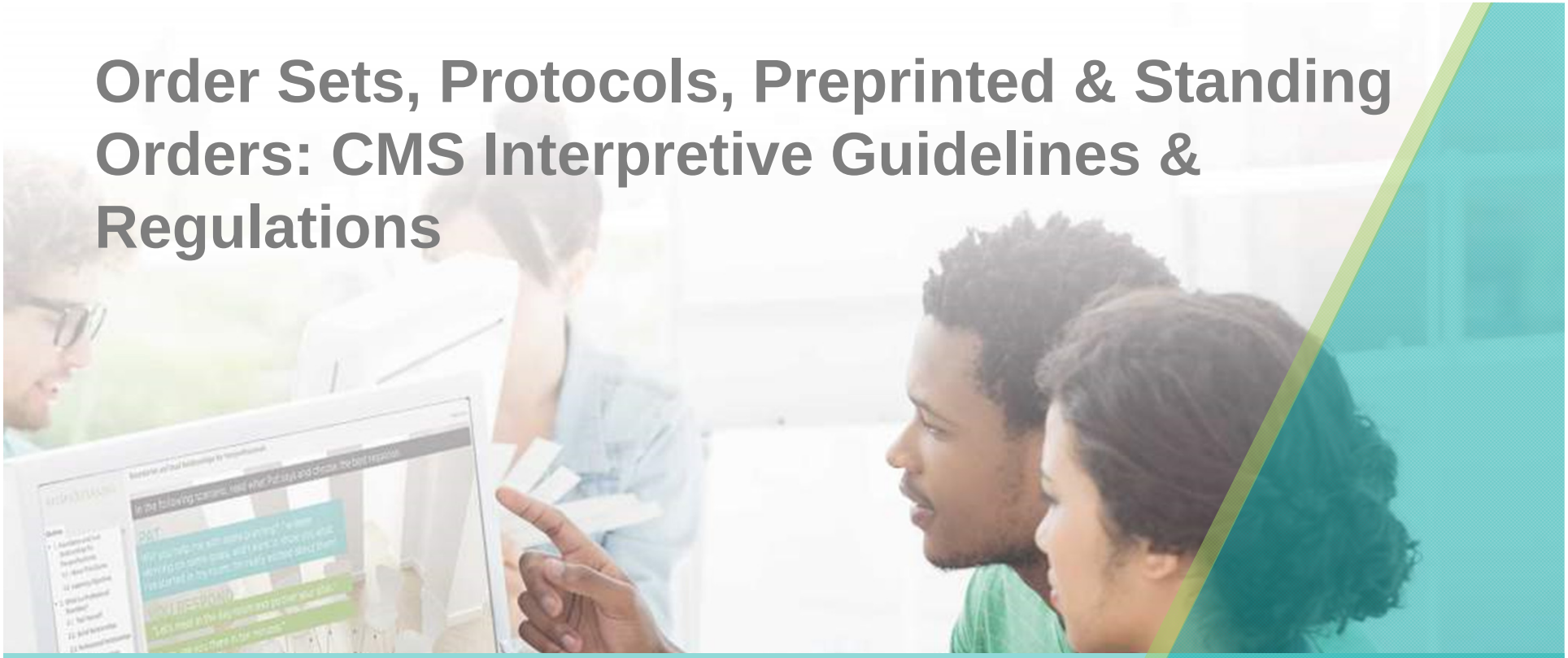
Order Sets, Protocols, Preprinted & Standing Orders: CMS Interpretive Guidelines & Regulations



Sue Dill Calloway

RELIAS LEARNING

Speaker

- Sue Dill Calloway RN Esq.
  CPHRM, CCMSCP, AD, BA, BSN, MSN, JD
- President Patient Safety and Healthcare Consulting
- 5447 Fawnbrook Lane
  Dublin, Ohio 43017
- 614 791-1468
  (Call with questions, no emails)
- sdill1@columbus.rr.com
- Email questions to CMS at hospitalscg@cms.hhs.gov

Objectives

- Describe CoP sections on standing orders.
- List protocols that must be approved by the medical staff.
- Describe tag 405, 406, 450, and 457.

You Don’t Want One of These

The Conditions of Participation (CoPs)

- Many revisions since 1986
- Hospital CoP Manual updated more frequently now so check website monthly
- First regulations are published in the **Federal Register** (FR) then CMS publishes the **Interpretive Guidelines** and some have **survey procedures** [2]
  - Hospitals should check this website once a month for changes and can sign up to get the FR for free

[1] http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR

[2] www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp

CMS Standing Orders

- CMS has an email address that you can send questions to and get the answer in writing
  - Questions to **hospitalscg@cms.hhs.gov**
- CMS publishes 165 page final regulations changing the CMS CoP and has section on standing orders
- Moved standing orders to 457 in Medical Records which is the primary section
- So now in sections 405, 406, 450, and 457
- So need to be aware of all 4 tag numbers
- Consider citing these in your P&O

Final IGs on Standing Orders

A-0457

(Rev.)

§482.24(c) ***(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:***

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Interpretive Guidelines §482.24(c)(3)

What is covered by this regulation?

There is no standard definition of a "standing order" in the hospital community at large (77 FR 29055, May 16, 2012), but the terms "pre-printed standing orders," "electronic standing orders," "order sets," and "protocols for patient orders" are various ways in which the term "standing orders" has been applied. For purposes of brevity, in our guidance we generally use the term "standing order(s)" to refer interchangeably to pre-printed and electronic standing orders, order sets, and protocols. However, we note that the lack of a standard definition for

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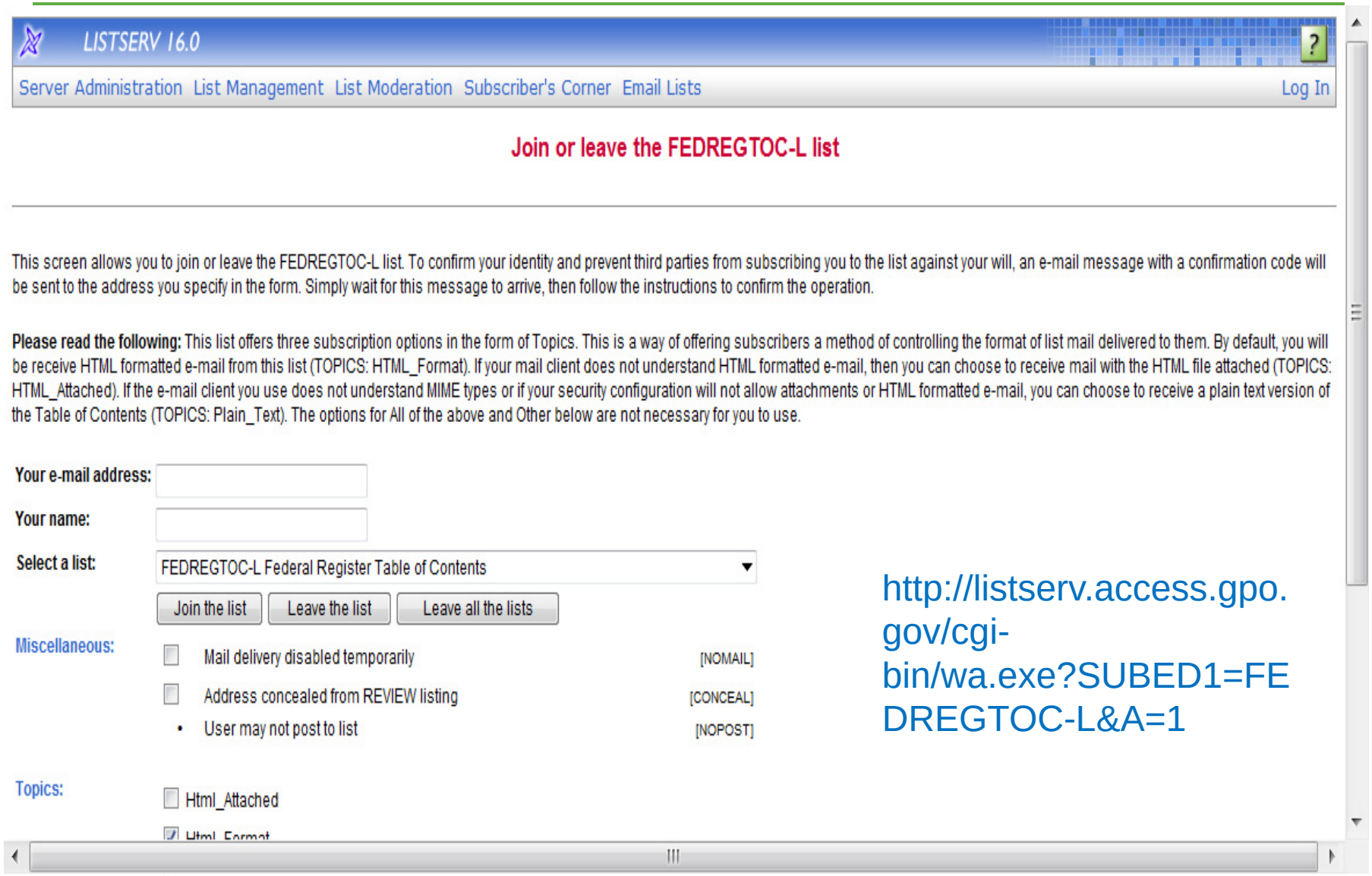


http://listserv.access.gpo.gov/cgi-bin/wa.exe?SUBED1=FEDREGTOC-L&A=1

Location of CMS Hospital CoP Manuals

Medicare State Operations Manual

Appendix

Email questions to CMS at hospitalscg@cms.hhs.gov

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

CMS Hospital CoP Manuals new address
www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

App. No.	Description	PDF File
A	Hospitals	2,185 KB
AA	Psychiatric Hospitals	606 KB

CoP Manual Also Called SOM

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

Table of Contents
(Rev. 151, 11-20-15)

www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

Transmittals for Appendix A

Survey Protocol

Introduction

- Task 1 - Off-Site Survey Preparation
- Task 2 - Entrance Activities
- Task 3 - Information Gathering/Investigation
- Task 4 - Preliminary Decision Making and Analysis of Findings
- Task 5 - Exit Conference
- Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module

Psychiatric Unit Survey Module

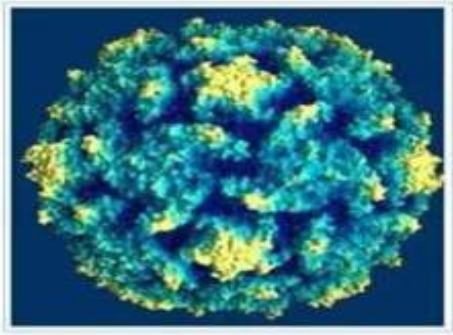
Rehabilitation Hospital Survey Module

Inpatient Rehabilitation Unit Survey Module

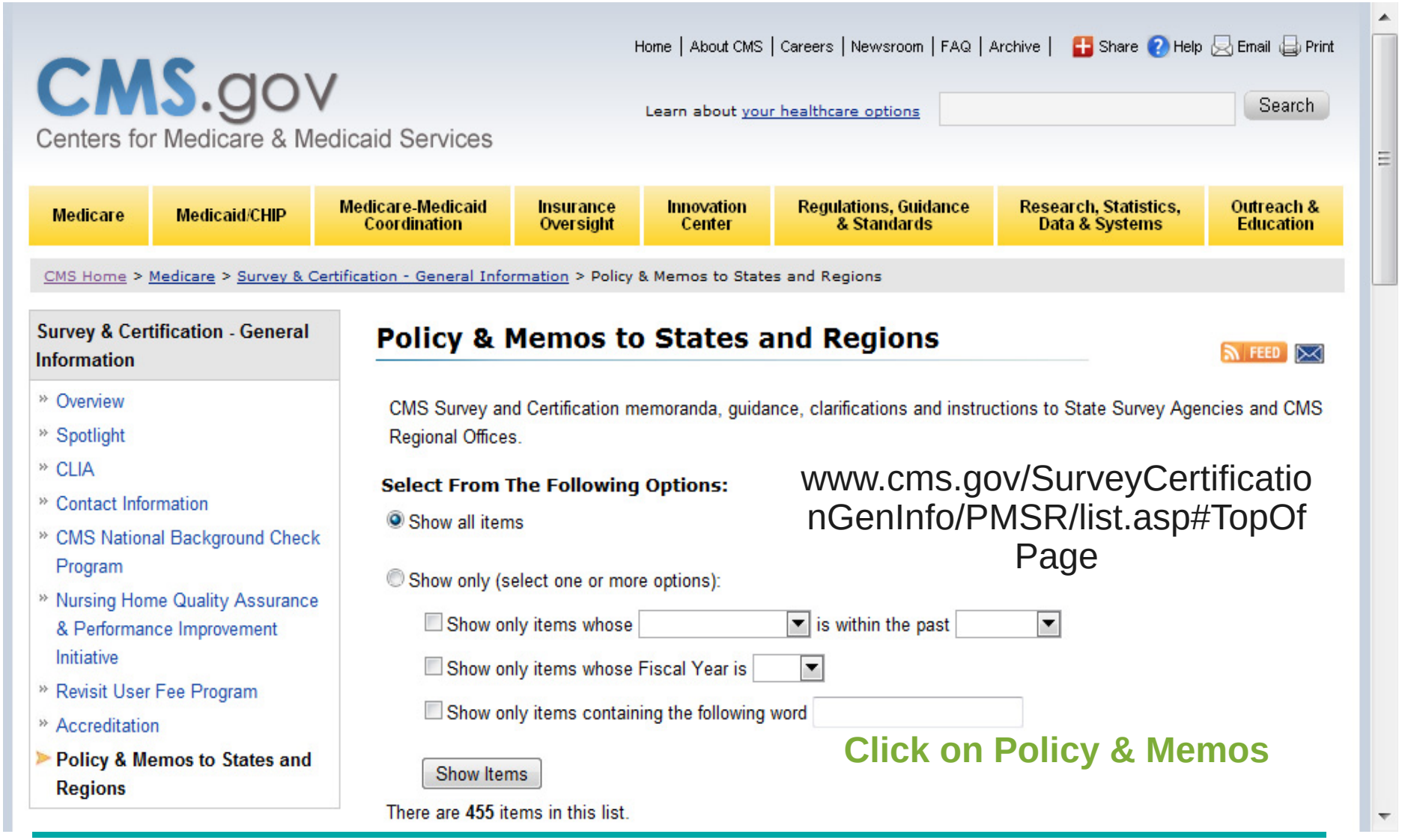
Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines

Email questions **hospitalscg@cms.hhs.gov**



CMS Survey and Certification Website



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

Click on Policy & Memos

CMS Survey Memos

Policy & Memos to States and Regions

CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.

Show entries: 10

Filter On:

Title	Memo #	Posting Date	Fiscal Year
Certification Number (CCN) State Codes –State Operations Manual (SOM) Section 2779A Revisions	16-09-ALL	2016-03-11	2016
Advance Copy – Interpretive Guidelines for the Organ Transplant Conditions of Participation (CoPs) at 42 Code of Federal Regulations (CFR) §§ 482.68 through 482.104	16-10-Transplant	2016-03-11	2016
National Downtime of the Quality Improvement and Evaluation System (QIES)	16-12-ALL	2016-03-11	2016
Critical Access Hospital (CAH) Recertification Checklist for Evaluation of Compliance with the Location and Distance Requirements	16-08-CAH	2016-02-12	2016
FY 2015 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program	16-07-AO	2016-01-29	2016
Medicare Learning Network (MLN) Infection Control Courses	16-06-ALL	2016-01-22	2016

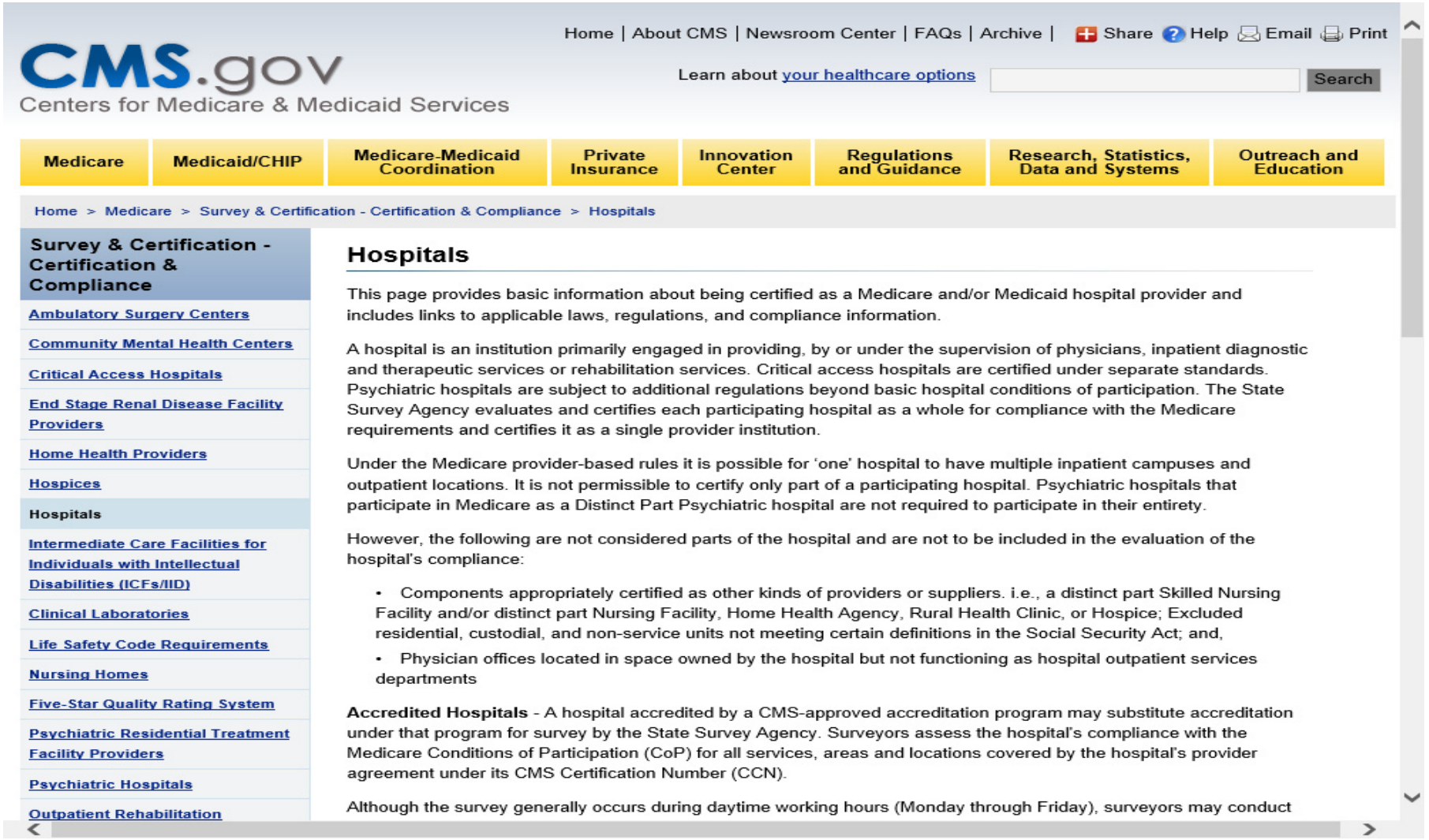
Access to Hospital Complaint Data

- CMS issued Survey and Certification memo on regarding access to hospital complaint data
- Includes acute care and CAH hospitals
  - Does not include the plan of correction but can request
  - Questions to bettercare@cms.hhs.com
- This is the CMS 2567 deficiency data and lists the tag numbers
- Updated quarterly
  - Available under downloads on the hospital website at www.cms.gov

Access to Hospital Complaint Data

- There is a list that includes the hospital's name and the different tag numbers that were found to be out of compliance
  - Many on restraints and seclusion, EMTALA, infection control, patient rights including consent, advance directives and grievances and **standing orders**
- Two websites by private entities also publish the CMS nursing home survey data and hospitals
- The ProPublica website for LTC
- The Association for Health Care Journalist (AHCJ) websites for hospitals

Updated Deficiency Data Reports



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

Deficiency Data CMS Hospitals

Section	Tag	Nov 3, 2016
Administration of Drugs/Standing Orders	405	493
Standing Orders	457	42
Standing Orders for Drugs	406	34
MR Services/Standing Orders/ Date and Time of Order	450	215 **Total 784**

CMS Order Sets, Protocols, Standing Orders

- CMS has chosen **not to define** the differences between order sets, standing orders, pre-printed orders, and protocols
- CMS says nurses and other staff may administer drugs in accordance with pre-printed and electronic standing orders, orders and protocols which are collectively referred to as "standing orders" and effective June 2013 and radiology protocols effective July 10, 2015
  - These must address well defined clinical scenarios involving medication administration
  - Refers to MR chapter and created tag 457
  - Moved most of standing order information in tag 405 to 457
  - So now look at tag numbers **405, 406, 450, and 457 (and radiology)**

CMS Order Sets, Protocols, Standing Orders

- However, CMS establishes criteria and directions on the process and policy requirements and there are several key points
- Orders and protocols are approved by the Medical Staff (MEC) in conjunction with pharmacy and nursing leadership
- The orders and protocols must be consistent with nationally recognized and evidenced based guidelines

What is the Difference?

