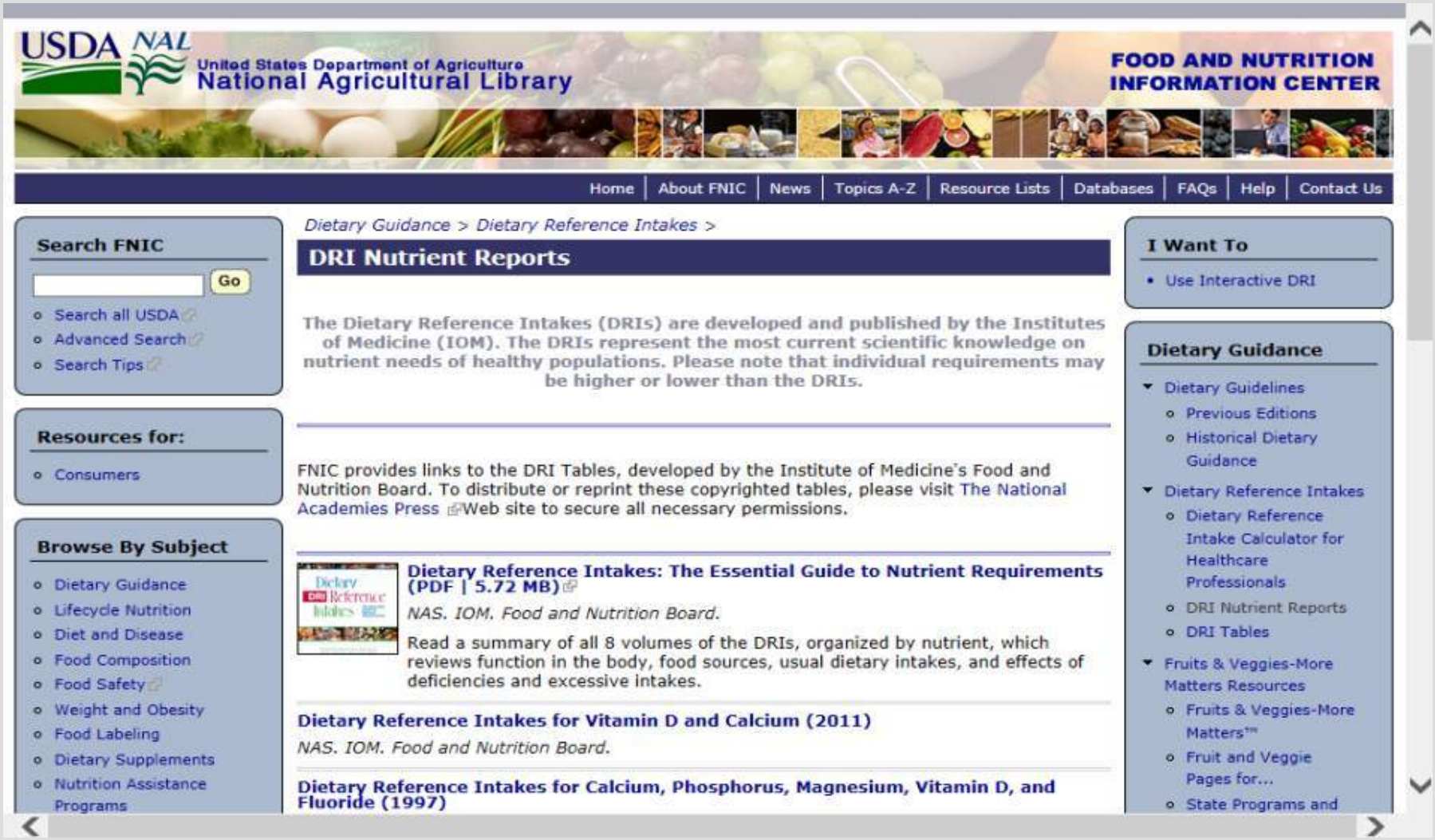
Dietary Services Old Guidelines

- Must follow recognized dietary practices
- For example, the IOM's Food and Nutrition Board's DRI or Dietary Reference Intake 4 reference values
  - RDA or the recommended dietary allowance is average dietary intake of a nutrition sufficient of healthy people
  - Adequate Intake (AI) for a nutrient is similar to the ESADDI and is only determine when an RDA cannot be determined
    - Estimated Safe and Adequate Daily Intake (ESADDI)
    - AI is based on observed intakes of the nutrient by a group of healthy persons

Dietary Services Old Guidelines

- IOM's Food and Nutrition Board's DRI or Dietary Reference Intake 4 reference values (continued)
  - Tolerable Upper Intake Level (UL) is highest daily intake of a nutrient that is likely to pose no risks of toxicity for most people
    - As the UL increase, risk increases
  - Estimated Average Requirement (EAR) is the amount of the nutrient that is estimated to meet the requirement of half of the health people

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.

Interactive DRI Tool and Tables

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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

Dietary Services Old Guidelines

- Therapeutic diets may help meet the patient's nutritional needs
- Patients must be assessed to determine if a therapeutic diet is needed
  - Include in the patient's care plan
  - Include the need to monitor intake
  - Include if need daily weights, I&O, or lab values

Nutritional Assessment Old Guidelines

- Patient May Need Comprehensive Assessment if:
  - Medical or surgical conditions or physical status interferes with their ability to digest or absorb nutrients
  - Patient has S&Ss indicating a risk for malnutrition
    - Such as anorexia, bulimia, electrolyte imbalance, dysphagia, ESRD or certain medications
  - Or if the patient's medical condition is adversely affected by intake and so a special diet is needed
    - CHF, renal disease, diabetes, etc.

Dietary Old Guidelines

- Patient may need comprehensive assessment if (continued):
- Patient receiving artificial nutrition
  - Tube feeding, TPN, or peripheral parenteral nutrition
- Need an order for diets, including therapeutic diet, from practitioner responsible for care
- Dietician or qualified nutritional specialist can be C&P to order diet as consistent with state law

Survey Procedure Old Guidelines

- Surveyor will verify the dietician is qualified
- Will ask how CAH uses DRIs in its menus to meet the nutritional needs of patients
- Will make sure patients were screened and assessed
- Will make sure all diets are ordered
- Will make sure dietary intake and nutritional status are being monitored as appropriate and swing beds patients aren't losing weight and maintaining protein level

The End Questions???

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