- **What is the difference between an order set, standing order and protocol?**
- An **order set** is a list of individually selectable interventions that the ordering practitioner may choose from
  - Tool designed to help practitioners as they write orders
- An order set is an evidence based statement of best practice in the prevention, diagnosis, or management of a given symptom, disease, or condition for individual patients under normal circumstances

What is the Difference?

- Examples might include evidenced based order sets (printed or electronic) for:
  - Acute MI, CHF, or Pneumonia,
  - CABG, stroke, asthma, ventilation weaning,
  - Total knee replacement, total hip replacement, hip fracture,
  - Sepsis, flu immunization
  - It is important to know what the different organizations standards are such as ENA, ACEP, AORN, ASPAN, CDC, ISMP, etc.

Sample Admit Orders AAFP

SAMPLE ADMIT ORDERS

All 30 of the standardized admit orders developed by the Scott & White Clinic at College Station, Texas, can be downloaded below. The orders may require some alteration before being used in your practice.

NOTE: The admit orders have been updated since their publication in this issue of *FPM*. You will be downloading the most current version.

Download in PDF format

Download as MS Word document

The admission orders cover the following conditions:

- Acute epiglottitis
- Asthma
- Chest pain – R/O MI
- Childhood bacterial meningitis
- Community-acquired pneumonia
- CVA
- Dementia
- Diabetic ketoacidosis
- DVT
- DVT discharge orders
- DVT home health care orders
- DVT (Lovenox therapy)
- GI bleed
- Hepatic encephalopathy
- HIV pneumonia
- Hyperkalemia
- Hypernatremia

TOP

www.aafp.org/fpm/2001/1000/p49.html

ASA OVERDOSE ADMISSION ORDER

Name: _____ Age: _____ DOB: ____ /____ /____ Medical record #: _____

1. Status: ☐ Observation ☐ Admission ☐ Medical floor ☐ ICU ☐ Other telemetry

2. Attending: Dr: _____ phone: _____-_____

3. Admitting Diagnosis: ASA Overdose
Associated Diagnoses: _____

4 Condition: ☐ Stable ☐ Fair ☐ Serious ☐ Critical
Code Status: ☐ Full Code ☐ DNR

5. Allergies: _____ _____

6. Diet: ☐ NPO ☐ Clear liquid ☐ AHA step 2 ☐ ADA_____ calories
☐ Other_____

7. Activity: ☐ Bed rest with bathroom privileges

8. Nursing: ☐ Vital signs every 4 hrs for 24 hrs then every 4 hrs if stable
☐ Suicide precautions
☐ Gastric lavage in ER with activated charcoal
☐ Consider dialysis if serum salicylate greater than 70 mg/dl

9. Medications: ☐ Vitamin K 10 mg IM now
☐ Guaiac all stools
☐ Other _____

10. IV: ☐ Dextrose 5% in 1/2 normal saline with 44 mEq bicarbonate/L @ 300 mL/hr (forced alkaline diuresis)

11. Lab: ☐ ABGs
☐ Hemogram
☐ Lytes
☐ Glucose
☐ Salicylate level, if not done in ER

12. Consult: ☐ Psych ☐ Social services ☐ MHMR

ASTHMA ADMISSION ORDER

Name: _____ Age: _____ DOB: ____ /____ /____ Medical record #: _____

1. Status: ☐ Observation ☐ Admission ☐ Medical floor ☐ Monitored bed ☐ Other _____

2. Attending: Dr: _____ phone: _____-_____

3. Admitting Diagnosis: Asthma Exacerbation
Associated Diagnoses: _____

4.Condition: ☐ Stable ☐ Fair ☐ Serious ☐ Critical
Code Status: ☐ Full Code ☐ DNR

5. Allergies: _____

6. Diet: ☐ NPO ☐ Clear liquid ☐ AHA step 2 ☐ ADA _____ calories
☐ Other _____

7. Activity: ☐ Bed rest with bedside commode ☐ Bathroom privileges ☐ Up ad lib

8. Nursing: ☐ Vital signs every 4 hrs for 24 hrs then every shift
☐ Notify MD for: T > 101.5, HR > 120, BP < 90/60 or > 180/110
Pulse ox < 90%, decrease level of consciousness or respiratory distress
☐ I&O

9. Medications: ☐ Albuterol nebulizer every _____ hrs and prn
☐ Methylprednisone 125 mg IV bolus now, then 80 mg IVP every 8 hrs
☐ Tylenol 500 mg 2 tabs PO every 4 hrs prn temp > 101 or pain
☐ Ambien 10 mg PO at bedtime prn insomnia

10. IV: ☐ IV lock; flush per routine
☐ IV _____@ mL/hr

11. Lab: ☐ Admission: hemogram, basal metabolic profile
☐ ABG if pulse ox < 90% or if severe respiratory distress or decreased LOC develops

12. Diagnostic Studies: ☐ CXR on admission

What is the Difference?

- A **standing order** is an order (orders) that may be initiated without an initial order by the physicians or LIP by the nurse if the patient meets certain criteria
- Standing orders are written documents that contain orders for the patient based on various stipulated clinical situations
- They usually name the condition and prescribe the action to be taken in caring for the patient
- They are commonly used in ICU's, CCUs, and the emergency department
  - Note some hospitals use standing order and protocol interchangeable

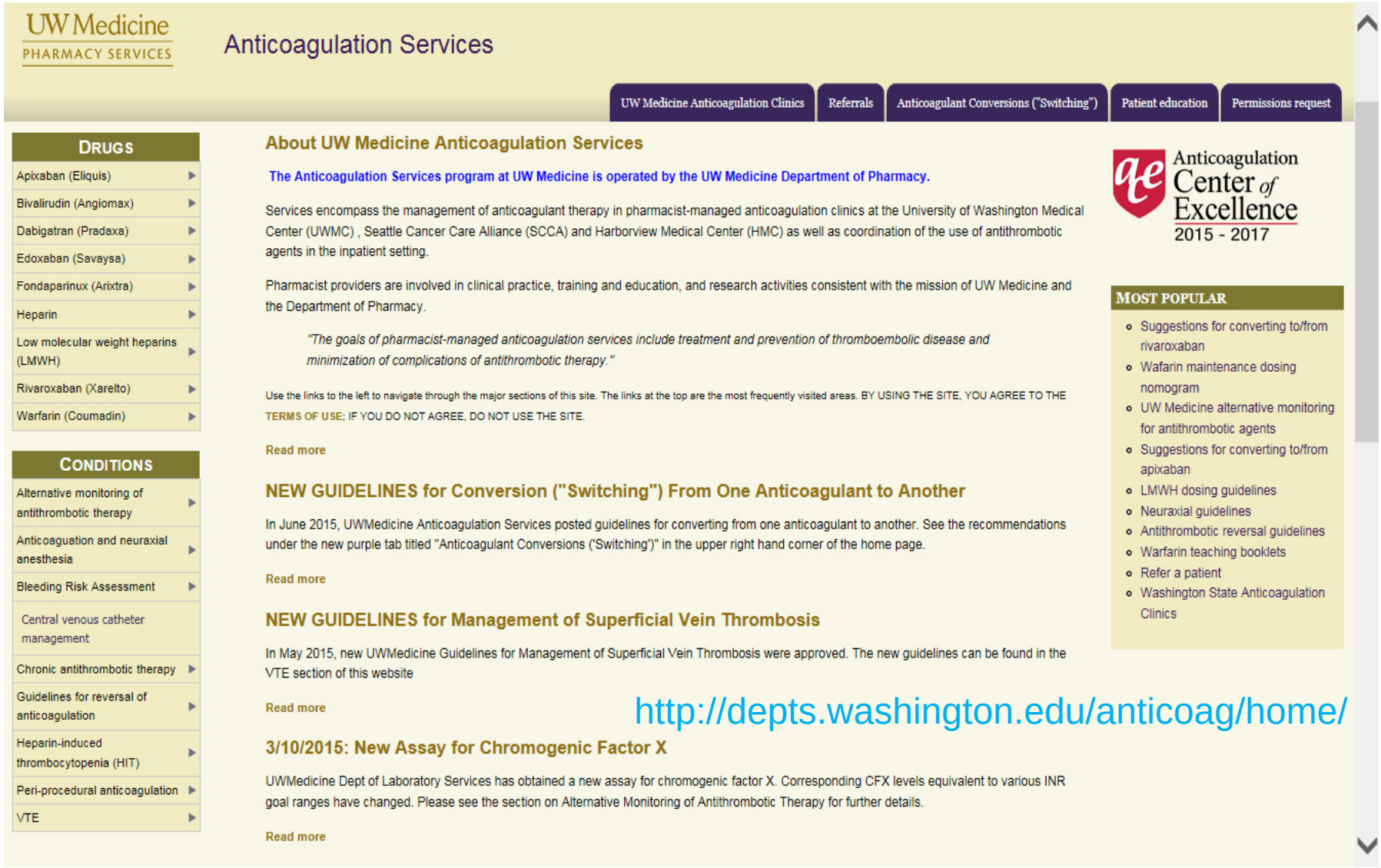
Standing Orders

- Those criteria and the resulting orders require prior approval in policy by the medical staff
- Example; Start an IV in the ED on a patient having chest pain
- Give tetanus (Tdap for an adult) to a patient in the ED who has not had one in the specified period
- Give ACLS drugs to a patient in cardiac arrest
- Example: The surgery center has a pre-op standing order to start an IV on all patients of 1000 cc 0.9 NaCl at 25 cc an hour

What is the Difference?

- A **protocol** also requires the patient to meet certain clinical criteria, but there must be an order to initiate the protocol
- It is a step by step statement of a procedure routinely used in the care of individual patients to assure that the intended effect is reliably achieved
- Example would be a heparin protocol for a patient having a MI in the emergency department and the physician has ordered the same
- Important thing is to understand the CMS standards for what the hospital is doing

Example of a Heparin Protocol UW



Changes to Heparin Power Plans and Infusions
Quick Guide for Nurses

New Power Plans
Provider will choose from:

Heparin, Rx Heparin Infusion Standard Protocols
Heparin, Rx Heparin Infusion, Provider Managed

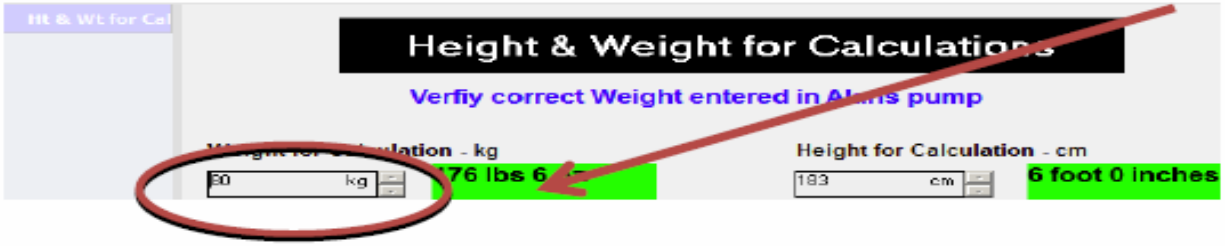
Standard Protocol – *(most infusions)* nurse managed adjustments using algorithms **Provider Manag**
– provider must order **EVERY** dose change

For Standard Protocol (nursing managed algorithms) -

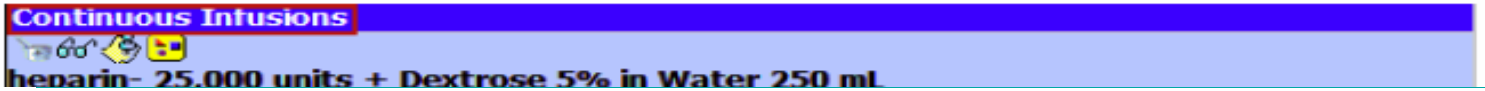
*Loading doses and starting ranges will be based on ***INDICATION***

- Acute Thrombosis Treatment
- AFib, Valve Replacement, Peri Op Bridging, or Other
- Acute Coronary Syndrome
- Stroke

*Dosing will be ***WEIGHT BASED*** – Use "Weight for Calculations" in ORCA



What you will see on the EMAR
*Continuous Infusion



*Nurses will make dose adjustments using algorithms

Regular and *Low* Intensity

REGULAR Intensity Algorithm (PTT Goal: 60 to 100)

PTT (seconds)	PRN RE-BOLUS	INFUSION HOLD TIME	CHANGE INFUSION RATE (units/kg/hr)	NEXT PTT
< 40	ONLY if ordered by provider -- see PRN orders	None	Increase by 3 units/kg/hr	6 hours
40-49	ONLY if ordered by provider -- see PRN orders	None	Increase by 2 units/kg/hr	6 hours
50-59	ONLY if ordered by provider -- see PRN orders	None	Increase by 1 units/kg/hr	6 hours
60-100	**None**	**None**	**NO CHANGE**	**6 hours x1, then q AM**
101-110	None	None	Decrease by 1 units/kg/hr	6 hours
111-120	None	None	Decrease by 2 units/kg/hr	6 hours
121-150	None	30 minutes	Decrease by 2 units/kg/hr	6 hours
151-199	None	60 minutes	Decrease by 3 units/kg/hr	6 hours

LOW Intensity Algorithm (PTT Goal: 60 to 80)

PTT (seconds)	PRN RE-BOLUS	INFUSION HOLD TIME	CHANGE INFUSION RATE (units/kg/hr)	NEXT PTT
< 40	ONLY if ordered by provider -- see PRN orders.	None	Increase by 3 units/kg/hr	6 hours
40-49	ONLY if ordered by provider -- see PRN orders.	None	Increase by 2 units/kg/hr	6 hours
50-59	ONLY if ordered by provider -- see PRN orders.	None	Increase by 1 units/kg/hr	6 hours
60-80	**None**	**None**	**NO CHANGE**	**6 hours x1, then q AM**
81-100	None	None	Decrease by 1 units/kg/hr	6 hours
101-120	None	30 minutes	Decrease by 2 units/kg/hr	6 hours
121-150	None	60 minutes	Decrease by 2 units/kg/hr	6 hours
151-199	None	60 minutes	Decrease by 3 units/kg/hr	6 hours

UW Medicine

Intravenous Heparin - STANDARD Protocol

****Check orders to determine which algorithm to use****

REGULAR Intensity (PTT Goal: 60 to 100)

PTT (seconds)	PRN RE-BOLUS	INFUSION HOLD TIME	CHANGE INFUSION DOSE (units/kg/hr)	NEXT PTT
< 40 (Notify provider for any PTT<50)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 3 units/kg/hr	6 hours
40-49 (Notify provider for any PTT<50)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 2 units/kg/hr	6 hours
50-59 (Notify provider for 2 consecutive PTTs 50-59)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 1 units/kg/hr	6 hours
60-100	**None**	**None**	**NO CHANGE**	**6 hrs (after 2 consecutive PTTs in range, check PTT q AM)**
101-110	None	None	Decrease by 1 units/kg/hr	6 hours
111-120	None	None	Decrease by 2 units/kg/hr	6 hours
121-150	None	30 minutes	Decrease by 2 units/kg/hr	6 hours
151-199	None	60 minutes	Decrease by 3 units/kg/hr	6 hours

«LOW» Intensity (PTT Goal: 60 to 80)

PTT (seconds)	PRN RE-BOLUS	INFUSION HOLD TIME	CHANGE INFUSION DOSE (units/kg/hr)	NEXT PTT
< 40 (Notify provider for any PTT<50)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 3 units/kg/hr	6 hours
40-49 (Notify provider for any PTT<50)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 2 units/kg/hr	6 hours
50-59 (Notify provider for 2 consecutive PTTs 50-59)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 1 units/kg/hr	6 hours
60-80	**None**	**None**	**NO CHANGE**	**6 hrs (after 2 consecutive PTTs in range, check PTT q AM)**
81-100	None	None	Decrease by 1 units/kg/hr	6 hours
101-120	None	30 minutes	Decrease by 2 units/kg/hr	6 hours
121-150	None	60 minutes	Decrease by 2 units/kg/hr	6 hours
151-199	None	60 minutes	Decrease by 3 units/kg/hr	6 hours

Nevada Board of Nursing

NEVADA STATE BOARD OF NURSING
ADVISORY OPINION

OPERATIONAL DEFINITIONS
FOR
PROTOCOL, STANDING ORDERS, AND PREPRINTED ORDER SET

"**Protocol**" means a series of actions (which may include a number of medications) that may be implemented to manage a patient's clinical status. A protocol allows the application of specific interventions to be decided by the nurse based on the patient meeting certain criteria outlined in the protocol as long as the intervention is within the scope of practice of the nurse. A protocol includes alternative actions or "exceptions" to the prescriptive orders that allows for individual patient circumstance as assessed by the nurse. These "exceptions" are addressed by application of an algorith that is a step-by-step procedure for solving a problem or accomplishing the intervention. An agency may, if it chooses, have protocols that are developed by authorized practitioners and are designed to standardize and optimize patient care in accordance with current clinical guidelines or standards of practice.

"**Standing orders**" means medical treatment orders generated by an authorized prescriber who identifies an action or medication that must be implemented or administered. The use of standing orde must be documented as an order in the patient's medical record and signed by the authorized practitior responsible for the care of the patient, but the timing of such documentation should not be a barrier to effective emergency response, timely and necessary care, or other patient safety advances.

While there is significant merit to the use of standing orders, there is also the potential for harm to patients if agencies use such orders so that nurses are routinely expected to make clinical decisions outside their scope of practice. This is a complex issue that requires careful consideration by agencies physicians, nurses and other licensed health care professionals, experts in patient safety and quality improvement, and patients.

"**Preprinted order set**" refers to a tool generally designed to assist authorized practitioners as they wr orders. Order sets may include computerized programs that are the functional equivalent of hard copy preprinted order sets. Such tools may include a menu of medications or actions from which the authorized practitioner makes selections to be applied to a particular patient. They sometimes include a standard combination of medications and actions to be followed without amendment whenever the physician selects that order. All orders, preprinted or otherwise, in the medical record must be dated, timed, and authenticated by the person responsible for providing or evaluating the service provided.

RESOURCES:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Memorandum, October 24, 2008
Reviewed by the Nurse Practice Advisory Committee: 2/10/09
Approved by the Nevada State Board of Nursing: 3/18/09

What is the Difference?

- **Pre-printed order set** is a set of orders which is printed physician or LIP orders
- This prevents the physicians from having to write all the orders from memory
- Can be specific to a physicians such as their orders for total knee surgery
- Can be pre-printed orders to reflect order sets approved by the Medical Staff to promote best practices and the current evidenced based literature
- Has the potential to improve patient safety and outcomes

Preprinted Orders Vs Order Sets

- In some hospitals, preprinted orders were traditionally individual physician specific
- Order sets replaced these traditional ones in some hospitals
- Order sets in some hospitals are diagnosis specific and based on published guidelines and research
- Order sets are implemented only by the physician or licensed independent practitioner (LIP) or their delegate
  - Insulin order set, cellulitis order set, ACS thrombolytic therapy order set, newborn circumcision order set

Appendix

www.ahrq.gov/downloads/pub/advances2/vol2/Advances-Ehringer_17.pdf

Creating Preprinted Physician Orders for Clinical "best practice" Review

Criteria for consideration when creating or revising preprinted physician orders

	Content and Format	Yes
1	Orders reflect current "best practice"	
2	Orders are created in Arial 10- or 12-point font	
3	Orders do not contain unapproved abbreviations	
4	Orders do not contain confusing symbols (e.g., < and >)	
5	Blanket orders are not used. (i.e., Resume home meds).	
7	Order contains space for physician signature, physician ID #, and date	
8	Admission orders include "Admit as inpatient," "Outpatient," or "Observation Status," as appropriate	
9	Orders are single-sided (Reverse side of sheet should contain additional information or references only)	
	Medication Safety	**Yes**
10	Abbreviations, when used, are kept to a minimum	
11	Medication orders are not numbered	
12	Medication orders contain drug name, dose, route, and frequency	
13	If multiple routes are listed, order contains criteria to determine which route to use	
14	When possible, order contains dose written as **mg**, and not as **tablets** or **mL**	
15	Order does not contain multiple ranges	
16	Order contains indication for PRN medications	
17	Time frame is written for IV bolus / IV push orders	
18	Generic and trade names (if applicable) of medication are used	

Actions by the Clinical "Best Practice" Committee (CBP) may include:

	Arranging presentation of orders according to standardized format
	Adding indications of regulatory / Performance measures, etc.
	Adding DVT prophylaxis, vaccination status, smoking counseling, patient education, etc

So What's In Your Policy?

PRE-PRINTED PROVIDER ORDER SETS

- All pre-printed orders shall be created and approved by the appropriate FHS IDT or Leadership Team and provided on FHS forms. The FHS pre-printed orders have been reviewed, approved and aligned with medical staff rules and regulations, hospital policy, Joint Commission, CMS, Department of Health, FHS formulary and other relevant regulatory agencies.
- All relevant order sets involving medication are additionally reviewed by Pharmacy and the PT&T Committee and as needed the Medication Safety Leadership Team to ensure appropriate medication prescribing and ordering practices are followed.
- The Pre-Printed Provider Order Set process is supported centrally by the Clinical Effectiveness Division and its oversight Provider Orderset Standardization and Implementation Workgroup (POSSI).
- The use of pre-printed orders must be individualized, documented as an order in the patient's medical record and authenticated by a practitioner responsible for the care of the patient and authorized by the Medical Staff and state law scope of practices.
- The registered nurse verifies that the orders have been processed and indicates the time, date and signature next to the order.
- A Registered nurse may complete the order sets through use of verbal or telephone orders from an authorized practitioner provided that the orders are read back to the practitioner per policy.
- Items on the order set that do not have a box to check or are pre-checked are intended to be used for all patients. These items may be denoted by a bullet point or dash.
- Items that have a checkbox in front of them are only carried out if the box is checked. This provides customization to fit the individual patient needs and/or practitioner preference.
- Items without a checkbox or pre-checked that the physician does not want ordered must be lined out and initialed.
- Note: Some of the pre-printed orders have multiple choices within the individual medication sections as denoted by a line preceding the medication. Examples include oral/IV analgesics or anti-emetics. If there is no guidance provided as to the preferential order for medication administration.

So What's in Your Policy?

Standing medical orders: Orders, rules, regulations or procedures prepared by a physician or approved by a physician or the medical staff of an institution **for patients which have been examined or evaluated by a physician and which are used as a guide in preparation for and carrying out medical and/or surgical procedures.** These orders, rules, regulations or procedures are authority and direction for the performance of certain prescribed acts for patients by authorized persons, as distinguished from specific orders written for a particular patient.

Protocols: This term is defined narrowly by the TSBME and applies to Advanced Practice Nurses (APN) by the BON or to Physician Assistants as defined by TSBME. Delegated written authorization to initiate medical aspects of patient care, including authorizing a PA or APN to carry out or sign prescription drug orders pursuant to the Medical Practice Act (Texas Occupations Code §§157.051-157.060 and §193.6 (relating to the Delegation of the Carrying Out or Signing of Prescription Drug Orders to PAs and APNs). Protocols must be agreed upon and signed by the physician and the PA and/or APN, reviewed and signed at least annually, maintained onsite, and must contain a list of the types or categories of dangerous drugs available for prescription, limitations on the number of dosage units and refills permitted, and instructions to be given to the patient for follow-up monitoring or contain a list of the types or categories of dangerous drugs that may not be prescribed. Protocols shall be defined to promote the exercise of professional judgment by the PA or APN commensurate with their education and experience. Protocols used by a reasonable and prudent physician exercising sound medical judgment need not describe the exact steps that a PA or APN must take with respect to each specific condition, disease, or symptom.

XII. Relevant Federal and State Statutes

Texas State Board of Medical Examiners Scope of Standing Delegation Orders (22 Tex. Admin. Code §193.4)

XIII. Related UTMB Policies and Procedures

Prescription Refills in UTMB Access Center and Clinics

XIV. Additional References

What is the Difference?

- **A health care guideline** is an evidence-based statement of best practice in the prevention, diagnosis, or management of a given symptom, disease, or condition for individual patients under normal circumstances
- CMS requires that standards of practice and standards of care be entered into P&P and guidelines
- Examples: The CDC intravascular guidelines, CDC guidelines to prevent catheter associated UTI, CDC hand hygiene guidelines, ISMP IV Push guidelines etc.

ISMP Guidelines for Order Sets

ISMP DEVELOPS GUIDELINES FOR STANDARD ORDER SETS

From the March 11, 2010 issue

www.ismp.org/Tools/guidelines/default.asp

ISMP has long been an advocate for the use of standard order sets to minimize incorrect or incomplete prescribing, standardize patient care, and ensure clarity when communicating medical orders.(1–3) Whether in electronic or paper format, well-designed standard order sets have the potential to:

- Integrate and coordinate care by communicating best practices through multiple disciplines, levels of care, and services(4)
- Modify practice through evidence-based care(4)
- Reduce variation and un-intentional oversight through standardized formatting and clear presentation of orders(1–4)
- Enhance workflow with pertinent instructions that are easily understood, intuitively organized, and suitable for direct application to current information-management systems and drug administration devices(1–4)
- Reduce the potential for medication errors through integrated safety alerts and reminders(1–4)
- Reduce unnecessary calls to prescribers for clarifications and questions about orders. (1–4)

However, if standard orders are not carefully designed, reviewed, and maintained to reflect best practices and ensure clear communication, they may actually contribute to errors—many of which have been described in our newsletters and still occur today. In fact, the ISMP consulting team often identifies dozens of serious problems related to the content, format, and approval/maintenance of standard order sets when visiting healthcare organizations of all sizes and types. Below we describe the importance of paying careful attention to the design and maintenance of standard order sets as well as provide examples of commonly observed problems that can lead to serious errors. ***Guidelines for Standard Order Sets*** to help avoid these problems can be found on our Web site at: www.ismp.org/Tools/guidelines/default.asp.

Content

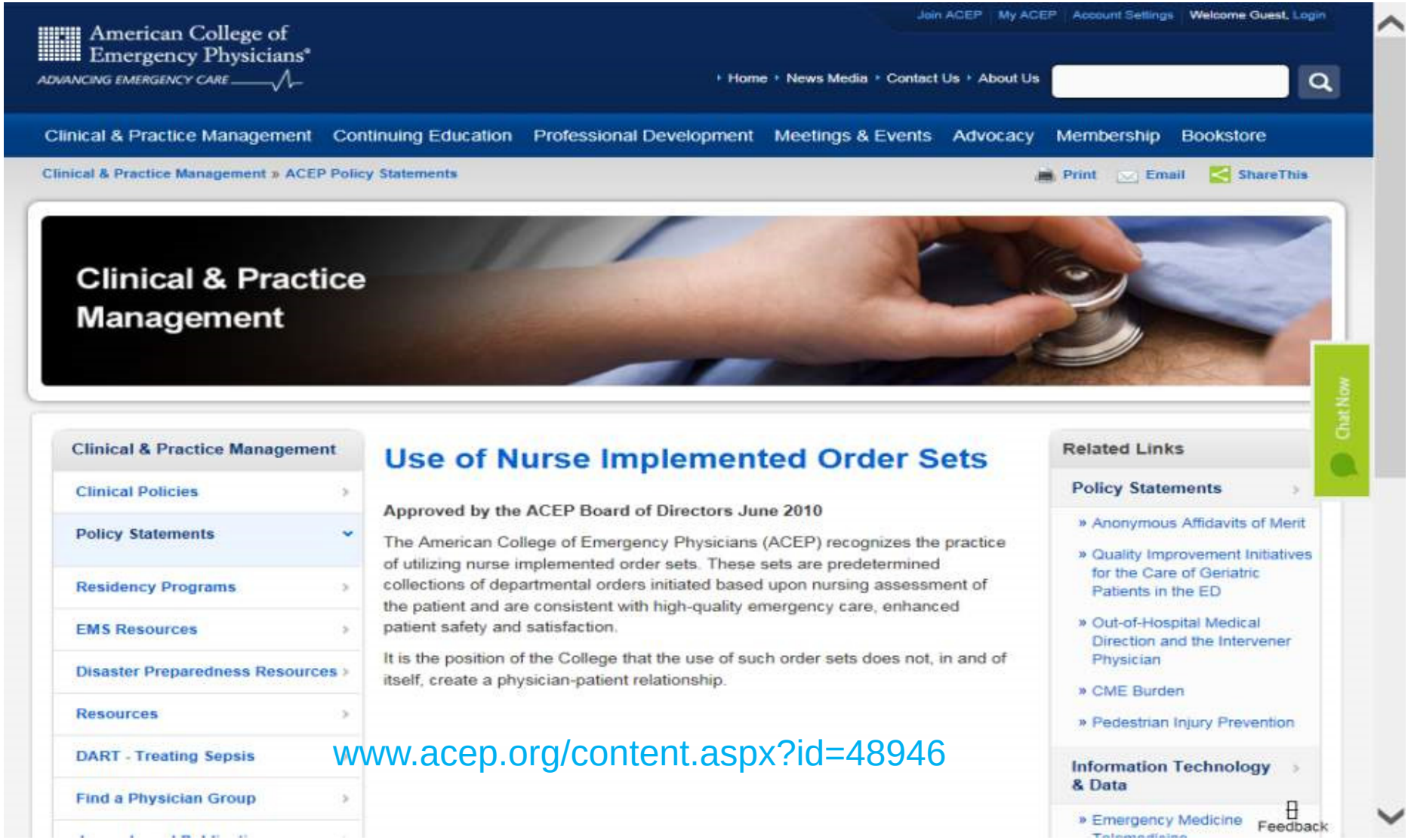
Careful attention to the content of standard order sets helps ensure they: 1) are complete, 2) include important orders be-yond what the prescriber may initially consider (e.g., specific monitoring requirements), 3) reflect current best practices,

Format

Layout and directions for use

- Follows an official standard format that has been approved by an appropriate interdisciplinary committee (e.g., pharmacy and therapeutics committee, safety committee, forms committee)
- Identifies the order set name at the top of the form/screen and, as appropriate, specifies the targeted patient population (e.g., adult, pediatric, neonatal, adult oncology)
- Differentiates similar order sets employed for similar conditions (e.g., different heparin order sets based on various clinical conditions)
- Includes directions for completing the order set at the top of the form/screen
- Uses a standard method (e.g., check boxes, circling) for prescribers to activate/select desired orders that minimizes confusion regarding how inactivated/unselected orders are to be interpreted (e.g., yes/no check boxes may be problematic regarding correct interpretation if the physician checks neither the yes nor no option; with paper order sets, a single box to check—activate—an order may be less error-prone)
- Separates orders into logical groupings of treatment, procedure, and medication orders
- Uses separate lines/entries for each medication order; multiple orders do not appear on one line or within a single entry
- Includes the name of the drug and dose/strength on the same line/entry
- Avoids listing products with look-alike names near each other
- Lists the most common or preferred drug, strength, and dose first, if multiple drugs, strengths, and doses are available from which to choose
- Uses "OR" to indicate when choices between products must be made and includes specific guidance regarding that choice
- Provides adequate space between the medication name and dose (e.g., "propranolol 20 mg, not propranolol20 mg, which may look like 120 mg), and between the numerical dose and unit of measure (e.g., 3 units, not 3Units, which can look like 30 units)
- Provides adequate space between numbers used to sequence orders and the actual orders themselves (to prevent misinterpretation of the

ACEP Nurse Implemented Order Sets



Often Used in ED for MI, Strokes, Anaphylaxis

EMERGENCY
STANDING ORDERS

Nurse initiated standing order based on medical staff approved policy (6019).
Orders with a "❑" are indicator choices and are NOT implemented unless checked. Initial bottom of each page.

RN: **May be initiated by Charge Nurse, Nursing Unit Supervisor, CNS or Nurse Clinician**
Call MRT as needed while implementing orders below
Call physician while below actions are in progress
Check box below to indicate which standing order was used during the emergency

Preliminary Actions for All Patients with Change in Condition:

1. Obtain/Confirm IV Access
2. Place patient on telemetry/cardiac monitoring
3. O_2 protocol (form # 34431)
4. Assess vital signs, Circulation, Airway, Breathing

❑ **Chest Pain/Suspected Myocardial Infarction:**

For patients exhibiting signs and symptoms of myocardial ischemia as evidenced by at least one of the following:

- Acute onset of substernal chest pain lasting > 2 minutes
- Pain radiating to arms, neck, jaw or back
- Nausea, vomiting
- Diaphoresis

1. Chest Pain box to patient's bedside
2. Obtain EKG stat
3. Nitroglycerin 0.4 mg sublingual q 5 min x 3 doses prn if systolic BP > 100

- **Tachycardia or bradycardia:**
  For symptomatic (low BP, weakness, shortness of breath, pallor, diaphoresis) patients with heart rate > 120 or < 40 beats/min

- **Suspected Pulmonary Edema/Acute Respiratory Distress/Acute Shortness of Breath:**
  For all patients exhibiting signs and symptoms of acute respiratory distress as evidenced by at least one of the following:
  - Rapid, labored breathing
  - Rales and wheezes
  - Productive cough with frothy sputum
  - Diaphoresis
  - Cyanosis

  1. ABG STAT
  2. Portable Chest X-ray STAT
  3. Ambu bag and suction set-up to bedside

- **Treatment of Anaphylaxis:**
  If the patient exhibits signs and symptoms of anaphylaxis as evidenced by: hives, angioedema, tongue or throat swelling, swelling of the conjunctiva, shortness of breath, wheezing or stridor:
  1. EPINEPHrine 1 mg/ml ampule: Give 0.5 mg IM in the mid outer thigh. If anaphylaxis symptoms are not reversed in 5-15 minutes, repeat x 1 dose.
  2. Benadryl (diphenhydramine) 25 mg IV push x 1 dose
  3. Pepcid (famotidine) 20 mg IV push x 1 dose
  4. Solu-Medrol (methlypredinsolone) 125 mg IV push x 1 dose

Nurse initiated standing order based on medical staff approved policy (6019).
Orders with a "❑" are indicator choices and are NOT implemented unless checked. Initial bottom of each page.

❑ **Narcotic-Induced Respiratory Depression:**

Following administration of an opiate (narcotic) analgesic, if the patient exhibits signs and symptoms of respiratory depression as evidenced by respiratory rate ≤ 8 breaths per min or apnea or agonal respirations:

1. Assess ABCs (airway, breathing and circulation)
2. Assist ventilation with bag valve mask and supplemental O_2 if required; Ambu bag to bedside
3. Narcan (naloxone) 0.4 mg in 10 ml Normal Saline (0.04 mg/ml). Administer 1 ml IV q 2 min prn until respiratory rate ≥ 10 or a max of 2 mg (5 doses)
4. If IV route is not available, administer undiluted Narcan (naloxone) 0.4 mg SQ or IM q 5 min prn until respiratory rate ≥ 10 or a max of 2 mg (5 doses)

❑ **Benzodiazepine-Induced Respiratory Depression:**

Following administration of a benzodiazepam {examples include: Versed (midazolam), Xanax (alprazolam), Ativan (lorazepam), Valium (diazepam)}, if the patient exhibits signs and symptoms of respiratory depression as evidenced by respiratory rate ≤ 8 breaths per min or apnea or agonal respirations

1. Assess ABCs (airway, breathing and circulation)
2. Assist ventilation with bag valve mask and supplemental O_2 if required; Ambu bag to bedside
3. Romazicon (flumazenil) 0.2 mg IV q 1 min prn until respiratory rate ≥10 or max of 1 mg (5 doses)

❑ **Symptomatic Hypotension (≥ 40 mm Hg drop in systolic baseline):**

1. Place patient in modified Trendelenburg position by leaving the head flat and elevating the patient's legs (do not place in Trendelenburg)
2. Remove topical that may cause hypotension, i.e. Nitroglycerin patch or paste, Duragesic (fentanyl) patch, and/or Catapress (clonidine) patch

CMS Requirements

- So what are the CMS requirements for order sets, protocols, pre-printed orders and standing orders?
  - Any hospital that accepts Medicare or Medicaid must follow these for all hospital patients
- CMS included a section in the June 7, 2013 changes to the Federal Register and added to tag 457
- CMS has now a total four sections on standing orders; tag 405, 406, 450, and 457 (and see radiology protocols)
  - Remember most of the information in tag 405 was moved to 457
- The development of protocols and standing orders is best described as a journey

Standing Orders, Protocols, Order Sets

- First, CMS said that a physician order was needed first and that standing orders had to be initiated before one could implement them
  - Hospitals argued this is not what the federal register said.
- CMS agrees and issues changes to the CoP manual October 17, 2008
- CMS issues “Standing Orders in Hospitals” memo October 24, 2008, S&C 12-5
  - It amended Tag 406 and 450 (which gets amended again June 5, 2009, March 15, 2013 IG, June 7, 2013, and November 2015)

Standing Order Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-10

DATE: **October 24, 2008**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: "Standing Orders" in Hospitals – Revisions to S&C Memoranda

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

Memorandum Summary

A. **Standing Order Clarification:** We are clarifying a portion of S&C-08-12 and S&C-08-18, issued on February 8 and April 11, 2008 respectively, regarding use of standing orders in hospitals. The use of standing orders must be documented as an order in the patient's medical record and signed by the practitioner responsible for the care of the patient, but the timing of such documentation should not be a barrier to effective emergency response, timely and necessary care, or other patient safety advances.
B. **Future Directions:** We express our interest in working with the professional

Revised Tag 405 and 406

Old Tag	New Tag
A -0404 – combine with A-0405 §482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3). **A -0405** (1) - All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.	**A-0405** **§482.23(c) Standard: Preparation and administration of drugs.** *(1)* Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice. *(i)* Drugs and biologicals *may be prepared and* administered *on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.* §482.23(c)(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.
A-0406	**A-0406** *§482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).* §482.23(c)(*3*)- With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy and who is responsible for the care of the patient as specified under §482.12(c). *§482.23(c)(3)(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.*

Tag 405 Standing Orders 2014

- Most of the sections on standing orders were moved to tag 457
- CMS says drugs must be administered in response to an order from a practitioner or on the basis of a **standing order**
- The standing order must subsequently be signed off or authenticated by the practitioner
  - This includes a date and time along with the signature
- The surveyor is to determine if there is a standing order and the right medications was given to the patient

Tag 405 Amended in 2014 & 2015

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-15-Hospital

DATE: **March 14, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-Operative Care of Patients Receiving IV Opioids

Memorandum Summary

- ***Medication Administration:*** We are updating our guidance for the hospital medication administration requirements to:
  - Make clear that the medication administration requirements under the nursing services condition of participation (CoP) are related to only some components of the overall hospital medication process, but that hospitals are expected, through this and the related requirements under the pharmaceutical services and quality assessment/performance improvement CoPs, to take a comprehensive approach to the medication process.
  - Update our guidance for IV medications and blood transfusions in general; and
  - Reflect the need for patient risk assessment and appropriate monitoring during and after medication administration, particularly for post-operative patients receiving IV opioid medications, in order to prevent adverse events.
- ***Immediate Post-operative Care:*** Clarification is also being made to the guidance for the surgical services CoP requirement for hospitals to have adequate provisions for immediate

Final Transmittal Issued June 6, 2014

CMS Manual System

Pub. 100-07State Operations
Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 116 | **Date: June 6, 2014**

SUBJECT: Revised State Operations Manual (SOM), Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for various provisions of 42 CFR 482.23(c), concerning medication administration, and 42 CFR 482.51(b)(4), concerning post-operative patient care.

NEW/REVISED MATERIAL - EFFECTIVE DATE: June 6, 2014
IMPLEMENTATION DATE: June 6, 2014

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0405/§482.23(c)Standard: Preparation and Administration of Drugs
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0409/§482.23(c)(4)/Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0412/§482.23(c)(6)/The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0957/§482.51(b)(4)/There must be adequate provisions for immediate post-operative care.

www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R116SOMA.pdf

405 Changed Compounding BUD

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

Table of Contents
(Rev. 151, 11-20-15)

Transmittals for Appendix A

Survey Protocol

Introduction

Task 1 - Off-Site Survey Preparation

Task 2 - Entrance Activities

Task 3 - Information Gathering/Investigation

Task 4 - Preliminary Decision Making and Analysis of Findings

Task 5 - Exit Conference

Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module

Psychiatric Unit Survey Module

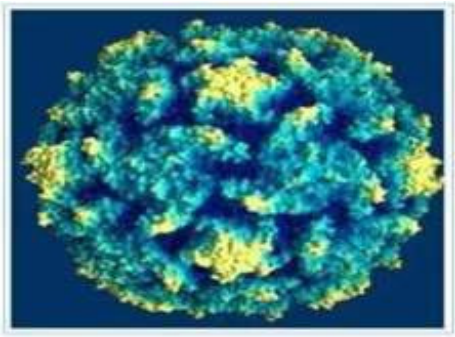
Rehabilitation Hospital Survey Module

Inpatient Rehabilitation Unit Survey Module

Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines

Email questions
hospitalscg@cms.hhs.gov



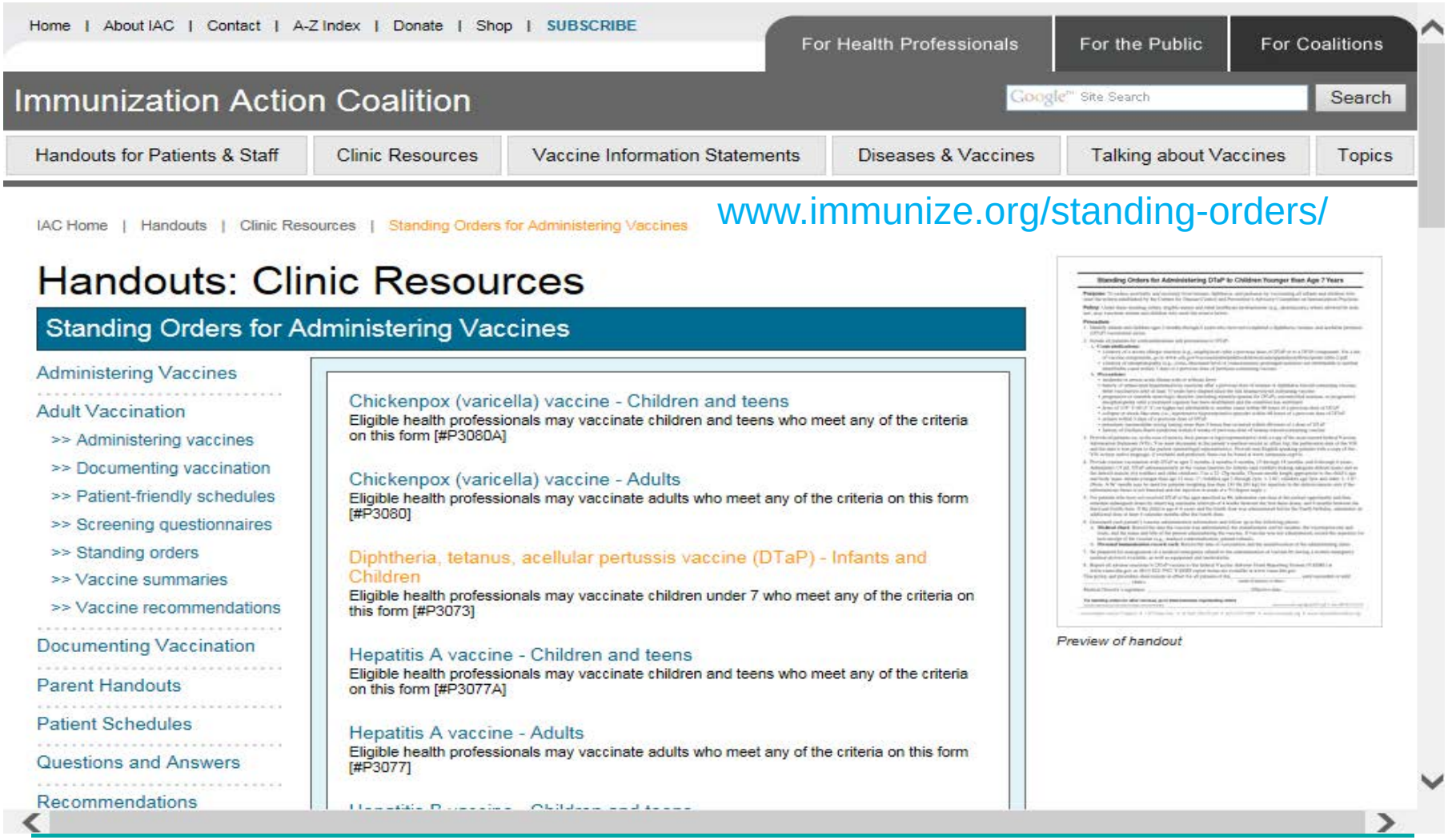
Tag 406, 407, and CMS 2008 Memo

- **Standard**: Drugs and biologicals must be prepared on the orders contained within pre-printed and electronic standing orders, order sets, and protocols only if meets the requirements of tag 457
  - Again, order can be signed by physician or practitioner (like a PharmD, NP or PA) who is allowed by state law, hospital P&P, and the Medical Staff
- Tag 406 requires that all orders for drugs and biologicals must include things like the name of the patient, date and time of the order, weight if applicable (be sure to only get weights on children in kilograms and not pounds), drug name, dosage, frequency, etc.

Tag 406 Flu and Pneumovac

- Order must be documented in the chart
  - Reiterated that flu and pneumonia vaccines can be administered per physician approved hospital policy after an assessment of the contraindications
  - There is no requirement for the physician or other practitioner to sign or authenticate the order
  - The Joint Commission recognizes the same exception

Standing Orders for Vaccines Website



Preview of handout

Standing Orders for Administering DTaP to Children Younger than Age 7 Years

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and pertussis by vaccinating all infants and children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate infants and children who meet the criteria below.

Procedure

1. Identify infants and children ages 2 months through 6 years who have not completed a diphtheria, tetanus, and acellular pertussis (DTaP) vaccination series.

2. Screen all patients for contraindications and precautions to DTaP:
   a. **Contraindications:**
      - a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of DTaP or to a DTaP component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
      - a history of encephalopathy (e.g., coma, decreased level of consciousness; prolonged seizures) not attributable to another identifiable cause within 7 days of a previous dose of pertussis-containing vaccine.
   b. **Precautions:**
      - moderate or severe acute illness with or without fever
      - history of arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid containing vaccine
      - progressive or unstable neurologic disorder (including infantile spasms for DTaP), uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized
      - fever of 105° F (40.5° C) or higher not attributable to another cause within 48 hours of a previous dose of DTaP
      - collapse or shock-like state (i.e., hypotensive hyporesponsive episode) within 48 hours of a previous dose of DTaP
      - seizure within 3 days of a previous dose of DTaP
      - persistent, inconsolable crying lasting more than 3 hours that occurred within 48 hours of a dose of DTaP
      - history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine

3. Provide all patients (or, in the case of minors, their parent or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, the publication date of the VIS

Vaccine Standing Order Program

American Journal of Health-System Pharmacy

Designing and Implementing a Hospital-Based Vaccine Standing Orders Program

Denise R. Sokos, Pharm.D., BCPS; Susan J. Skledar, B.S.Pharm., M.P.H.; Kelly A. Ervin, CPHT; Mary Patricia Nowalk, Ph.D., R.D.; Richard K. Zimmerman, M.D., M.P.H.; Dwight E. Fox, D.M.D.; Donald B. Middleton, M.D.

Disclosures

Am J Health Syst Pharm. 2007;64(10):1096-1102.

Comment Print

References

Steps in Implementation of a Vaccine SOP

The SOP eliminated the need for a patient-specific signed physician order; however, a significant issue to resolve was the need for the order to be in a recognizable format to facilitate detection and follow-through by the nursing staff. Therefore, the design of the standing order form was of critical importance. We designed it to resemble other physician order forms at our institution (Figure 1). We combined the patient risk assessment form with the actual vaccination order form to familiarize staff with the vaccination process. The patient risk assessment includes the Advisory Committee on Immunization Practices (ACIP) recommendations for assigning a patient's disease risk, contraindications to vaccination, and previous vaccination history.[1,17] The order specifies the vaccine administration date and time (e.g., "admission day 2 at 1700") and provides parameters for intramuscular or subcutaneous administration. The expert team determined that day 2 of admission was the earliest time that vaccination could practically be approached during the inpatient stay. This time frame was optimal, leaving adequate time for screening admissions, writing orders, allowing physicians to cancel the order if they chose, delivering the vaccine to the unit, educating patients, and administering the vaccine to consenting patients. However, we discovered that vaccine doses were being omitted because of morning and early afternoon discharges on admission day 2. The order was revised and currently specifies to administer the vaccine "now," and it stays active on the patient's profile until the vaccine is administered, refusal is charted, or the patient is discharged.

www.medscape.com/viewarticle/557741_5

Pneumococcal polysaccharide vaccine assessment and standing order form.

Medscape® www.medscape.com

UPMC
University of Pittsburgh Medical Center

PHYSICIAN ORDER SET

AUTHORIZATION IS GIVEN TO THE PHARMACY TO DISPENSE AND TO THE NURSE TO ADMINISTER THE GENERIC OR CHEMICAL EQUIVALENT WHEN THE DRUG IS FILLED BY THE PHARMACY OF THE UPMC HEALTH SYSTEM HOSPITAL - UNLESS THE PRODUCT NAME IS CIRCLED

IMPRINT PATIENT IDENTIFICATION HERE

Pneumococcal Polysaccharide Vaccine Assessment and Standing Order Form

Check all boxes that apply with a ☒

Risk Assessment – No Active Orders

Step 1: Determine the patient's risk:

- ☐ Age ≥ 65 years. **Proceed to Step 2.**
- ☐ Age 2 – 64 years with any of the following:
  Chronic Illnesses: cardiovascular disease, pulmonary disease (not asthma), diabetes mellitus, alcoholism, liver disease, sickle cell anemia, cerebrospinal fluid leaks, cochlear implant recipients, ***and/or***
  is *immunocompromised*: HIV infection, leukemia, lymphoma, Hodgkins disease, multiple myeloma, generalized malignancy, asplenic, chronic renal failure, nephrotic syndrome, organ or bone marrow transplantation, immunosuppressive medications
  Proceed to Step 2
- ☐ Age 2-64 years and an Alaskan native or of other Native American descent. **Proceed to Step 2.**
- ☐ Age 2-64 years with no risk factors. **Proceed to Order Section and check "do not administer vaccine" box.**

Step 2: Assess for contraindications:

- ☐ Hypersensitivity to vaccine component.
  Proceed to Order Section and check "do not administer vaccine" box
- ☐ Severe reaction to prior pneumococcal vaccine.
  Proceed to Order Section and check "do not administer vaccine" box
- ☐ Patient received chemotherapy within the last three months or may receive chemotherapy within two weeks.
  Proceed to Order Section and check "do not administer vaccine" box
- ☐ Patient's vaccinations are evaluated and administered in outpatient clinic/office
  Proceed to Order Section and check "do not administer vaccine" box
- ☐ No contraindications noted from available information:
  Proceed to Step 3.

Step 3: Assess previous vaccination history:

Order Section

- ☐ **Administer pneumococcal polysaccharide vaccine 0.5 ml:**
  - ☐ **deep IM in deltoid**
  - ☐ **Subcutaneous if INR > 1.5 or platelets < 100,000**
  - ☐ **Subcutaneous if patient is on heparin drip or warfarin**

  and give:
  - ☐ Now
  - ☐ **on** _____ **at** _____**:00**

- ☐ **Do NOT administer pneumococcal vaccine.**

Signature: _____

Printed Name: _____

Pager/phone:

Tag 406 Order Required

- Your state law sets forth the scope of practice and not CMS and determines if the person is a LIP such as nurse practitioners
- Orders may also be provided by others who are authorized such as podiatrists, nurse practitioner, pharmacists, dentists, optometrist, chiropractor, or clinical psychologists
- CMS does not want to be an obstacle to what state law permits so for example if state allow PharmD to manage anticoagulant clinic will allow to sign off order if done by MS approved protocol (July 16, 2012 FR)

CMS Changes

- CMS published some final changes to hospital CoP
- Several are important to the CMS dietary CoPs
  - Reiterated about not restricting scope of practice and deferring to the state law and state scope of practice
- Practitioner such as dietician (4-1-2015) and pharmacist can be C&P and either a member or not a member of the MS
  - So if state allows, board and MS can credential dieticians to order diet including TPN, therapeutic diet & supplemental feedings

Final Federal Register Changes

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, 440, 442, 482, 483, 485, 486, 488, 491, and 493

[CMS-3267-F]

RIN 0938-AR49

Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II

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

ACTION: Final rule.

SUMMARY: This final rule reforms Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This final rule also increases the ability of health care professionals to devote resources to improving patient care, by eliminating or reducing requirements that impede quality patient care or that divert resources away from providing high quality patient care. We are issuing this rule to achieve regulatory reforms under Executive Order 13563 on improving regulation and

CMS Memo on Standing Orders Oct 28, 2008

- Standing orders must be documented as an order in the patient's chart
- Standing orders must later be signed off by the physician, or other qualified practitioner, along with being dated and timed
- Went over standards for pre-printed orders discussed under tag 450
- All qualified practitioners responsible for the care of the patient and authorized by the hospital in accordance with State law and scope of practice are permitted to issue patient care orders

CMS Memo on Standing Orders Oct 28, 2008

- Standing orders should be evidenced based
- Many hospitals used protocols to standardize and optimize patient care in accordance with clinical guidelines or standards of practice
- Formal protocols may also be used with code team or rapid response teams
- Pre-printed orders are a tool designed to assist qualified practitioners as they write orders
- Preprinted orders are allowed but must be approved by the medical staff such as the MEC

Pre-printed Orders Tag 450

- Note in final IG, adds tag 457
- If a physician or LIP is using pre-printed order set, then must comply with the below sections
- A preprinted order set is a tool generally designed to assist qualified practitioners as they write orders
  - For example, an orthopedic surgeon goes to the cabinet and gets out his three page order sheets for total knee surgery

Pre-printed Orders Tag 450

- CMS states the physician must identify the total number of pages in the order set
  - Doctor documents 3 of 3 pages
  - Remember must sign, date and time the order
- If electronic medical record still need to date and time the order and affix electronic signature
- The physician or practitioner must sign, date, and time the last page of the orders also
- This includes initiating or signing either the top or the bottom of the pertinent pages

Pre-printed Orders Tag 450

- This was done to prevent alterations in the medical record
- If any additions, deletions, or strike outs are done in the order sheet then the physician or LIP needs to initiate to show that they made the change and not someone else
- Order sets may include computerized menu that are a functional equivalent of the preprinted order set
- In the case of electronic orders, the physician or LIP selects the orders and then affixes an electronic signature which includes a date and time

Standing Orders and Protocols

- CMS issued more than two dozen changes that went into effect June 7, 2013 and added tag number 457 devoted to only standing orders
- It was clarified that CMS is allowing for the administration of medications and biologicals on the orders contained within preprinted and electronic standing orders, order sets, and protocols for patient orders that meet their standards

Order Sets, Protocols, Standing Orders

- CMS notes there are many situations, besides rapid response teams, where standing orders would be helpful
- This includes the emergency department for things such as asthma, heart attacks, and stroke
- Again the ED staff would need to enter the order in the chart and sign off the orders as discussed

Tag 457 Added by CMS June, 2013

Old Tag	New Tag
New content for this Tag number. Previous citations under old Tag A 0457 will be attributed to Tag A-0454	**A-0457** *§482.24(c)(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:* *(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;* *(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;* *(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and* *(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.*
A-0458	**A-0458** §482.24(c)(4) - All records must document the following, as appropriate:

Tag 457 Standing Orders

- **Standard:** Hospitals can use preprinted and electronic standing orders, order sets, and protocols for patient orders only if the hospital has the following 4 things:
- Make sure the orders and protocols have been reviewed and approved by the MS (such as the MEC) and the hospital's nursing and pharmacy leadership
- Demonstrate that the orders and protocols are consistent with nationally recognized and evidenced based guidelines

A-0457

(Rev.)

§482.24(c) ***(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:***

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Interpretive Guidelines §482.24(c)(*3*)

What is covered by this regulation?

There is no standard definition of a "standing order" in the hospital community at large (77 FR 29055, May 16, 2012), but the terms "pre-printed standing orders," "electronic standing orders," "order sets," and "protocols for patient orders" are various ways in which the term "standing orders" has been applied. For purposes of brevity, in our guidance we generally use the term "standing order(s)" to refer interchangeably to pre-printed and electronic standing orders, order sets, and protocols. However, we note that the lack of a standard definition for these terms and their interchangeable and indistinct use by hospitals and health care

Tag 457 Standing Orders

- Ensure that there is periodic review the standing orders conducted by MS, nursing and pharmacy leadership to determine the usefulness and safety
- Ensure that the standing orders are dated, timed, and authenticated by the ordering physician or other practitioner responsible for the care of the patient
  1. As long as practitioner is acting in accordance with state law
  2. Scope of practice
  3. Hospital P&P and
  4. MS bylaws and R/R

Tag 457 Standing Orders

- No standard definition of standing orders
- For brevity CMS uses standing orders to include pre-printed orders, electronic standing orders, order sets and protocols
  - Said these are forms of standing orders
- States lack of standard definition may result in confusion
- Not all preprinted and electronic order sets are considered a standing order covered by this regulation

Tag 457 Standing Orders

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

Tag 457 Standing Orders

- In cases, where a nurse can initiate without a prior specific order,
  - Then policy and practice must meet these regulations
  - Doesn’t matter what it is called
  - Must meet certain pre-defined clinical situations
  - Emergency response or part of an evidenced-based treatment where it is NOT practical for a nurse to obtain a written order or verbal order
- Hybrids still require compliance with this section
  - Order set has a protocol for nurse initiated such as KCL

Standing Order Requirements 457

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

Standing Order Requirements 457

- Triage and initialing screening to stabilize ED patients presenting with symptoms of MI, stroke, asthma
- Post-operative recovery areas like PACU
- Timely provisions of immunizations
- Can’t be used when prohibited by state or federal law so no standing orders on R&S
- CMS has set forth a number of minimum requirements for standing orders that must be present for a well-defined clinical scenario

Minimum Requirements for Standing Orders

- Must be approved by MS, nursing and pharmacy leadership
- P&P address how it is developed, approved, monitored, initiated by staff and signed off or authenticated
  - Make sure new staff or LIPs **trained** on protocols
- Must have specific criteria identified in the protocol for the order for a nurse or other staff to initiate
  - Such as a specific clinical situation, patient condition or diagnosis
  - Must include process to have them **signed off**

Minimum Requirements for Standing Orders

- Hospital must document standing order is consistent with nationally recognized and evidenced based guidelines
- Burden is on the hospital to show there is sound basis for the standing order so consider citing resource
- Must have regular review to ensure its still useful and a safe order
- P&P address how to correct it, revise or modify
- Must be placed in the order section of the chart
- Must be dated, timed, and signed

Tag 457 Standing Orders

- Make sure there is periodic and regular review of the orders and protocols conducted by the MS, nursing and pharmacy leadership to determine the continued usefulness and safety
- Make sure they are dated, timed, and authenticated promptly in the medical record
  - Signed off by the ordering practitioner or another practitioner on the case
  - Could be signed off by non-physician (PA, NP) if allowed by hospital policy, state law, the person's state law scope of practice, and MS bylaws or R/R

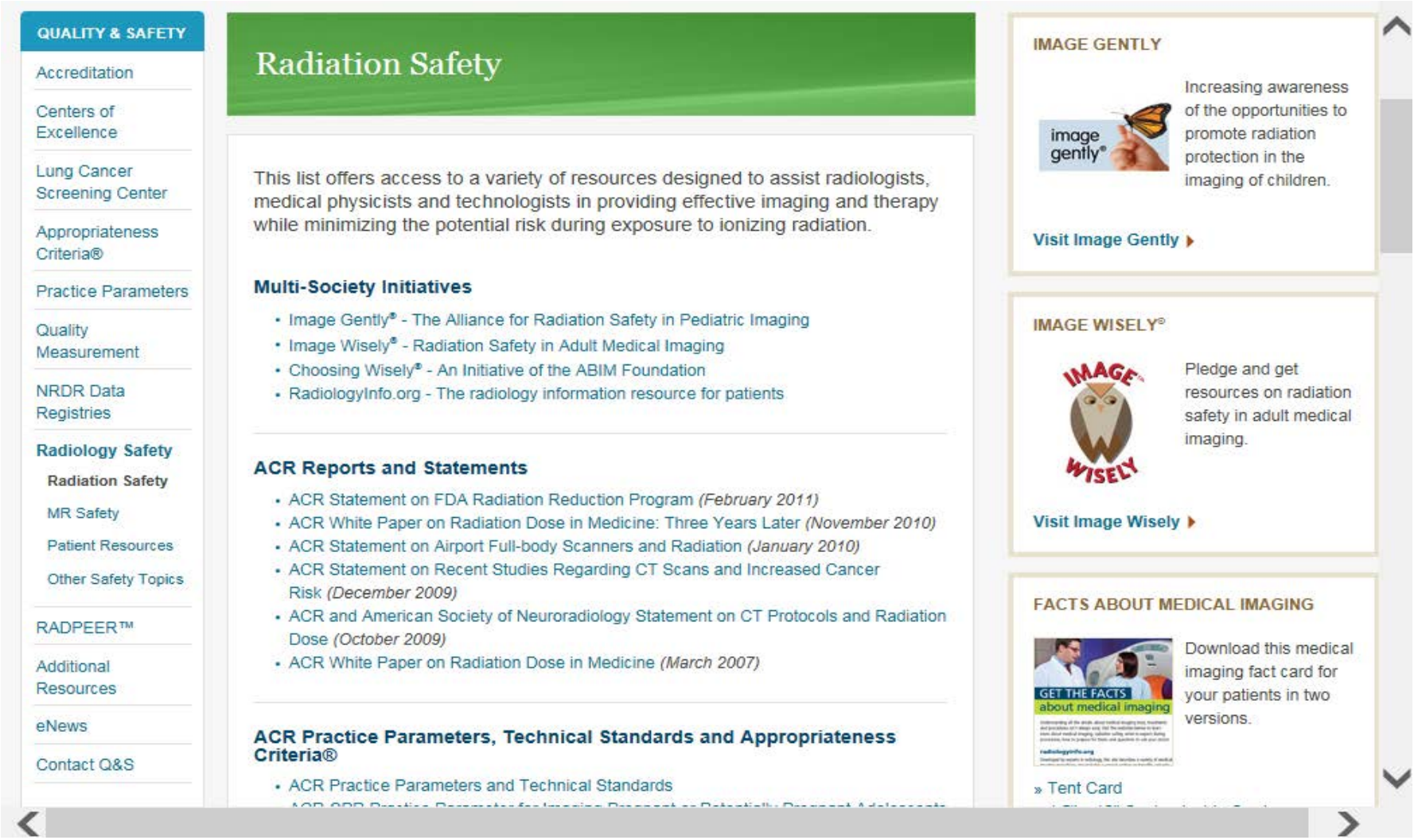
Radiology Protocols

- CMS issues a survey memo May 15, 2015 rewriting the radiology and nuclear medicine standards
- These were finalized in a transmittal issued on 7-10-2015
- 41 pages memo and make sure radiology department directors and radiologists have a copy of this
- These contained several protocol requirements for the radiology department

Radiology Protocols

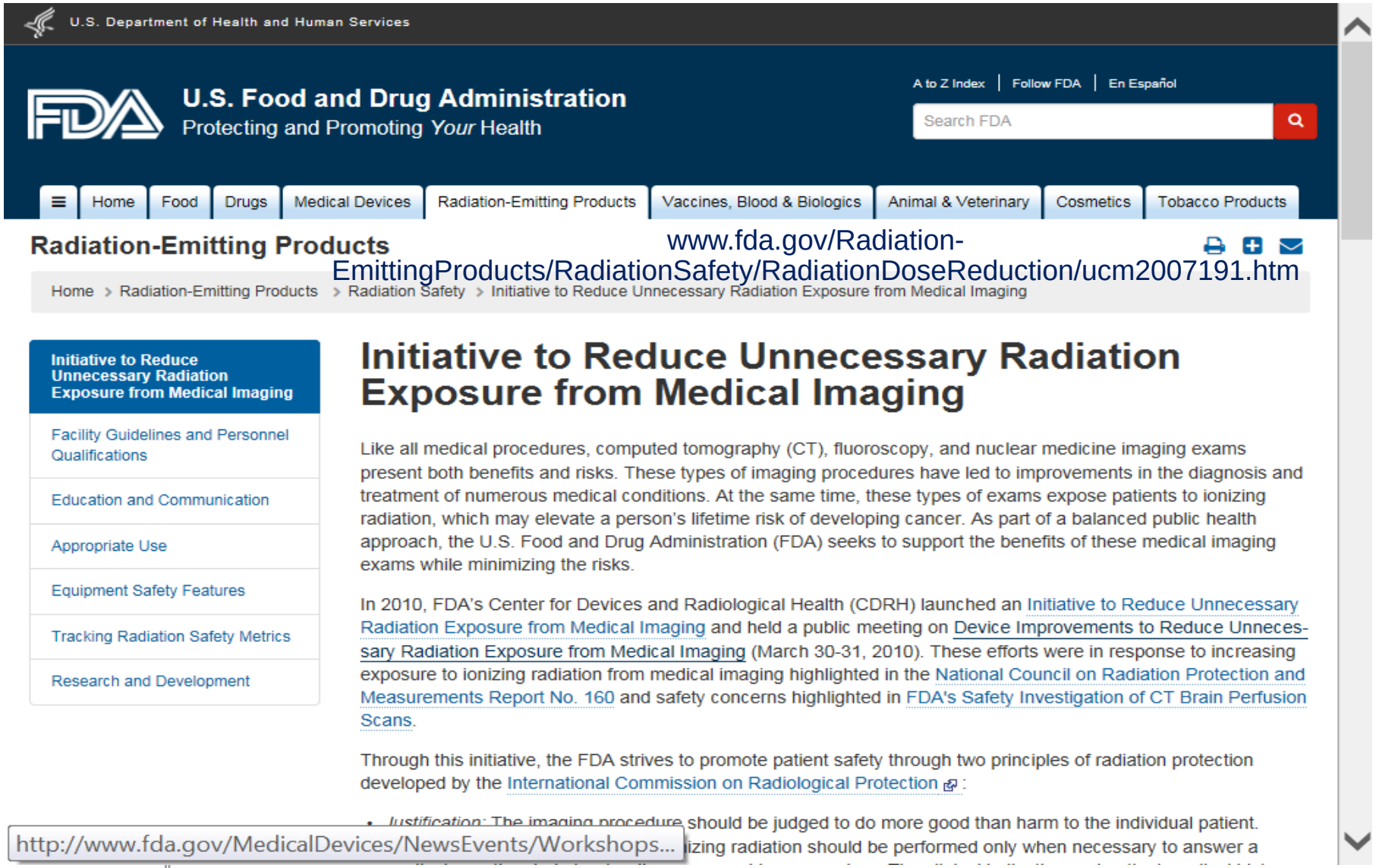
- There are also many required policies
- Must have written protocols developed or approved by the radiology director in conjunction with radiology staff to make sure diagnostic and therapeutic procedures are performed safety
  - Such as radiology techs, patient safety officer, physicist, etc.
- Must ensure that protocols for the various types of ionizing radiation diagnostic or therapeutic imaging modalities are designed to minimize the amount of radiation while maximizing the yield and producing diagnostically acceptable image quality

ACR Radiation Safety Resources



www.acr.org/Quality-Safety/Radiology-Safety/Radiation-Safety

FDA Reduce Unnecessary Radiation Exposure



Radiology Protocols

- Existing protocols must be reviewed periodically and updated
- Must follow accepted protocols to ensure the correct quality, quantity, and placement of radiation
- Policies and protocols to identify patients at high risk for adverse events for whom the radiologic study or procedure might be contraindicated
    - Pregnant women, individuals with known allergies to contrast agents, individuals with implanted devices, etc.

Free Resource AHRQ 2016 185 Pages

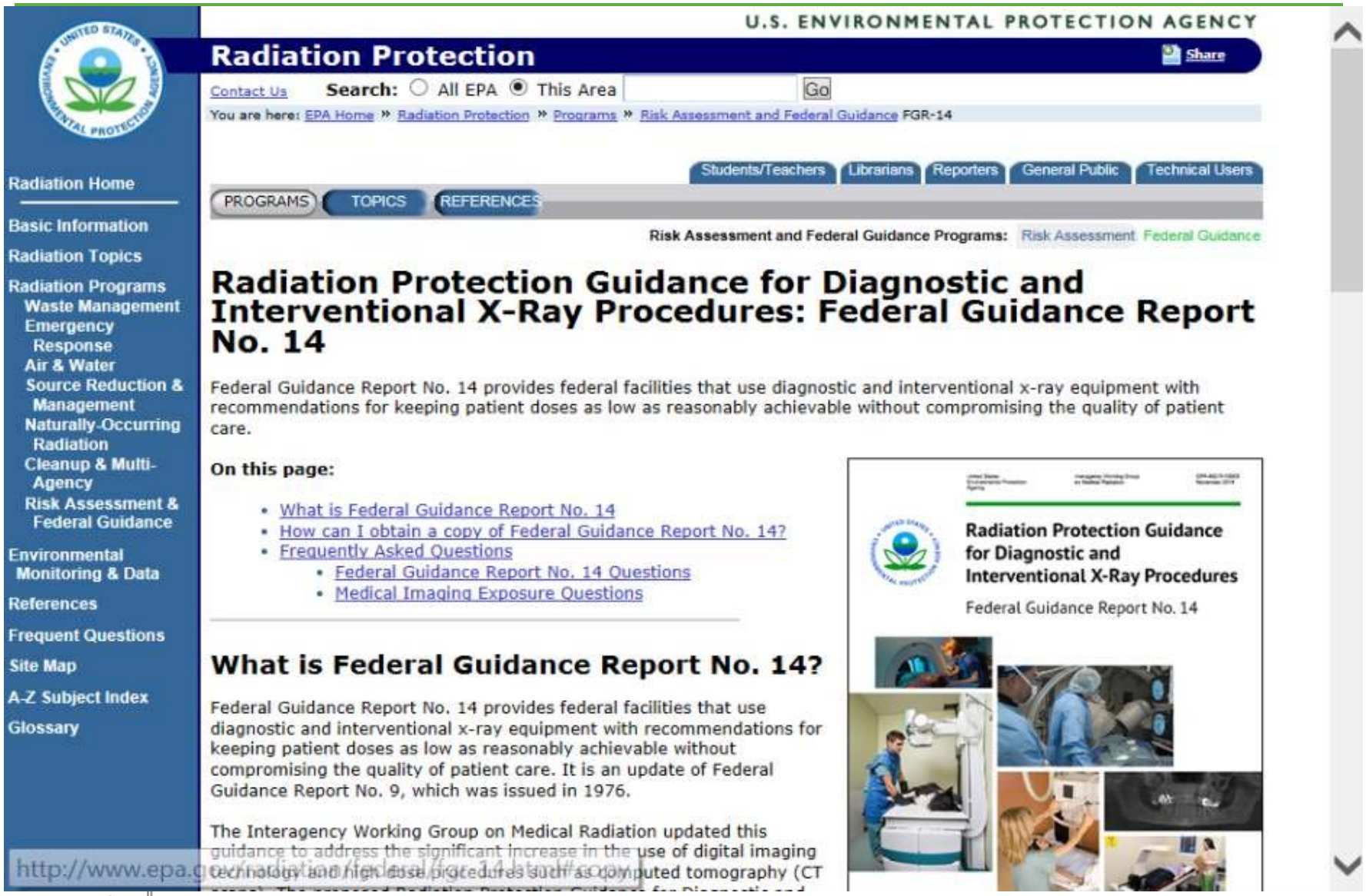
Contrast Induced Nephropathy Toolkit

http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/cin/Pages/home.aspx

Radiology Protocols

- The surveyor is to verify that there are written hospital policies and procedures and protocols for specific radiologic services modalities
- They must be based on identified professionally approved standards
- Must address the ALARA principle as well as the other safety and risk-reduction measures discussed in the guidance
  - As Low as Reasonably Achievable which is defined by the EPA to minimize exposure to ionizing radiation as low as reasonably achievable

ALARA Federal Guidance



U.S. ENVIRONMENTAL PROTECTION AGENCY

Radiation Protection

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Risk Assessment and Federal Guidance Programs: Risk Assessment Federal Guidance

Radiation Home

Basic Information

Radiation Topics

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Glossary

Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures: Federal Guidance Report No. 14

Federal Guidance Report No. 14 provides federal facilities that use diagnostic and interventional x-ray equipment with recommendations for keeping patient doses as low as reasonably achievable without compromising the quality of patient care.

On this page:

- What is Federal Guidance Report No. 14
- How can I obtain a copy of Federal Guidance Report No. 14?
- Frequently Asked Questions
  - Federal Guidance Report No. 14 Questions
  - Medical Imaging Exposure Questions

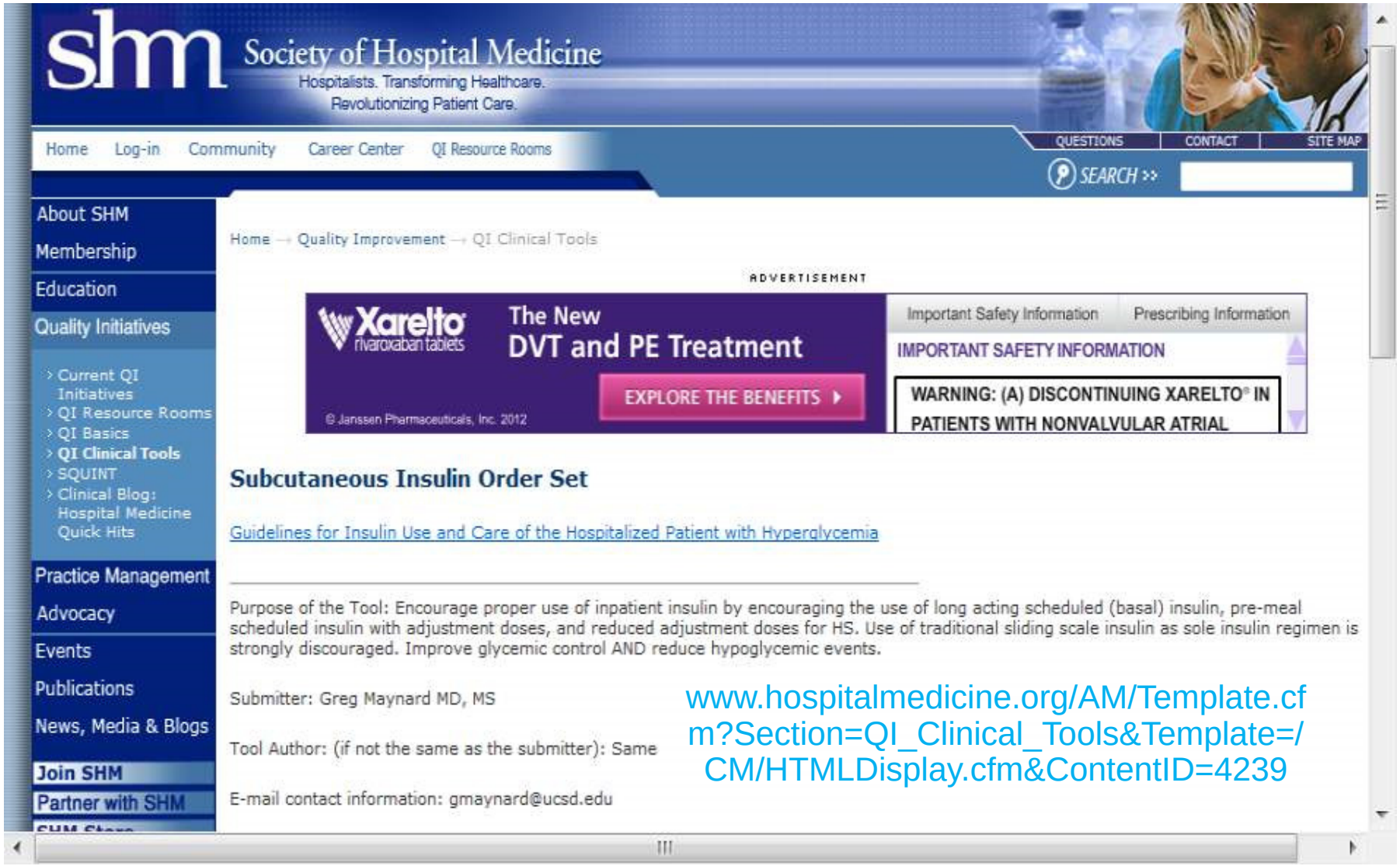
What is Federal Guidance Report No. 14?

Federal Guidance Report No. 14 provides federal facilities that use diagnostic and interventional x-ray equipment with recommendations for keeping patient doses as low as reasonably achievable without compromising the quality of patient care. It is an update of Federal Guidance Report No. 9, which was issued in 1976.

The Interagency Working Group on Medical Radiation updated this guidance to address the significant increase in the use of digital imaging technology and high dose procedures such as computed tomography (CT

http://www.epa.gov/radiation/federal/fgr-14.html#copy

Subq Insulin Order Set



www.hospitalmedicine.org/AM/Template.cfm?Section=QI_Clinical_Tools&Template=/CM/HTMLDisplay.cfm&ContentID=4239

Insulin Drip Protocol

THE *NEW** YALE INSULIN DRIP PROTOCOL

The following insulin drip protocol is intended for use in hyperglycemic adult patients in an ICU setting, but is not specifically tailored for those individuals with diabetic emergencies, such as diabetic ketoacidosis (DKA) or hyperglycemic hyperosmolar syndrome (HHS). When these diagnoses are being considered, or if BG≥ 500 mg/dL, an MD should be consulted for specific orders. Also, please notify an MD if the response to the insulin drip is unusual/unexpected, or if any situation arises that is not adequately addressed by these guidelines. The starting dose, adjustments, and glucose targets have been intensified.

Initiating An Insulin Drip

1.) **INSULIN INFUSION**: Mix 1 units Regular Human Insulin per 1 cc 0.9 % NaCl. Administer via infusion pump (in increments of 0.5 U/hr).
2.) **PRIMING**: Flush 50 cc of Insulin/NS drip through all IV tubing, before infusion begins (to saturate the insulin binding sites in the tubing)
3.) **THRESHOLD**: IV insulin is indicated in any critically ill patient with persistent BG ≥ 140 mg/dl; consider use if BG ≥ 110 mg/dl.
4.) **TARGET BLOOD GLUCOSE (BG) LEVELS: 90-119 mg/dL***.
5.) **BOLUS & INITIAL INSULIN DRIP RATE**: If initial BG ≥ 150, divide initial BG level (mg/dL) by 70, then round to nearest 0.5 units for bolus AND initial drip rate. If initial BG < 150 mg/dl, divide by 70 for initial drip rate only (i.e., NO bolus)

Examples: 1) Initial BG 335 mg/dL: 335 ÷ 70 4.78, rounded ↑ to 5: 5 units IV bolus + start drip @ 5 units/hr.
2) Initial BG 148 mg/dL: 148 ÷ 70 2.11, rounded ↓ to 2: start drip @ 2 units/hr (NO bolus)

Fingerstick (FS) Blood Glucose Monitoring

1.) Check FS hourly until stable (defined as 3 consecutive values in target range). In hypotensive patients, capillary blood glucose (i.e.,fingersticks) may be inaccurate and obtaining a blood sample from an indwelling vascular catheter may be preferable.
2.) Once stable, check FS q 2 hours; once stable x 12-24 hours, FS checks can be spaced to q 4 hours IF:
a) no significant change in clinical condition AND b) no significant change in nutritional intake
3.) If any of the following occur, consider the temporary resumption of hourly FS monitoring, until BG is again stable:
a) any change in insulin drip rate (i.e. BG out of target range) b) significant changes in clinical condition
c) initiation or cessation of pressor or steroid therapy d) initiation or cessation of dialysis or CVVH
e) initiation, cessation, or rate change of nutritional support (TPN, PPN, tube feedings, etc.)

Changing the Insulin Drip Rate

If BG < 50 mg/dL:
D/C INSULIN DRIP **Give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes**
⇒ When BG ≥ 90 mg/dL, wait 1 hour, recheck BG, then restart drip at 50% of most recent rate (if BG still ≥ 90 mg/dL

If BG 50-69 mg/dL:
D/C INSULIN DRIP If symptomatic (or difficult to assess), give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes

ICSI Protocols

Opioid Prescribing Protocol

Alcohol Withdrawal Treatment Protocol

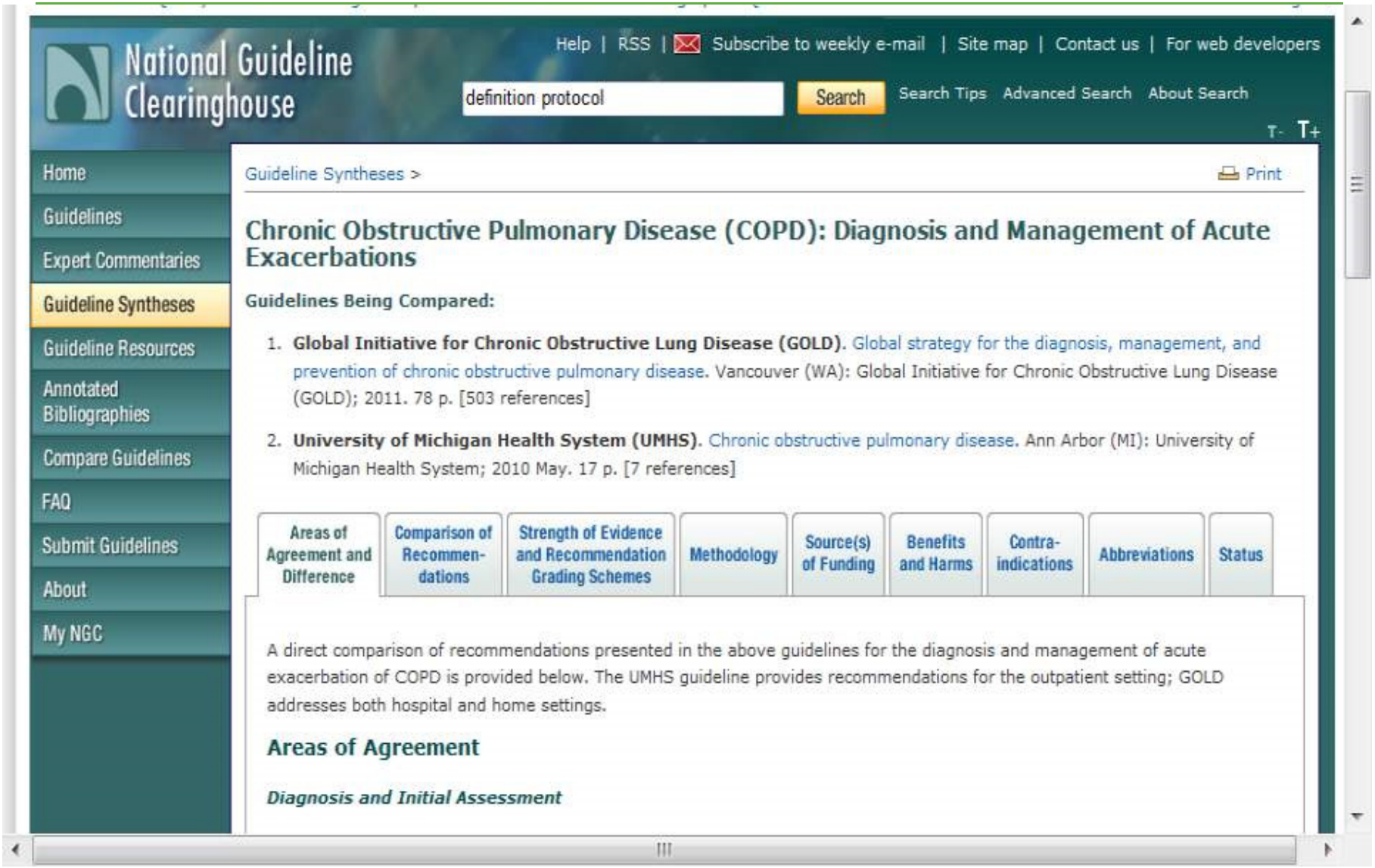
Evidence-Based Revision of an Alcohol Withdrawal Order Set Treatment Protocol

Background: Every year several hundred thousand hospitalized patients are treated with alcohol withdrawal, either as a primary or secondary diagnosis. In 2003, due to high numbers of our patient population experiencing alcohol withdrawal, the Medical ICU at the XXXX Hospital, implemented a symptom triggered alcohol withdrawal order set protocol which incorporated the standardized CIWA scale (Clinical Institute Withdrawal Assessment), and treated primarily with oral clorazepate or oral or intravenous (IV) lorazepam. The order set was expanded in 2005 to include all inpatient areas, dividing the orders into treatment of intensive Emergency/ICU patients and less intensive Medical/Surgical patients. In May 2008, because of concerns among several of the MICU physicians and nurses, the MICU Outcomes Committee reviewed the most current alcohol withdrawal literature for evidence-based best practice protocols and subsequently modified the alcohol withdrawal order set. Physician concerns included: 1) Patients receiving large benzodiazepines doses on the current protocol causing over sedation which required intubation to protect the patient's airway; 2) Patients receiving a continuous infusion of lorazepam which delayed extubation by several days. Nursing concerns included increasing benzodiazepine usage due to the lack of adjunct medications to manage associated alcohol withdrawal symptoms such as agitation, delirium, and adrenergic stimulation with hypertension and tachycardia.

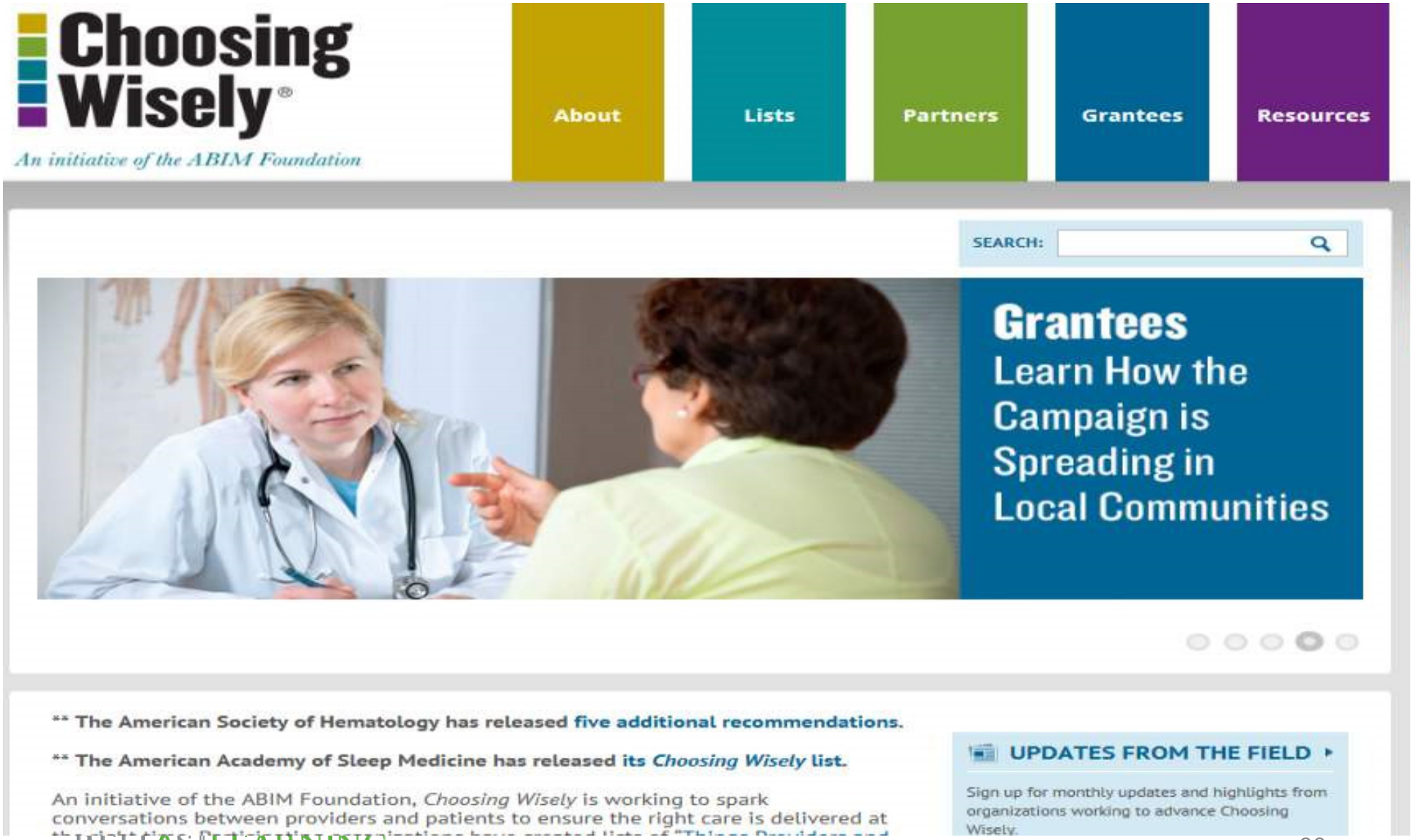
Purpose: The purpose of this evidence-based project was to revise the XXXX alcohol withdrawal treatment practice order set based on the evidence and to include adjunct medications to improve patient safety and outcomes.

Methods: The Multidisciplinary MICU Outcomes Committee revised the alcohol withdrawal order set to include additional evidence-based adjunct medications to reduce

Guidelines www.guidelines.gov



Choosing Wisely www.choosingwisely.org/



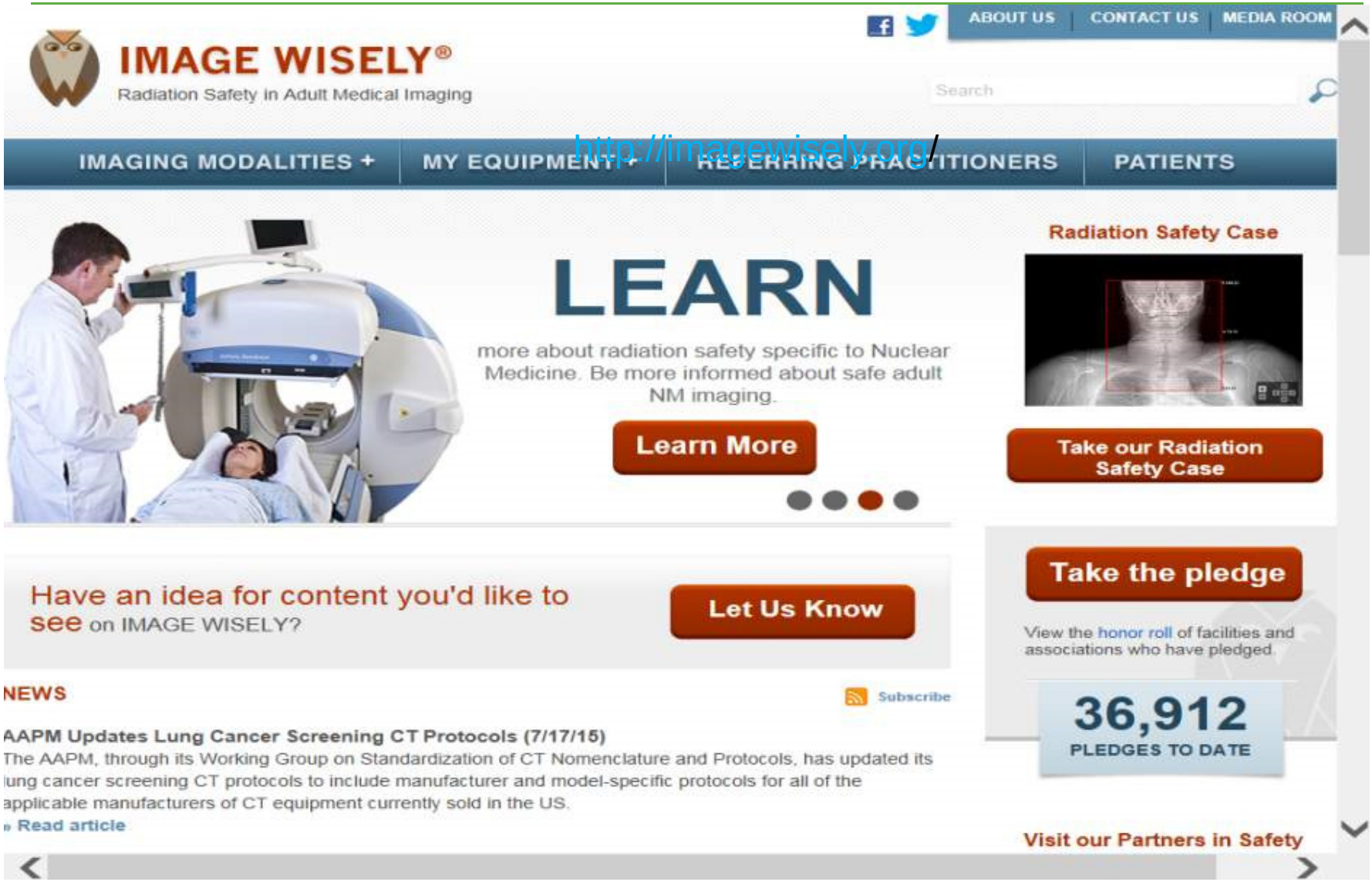
Specialty Society Lists of Five Things Physicians and Patients Should Question (for physicians):

- AMDA – The Society for Post-Acute and Long-Term Care Medicine
- American Academy of Allergy, Asthma & Immunology
- American Academy of Dermatology
- American Academy of Family Physicians
- American Academy of Hospice and Palliative Medicine
- American Academy of Neurology
- American Academy of Nursing
- American Academy of Ophthalmology
- American Academy of Orthopaedic Surgeons
- American Academy of Otolaryngology — Head and Neck Surgery Foundation
- American Academy of Pediatrics
- American Academy of Physical Medicine and Rehabilitation
- American Academy of Sleep Medicine
- American Association for Pediatric Ophthalmology and Strabismus
- American Association for the Study of Liver Diseases
- American Association of Blood Banks
- American Association of Neurological Surgeons and Congress of Neurological Surgeons
- American College of Cardiology
- American College of Chest Physicians and American Thoracic Society
- American College of Emergency Physicians
- American College of Medical Toxicology and American Academy of Clinical Toxicology
- American College of Obstetricians and Gynecologists

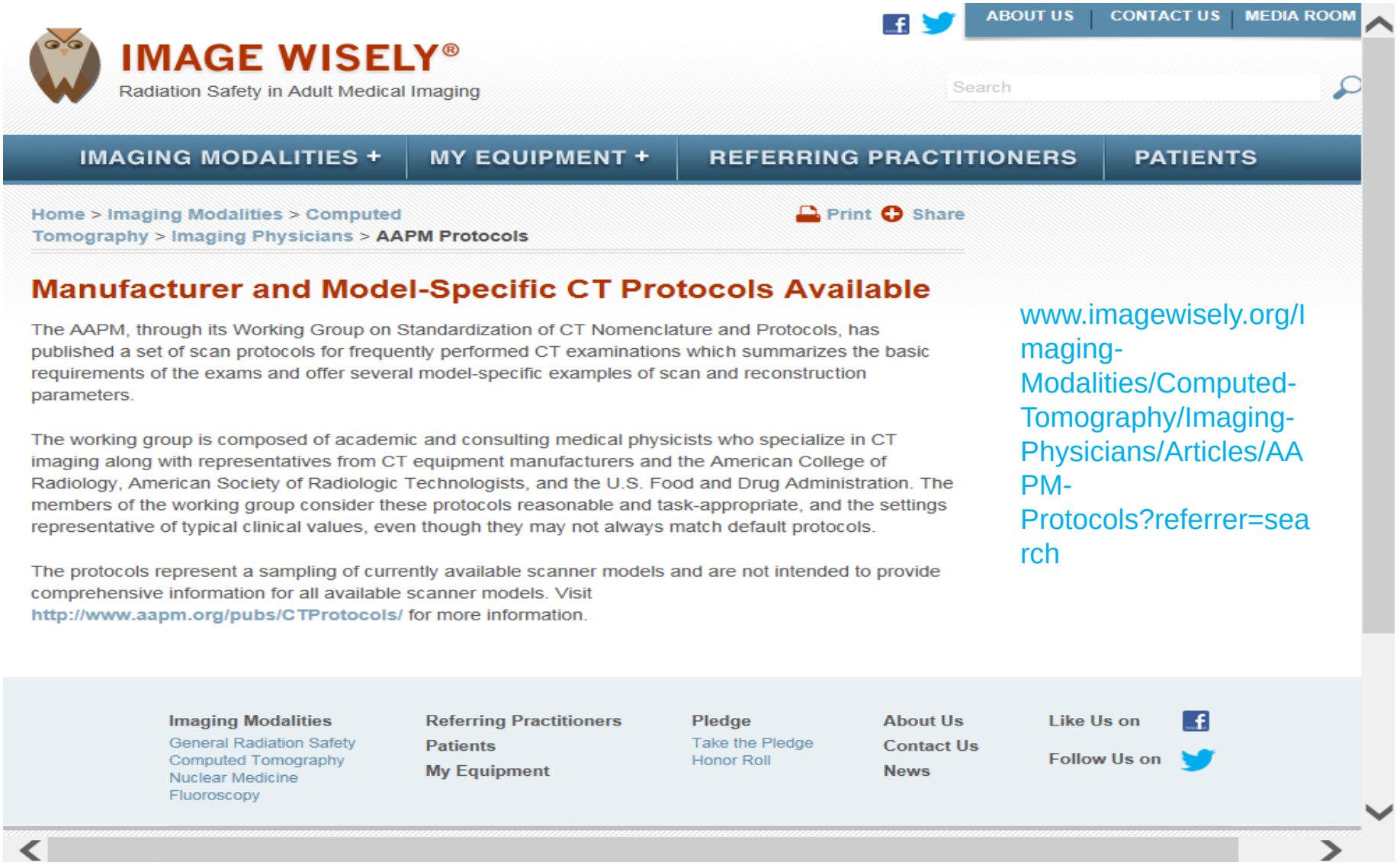
Patient-Friendly Resources from Specialty Societies and Consumer Reports:

- Allergy tests: When you need them and when you don't
- Antibiotics for ear infections in children: when you need them...
- Antibiotics for pink eye...
- Antibiotics for urinary tract infections in older people
- Antibiotics for your skin: When you need them...
- Antibiotics: When you need them...
- Antibiotics: When children need them for respiratory illness
- Bone-density tests: When you need them...
- Breast Biopsy - Know your options
- Breast cancer treatment - A better way to check the lymph nodes.
- Cancer care at the end of life: When to stop cancer treatment
- Carotid artery surgery: When you need it...
- Chest X-rays before surgery: When you need them...
- Cholesterol drugs for people 75 and older: When you need them...
- Choosing pain relievers with kidney disease/heart problems
- Chronic kidney disease: Making hard choices
- Colonoscopy: When you need it...
- CT scans for children with head Injuries: When they need them...
- CT scans to find lung cancer in smokers: When you need them...
- Dental fillings that contain mercury: Removing them is a bad idea
- Drugs to boost white blood cells for chemotherapy patients: When you need them...

Image Wisely

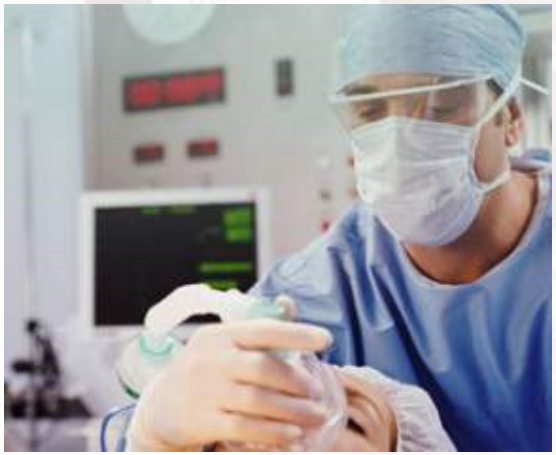


CT Protocols Available



www.imagewisely.org/Imaging-Modalities/Computed-Tomography/Imaging-Physicians/Articles/AAPM-Protocols?referrer=search

Joint Commission Hospital Standards on Protocols, Standing Orders and Order Sets



Joint Commission Standards MM.04.01.01

- No definition of standing order, protocol, or order set in the glossary
- However, MM.04.01.01 EP1 defines standing order
- Standing orders:
  - A pre-written medication order and specific instructions from the licensed independent practitioner (LIP) to administer a medication to a person in clearly defined circumstances

TJC MM.04.01.01 Standing Orders

- Added MM.04.01.01, EP 15, effective September 1, 2012 regarding pre-printed and standing orders
- To bring TJC standards into compliance with CMS changes
- Standard: Medication orders are clear and accurate
- For hospitals that use TJC for deemed status (DS)
- Processes for the use of pre-printed and electronic standing orders, order sets, and protocols for medications orders must include the following:

TJC Standing Orders, Order Sets MM.04.01.01

- The Medical Staff (MS), Nursing and Pharmacy need to review and approve all standing orders and protocols
- The hospital must evaluate standing orders and protocols to ensure they are consistent with nationally recognized and evidence based guidelines
- There must be a regular review of standing orders and protocols by MS, Nursing, and Pharmacy to determine their continued usefulness and safety

TJC Standing Orders, Order Sets MM.04.01.01

- Standing orders and protocols
  - Must be dated and **timed**
  - Must be signed off or authenticated by the ordering practitioner or a practitioner responsible for the patient's care
  - Must be in accordance with professional standards of practice, and law and regulation
  - Must be consistent with hospital policies and procedures and MS bylaws and rules & regulations

MM.02.01.01 Hospital Selects Medications

- **Standard:** The hospital selects and obtains medications
- Recently, hospitals have experienced many problems related to drug shortages and outages
- EP 12 States that's the hospitals develops and approves written medication **substitution protocols** to be use in the event of a medication shortage or outage
- EP 13 States hospital must implement its approved **medication substitution protocols**

MM.02.01.01 Medication Substitution Protocol

- EP14 Hospital needs to have a process to communicate to the physicians and LIPs and staff about the **medication substitute protocol** for shortages and outages
- EP 15 Hospital implements its process to communicate to all of the above who participate in medication management about the **medication substitution protocols** for shortages and outages
- Hospitals can sign up to get email updates on drug shortages and outages from the FDA
- ASHP also has good resources on the same

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Drugs

www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

Home › Drugs › Drug Safety and Availability › Drug Shortages

Drug Safety and Availability

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- Current Drug Shortages Index
- Current Drug Shortages A - D
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- Current Drug Shortages O - R
- Current Drug Shortages S - Z
- Resolved Drug Shortages
- Drugs to be Discontinued
- How to Report a Shortage or Supply Issue
- Frequently Asked Questions About Drug Shortages

Drug Shortages

FDA takes great efforts, within its legal authority, to address and prevent drug shortages, which can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. The agency works closely with manufacturers of drugs in short supply to communicate the issue and to help restore availability. FDA also works with other firms who manufacturer the same drug, asking them to increase production, if possible, in order to prevent or reduce the impact of a shortage.

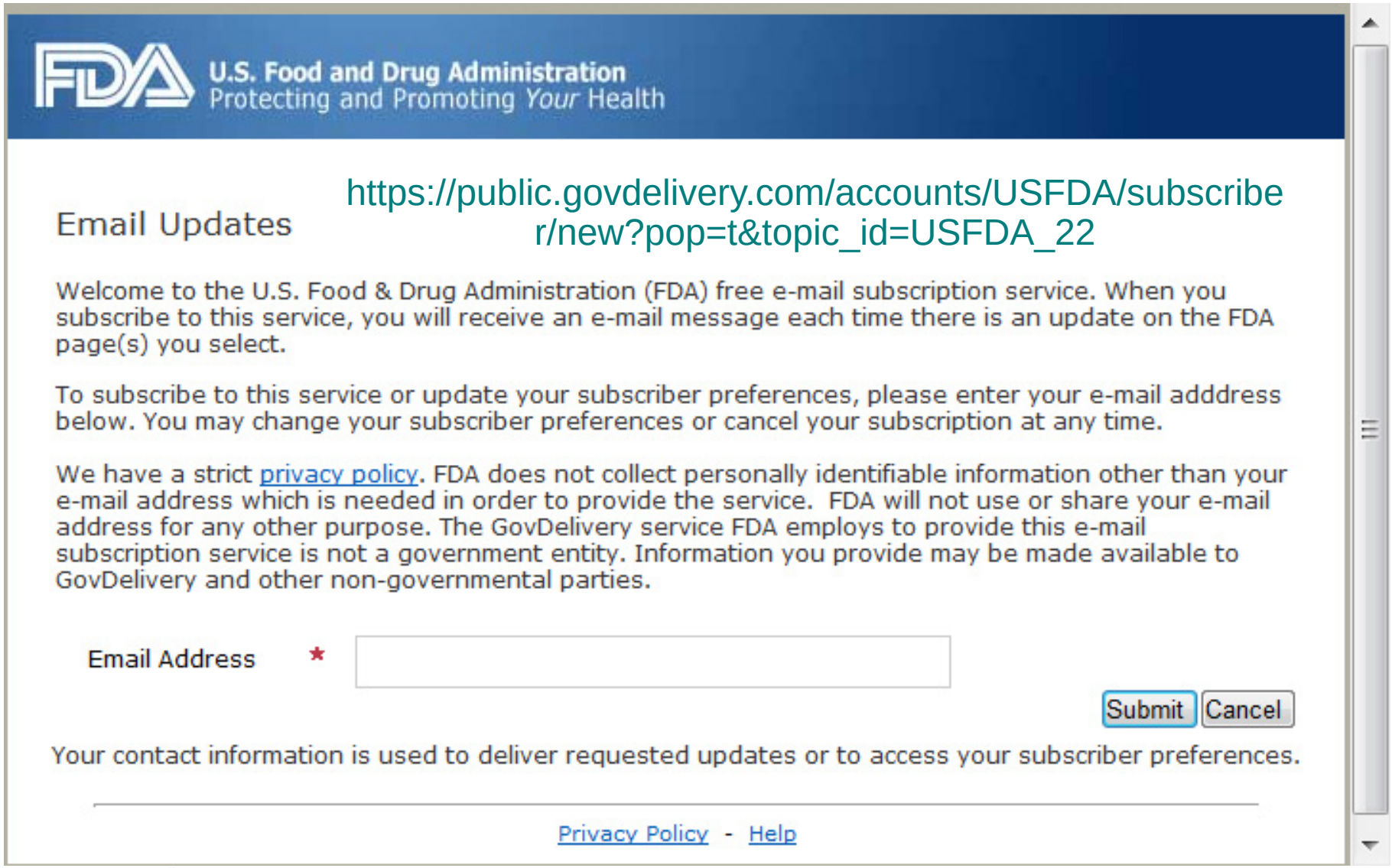
Manufacturers are not required to report information, such as reasons for shortages or the expected duration of shortages. However, many companies voluntarily provide shortage information that FDA posts on its website. FDA encourages and appreciates all reporting of shortages by manufacturers. Shortage notifications and updates may be reported to FDA at drugshortages@fda.hhs.gov.

Drug Shortages Information

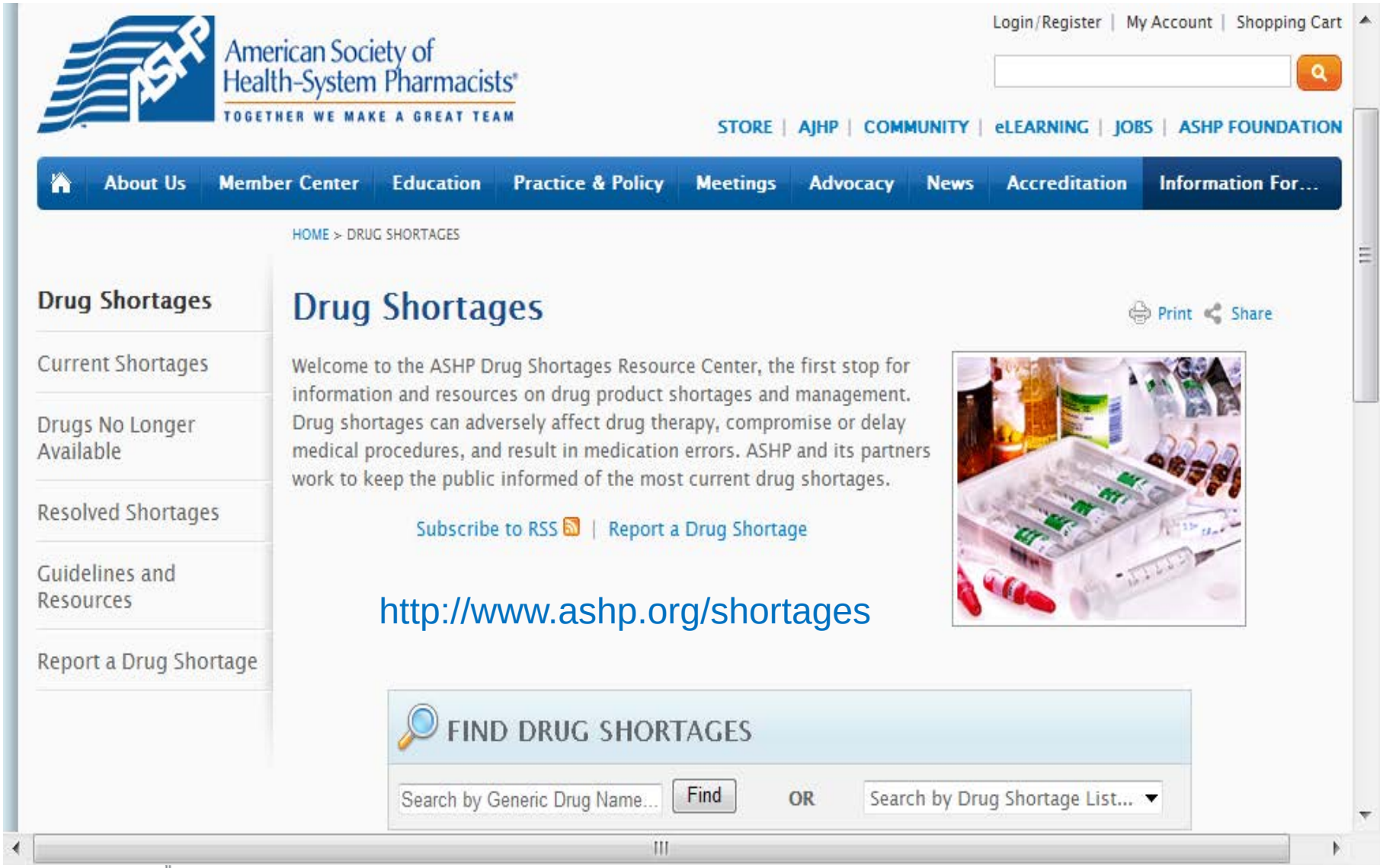
Spotlight

- 2012-2013 Influenza Season: Availability of Antivirals
- Meningitis Outbreak: Voriconazole and Liposomal Amphotericin B Availability Information
- Fact Sheet: Drug Products in Shortage in the United States
- FDA Report: A Review of FDA's Approach to Medical Product Shortages
- Statement from FDA and HHS on Drug Shortages

Email Updates on Drug Shortages



ASHP Drug Shortages Resources



ASHP Resources on Managing

ASHP REPORT

ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems

DEVELOPED BY AN ASHP EXPERT PANEL ON DRUG PRODUCT SHORTAGES: ERIN R. FOX, ANNETTE BIRT, KEN B. JAMES, HEATHER KOKKO, SANDRA SALVERSON, AND DONNA L. SOFLIN

Am J Health-Syst Pharm. 2009; 66:1399-406

Purpose

Drug product shortages can adversely affect drug therapy, compromise or delay medical procedures, and result in medication errors.[1,2] Health care professionals are increasingly concerned about the clinical effect that shortages have on patients and the tremendous resources required to address shortages.[3-5] Adverse patient outcomes related to drug product shortages[1,2,6-9] have prompted aggressive management strategies by health care providers and gained the attention of the Joint Commission,[10] the government,[11,12] and the media.[13,14] Drug product shortages adversely affect health-system finances by increasing the cost of delivering patient care, largely through higher drug acquisition and personnel costs.[6] In addition, shortages create a high level of frustration for everyone involved, including purchasing agents, pharmacists, nurses, physicians, and patients.[7]

Managing drug product shortages is particularly complex for practitioners in hospitals and health systems (hereinafter, "health systems"), because these facilities routinely treat patients with acute or emergent conditions, use a significant number of medically necessary or single-source products, and use high-cost new drug technologies. These health care providers are challenged during drug product shortages to ensure the provision of seamless, safe, and therapeutically equivalent drug therapy, preferably at comparable costs. The pharmacy department must take a leadership role in efforts to develop and implement appropriate strategies and processes for inform-

Developed through the ASHP Council on Pharmacy Management and approved by the ASHP Board of Directors on January 15, 2009. These guidelines supersede the ASHP Guidelines on Managing Drug Product Shortages dated March 28, 2001.

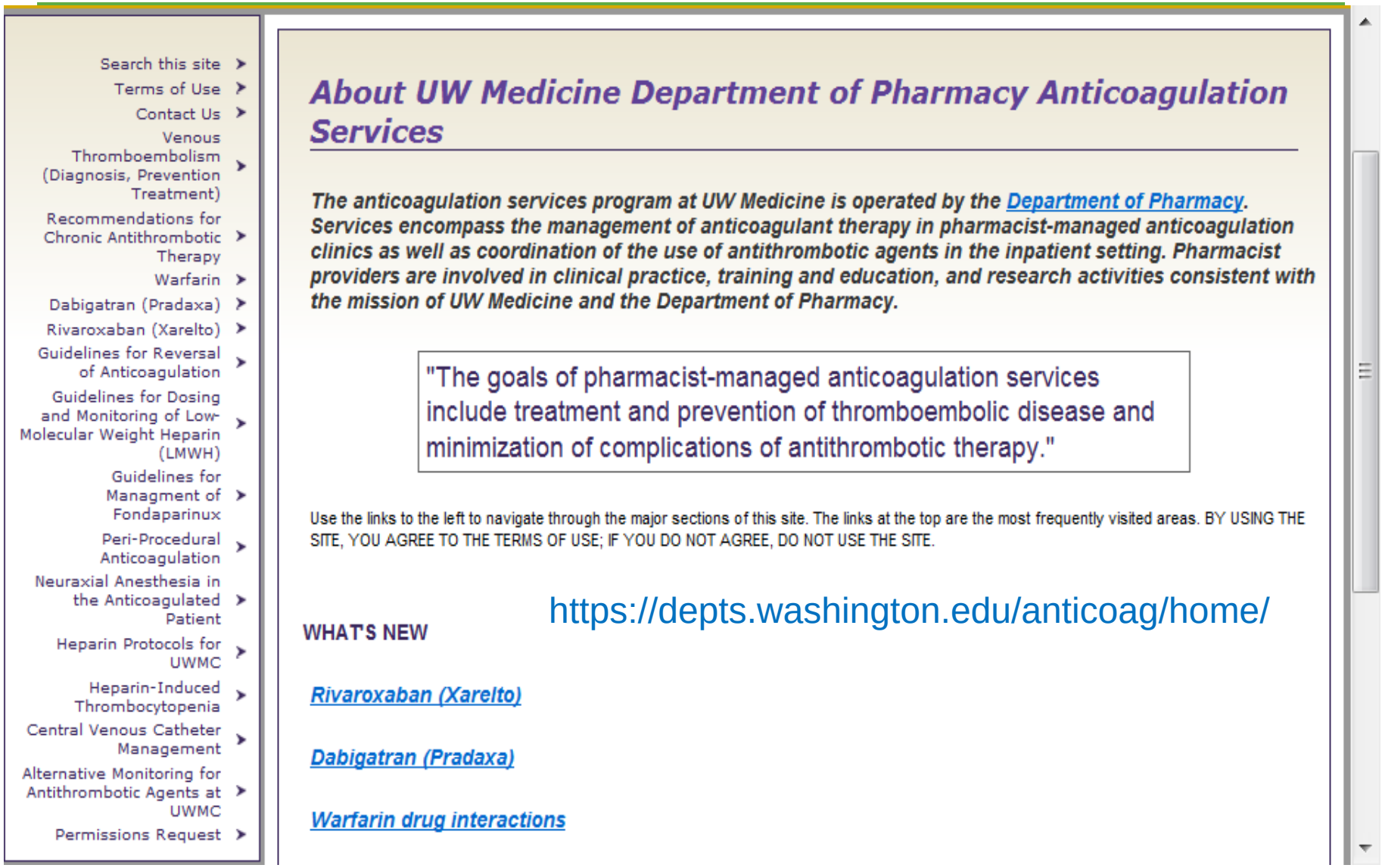
ERIN R. FOX, PHARM.D., is Director, Drug Information Service, University of Utah Hospitals & Clinics, Salt Lake City. ANNETTE BIRT, M.B.A., M.P.H., is Pharmacy Communications Manager, Novation, Irving, TX. KEN B. JAMES, PHARM.D., is Supervisor, Drug Information Services, Kaiser-Permanente Medical Center, Santa Clara, CA. HEATHER KOKKO, PHARM.D., is Manager, Pharmacy Support Services, Department of Pharmacy Services, and Clinical Assistant Professor, Medical University of South Carolina, Charleston, SC. SANDRA SALVERSON, PHARM.D., BCPS, is Drug Information/Infectious Disease

Davis, Pharm.D., FASHP; Rosario (Russ) J. Lazzaro, M.S.; Tom Kaye; Richard I. Sakai, Pharm.D., FASHP, FCSHP; J. G. Barbaccia, Pharm.D., FASHP; Dennis Tribble, Pharm.D.; Daniel Robinson, Pharm.D., FASHP; Phil Johnson, M.S., FASHP; Stephen Eckel, Pharm.D., M.H.A., BCPS; Kathleen M. Gura, Pharm.D., BCNSP, FASHP; Helen M. Calmes, Pharm.D., M.B.A.; Michael Anderson, Pharm.D. (AGA); Sally Brooks, M.D., AGSF (AGA); Shelly Gray, Pharm.D. (AGA); Mary McGuiggan, Pharm.D. (AGA); Peggy Odegard, Pharm.D. (AGA); Randall Rowen, Pharm.D. (AGA); Cathy Starner, Pharm.D. (AGA); Richard Stefanacci, D.O., M.G.H. (AGA); Eric Tangalos, M.D. (AGA); Anne-Marie Evriviades (AGA); Mark N. Brueckl, M.B.A. (AMCP); Kevin J. Colgan, M.A.; John D. Graberstein, Ph.D.; Mike Bruce, R.Pharm (Hons), M.P.S. (ACPR); Natasha Nicol

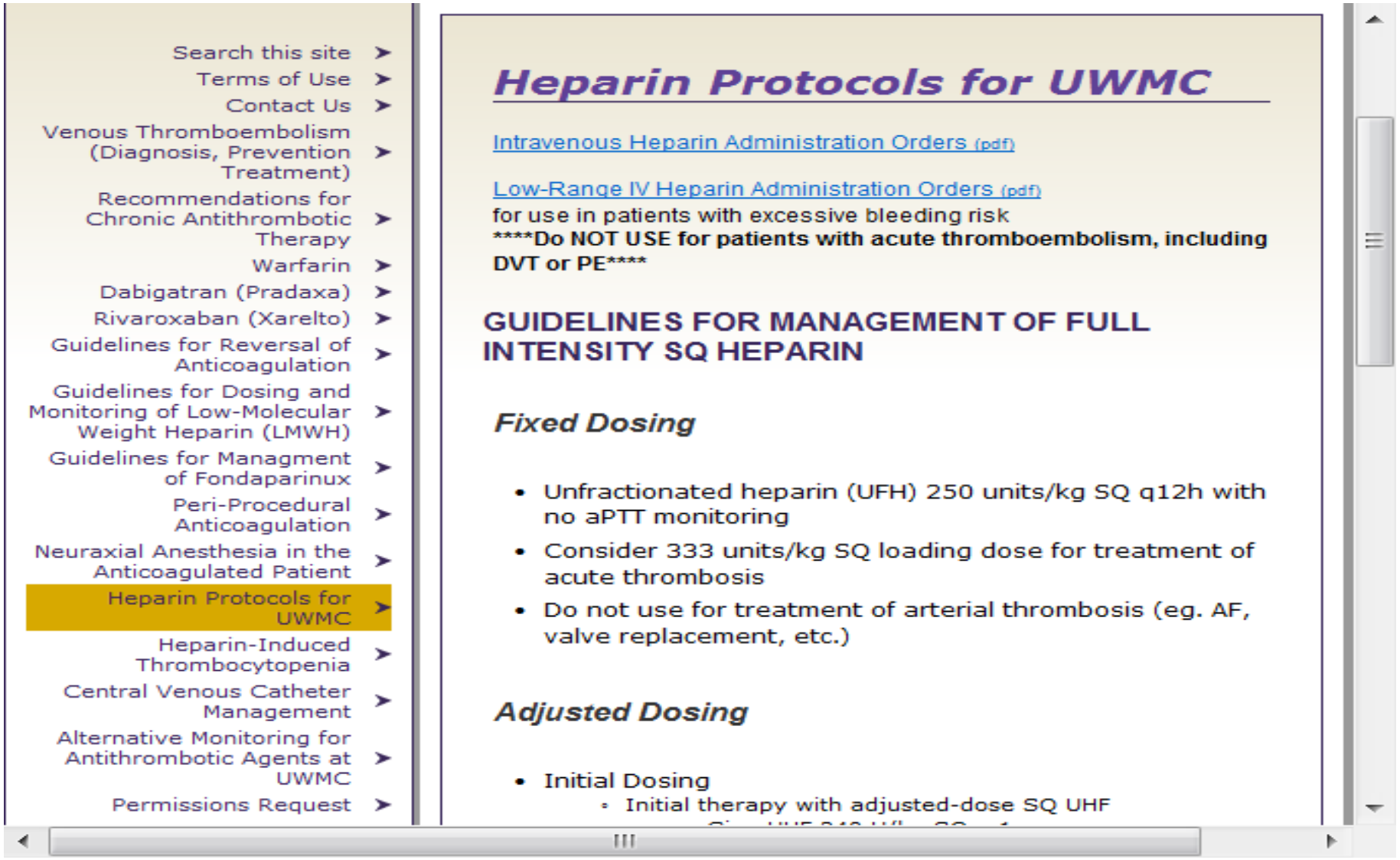
NPSG.03.05.01 Anticoagulant Protocols

- **Standard**: Reduce the likelihood of patient harm associated with anticoagulant therapy
- This standard applies to hospitals that provide anticoagulant therapy or long term prophylaxis for things like atrial fibrillation where it is expected label values will remain outside normal values
- Does not apply to short term use to prevent DVTs
- EP2 Hospitals must use approved **protocols** for the initiation and maintenance of anticoagulant therapy

University of Washington Anticoagulation



Heparin Protocol

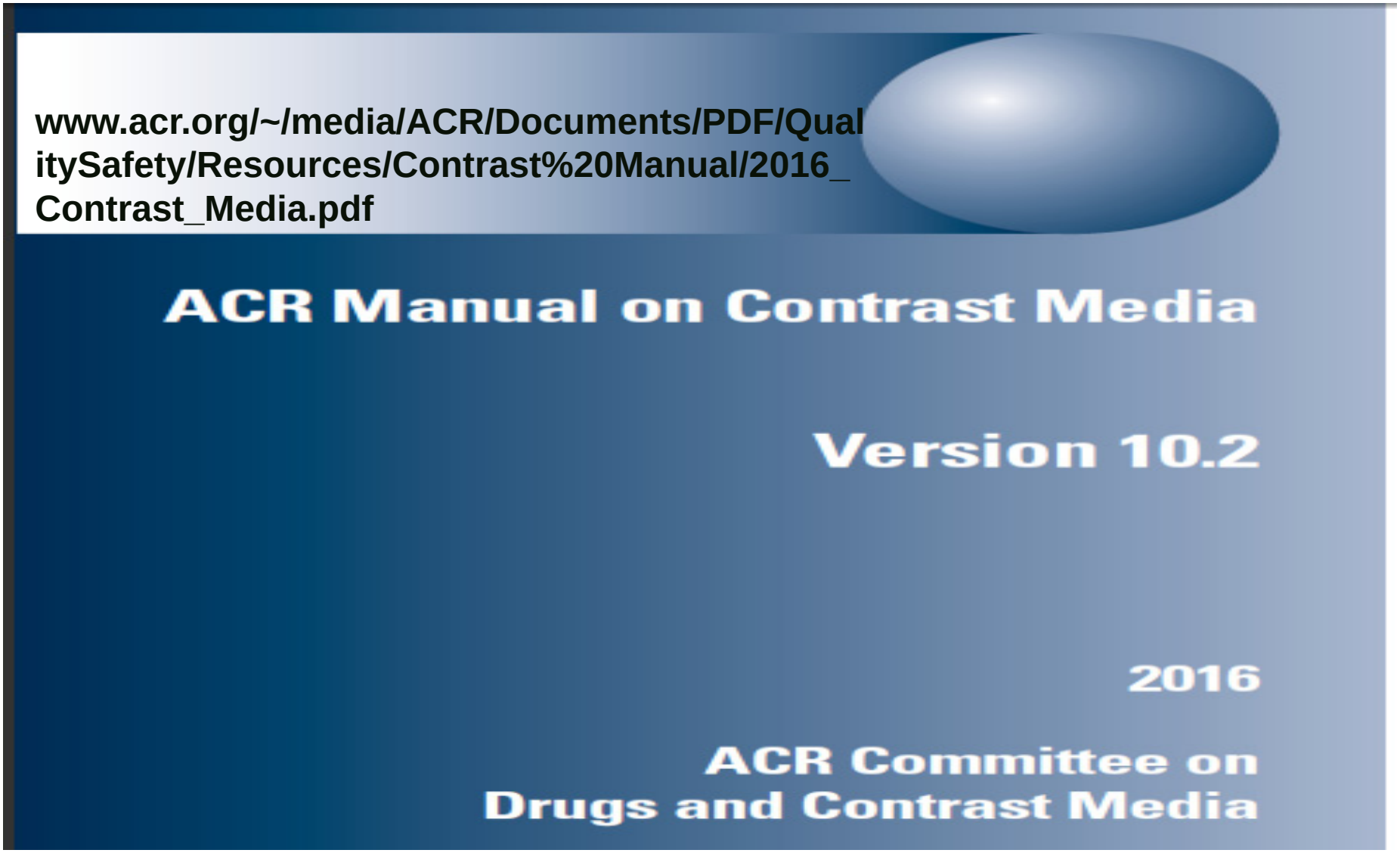


Other Sections Mentioning Protocols

- MM.05.01.01 A pharmacist reviews the appropriateness of all medication orders to be dispensed in the hospital
  - EP1 An exception to the rule is if the medication delay would harm the patient
  - The radiology department is expected to define through a protocol or a policy the role of the LIP in the direct supervision of a patient during and after IV contrast
  - Recommend **policy** and not a protocol for contrast (CMS)
- MM.06.01.05 Must have written process for use of investigational medication that specifies if patient involved in investigational protocol

ACR Contrast Manual

www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources/Contrast%20Manual/2016_Contrast_Media.pdf



Other Sections Mentioning Protocols

- NPSG.07.04.01 Related to central line associated bloodstream infections
  - Need **standardized protocol** and checklist
  - Need **standardized protocol** for sterile barrier precautions
  - Use **standardized protocol** to disinfect catheter hubs and injection ports
- PC.01.02.15 Hospitals in California must make sure dose of CT scan is recorded in the medical record or on the protocol page that lists the radiation dose

CHA Guidelines and Standing Orders

- The California Hospital Association (CHA) has a resource guide that hospitals may find helpful, especially hospitals in California
  - The full name of this document is “CHA Guidelines for Standing Orders, Standardized Procedures and Other Delegation Tools.”
  - It also provides several definitions that may be helpful although some of these definitions are found in California statutes or laws
  - The CHA Order Set Tool is available at http://www.calhospital.org/sites/main/files/file-attachments/final-_cha_final_phys_order_chart_6-1-12.pdf

Standing Orders & Be Aware of Any State Laws

CHA GUIDELINES FOR STANDING ORDERS, STANDARDIZED PROCEDURES AND OTHER DELEGATION TOOLS

This is intended as a tool to provide generalized guidance; please seek advice of counsel when utilizing delegation tools.
**Regulations and laws are constantly changing, the following summary is based on today's regulations.*

	What are they and who do they apply to?	What can or can't they be used for?	Special conditions for Medicare/Medi-Cal:
Standing Orders	• **Standing orders** are written orders used in the absence of a specific order for a specific patient provided by a licensed health care practitioner acting within the scope of his or her professional licensure.[1] • Standing orders are conditioned upon the occurrence of certain clinical events, initiated by the treating health care practitioner. All patients who meet the criteria for the order receive the same treatment. Once the triggering event is identified, an allied health professional (A.H.P) or licensed independent practitioner (L.I.P) may initiate treatment pursuant to a standing order.[2] • Standing orders can be used by a physician to authorize a nurse practitioner ("NP"),[3] or physician assistant ("PA")[4] to provide specified services. • Use of standing orders for medical assistants are limited and subject to specific rules and settings.[5] For example, a standing order is one of two ways to meet the statutory requirement for medical	• *Note: While the statutes and regulations described below deal almost exclusively with the use of standing orders in the context of administering drugs to patients, standing orders have a much broader application than just drug administration.* Final rules at 42 CFR §482.24 allow hospitals flexibility to use standing orders. Added requirement for medical staff, nursing, and pharmacy to approve written and electronic standing orders, orders sets and protocols. Orders and protocols must be based on nationally recognized and evidence-based guidelines and recommendations.[6] • In a hospital, standing orders for drugs may be used for specified patients when authorized by a person licensed to prescribe. A copy of the standing orders for a specific patient must be dated, timed, promptly signed by the prescriber, and included in the patient's medical record. Such standing orders shall	• Services billed to Medi-Cal that are the result of routine or standing orders for admission to a hospital are not reimbursable when applied indiscriminately to all patients. All patient orders, including standing orders for particular types of cases, must be specific to the patient and must represent necessary medical care for the diagnosis or treatment of a particular condition.[7] • While historically CMS has generally frowned on the use of standing orders, CMS recently proposed a rule that would allow hospitals to use standing orders under certain circumstances.[8]

CHA GUIDELINES FOR STANDING ORDERS, STANDARDIZED PROCEDURES AND OTHER DELEGATION TOOLS

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**Regulations and laws are constantly changing, the following summary is based on today's regulations.*

	What are they and who do they apply to?	What can or can't they be used for?	Special conditions for Medicare/Medi-Cal:
Standardized Procedures	Standardized procedures can be used by RNs, nurse-midwives, or NPs,[14] and mean <u>either</u> of the following: (1) Policies and protocols developed by a health facility licensed pursuant to Chapter 2 (commencing with § 1250) of Division 2 of the Health and Safety Code through collaboration among administrators and health professionals including **physicians** and nurses (e.g., an interdisciplinary committee). (2) Policies and protocols developed through collaboration among administrators and health professionals, including **physicians** and nurses, by an organized health care system which is not a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code. The policies and protocols shall be subject to any guidelines jointly promulgated by the Medical Board of California and the Board of Registered Nursing.[15]	• *Note: While many of the statutes and regulations described below deal exclusively with the use of standardized procedures in the context of administering drugs to patients, we believe that standardized procedures have a much broader application than just drug administration.*[16] • Standardized procedures may be used to legally allow RNs and NPs to perform some functions that would otherwise be considered the practice of medicine.[17] • The administration of dimethyl sulfoxide may be performed pursuant to standardized procedures developed by an organized health care system through collaboration among administrators and health professionals.[18] • A certified nurse-midwife or a NP following standardized procedures may dispense substances included in the California Uniform Controlled Substances	• Under both the Medi-Cal and Medicare programs, standing orders <u>cannot</u> be used to authorize the restraint of a patient, including when using drugs that meet the definition of a restraint.[20]

	What are they and who do they apply to?	What can or can't they be used for?	Special conditions for Medicare/Medi-Cal:
Protocols	(7) Specify the scope of supervision required for performance of standardized procedure functions, for example, immediate supervision by a **physician**. (8) Set forth any specialized circumstances under which the RN is to immediately communicate with a patient's **physician** concerning the patient's condition. (9) State the limitations on settings, if any, in which standardized procedure functions may be performed. (10) Specify patient record keeping requirements. (11) Provide for a method of periodic review of the Standardized procedures.[27] • Protocols typically apply to PAs, but may also apply to nurse mid-wives, NPs,[28] or polysomnographic technologists.[29] • With regard to PAs, a PA and his or her supervising physician shall establish written guidelines for the adequate supervision of the PA. This requirement may be satisfied by the supervising physician and surgeon adopting protocols for some or all of the tasks performed by the PA. The PA protocols shall comply with the following requirements:	• Note: While many of the statutes and regulations described below deal exclusively with the use of protocols in the context of administering drugs to patients, we believe that protocols have a much broader application than just drug administration.[30] • A certified nurse-midwife or a NP following protocol may dispense substances included in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).[31] • Protocols for Schedule II controlled substances shall address the diagnosis of illness, injury, or condition for which the Schedule II controlled substance is being administered, provided, or issued. The drugs listed in the protocols shall constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon.[32]	• Under the Medi-Cal program, a single physician is limited to supervising four PAs (full-time equivalents). The supervising physician and surgeon shall review, countersign and date a sample consisting of, at minimum, five percent of the medical records of patients treated by the PA functioning under the protocols within 30 days of the date of treatment by the PA.[33] • CMS suggests that a hospital's anesthesia services policy should include protocols for supportive life functions, e.g., cardiac and respiratory emergencies.[34] • CMS suggests that hospitals develop substitution protocols to address medication shortages.[35]

NY State Hospital Sepsis Protocol

www.health.ny.gov/regulations/recently_adopted/docs/2013-05-01_hospital_sepsis_protocols.pdf

Hospital Sepsis Protocols

Effective date: 5/1/13

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 2800 and 2803 of the Public Health Law, Sections 405.2 and 405.4 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraphs (6) and (7) of subdivision (f) of section 405.2 are amended and a new paragraph (8)

Protocols for Suicidal Patients in Office

Protocol for Suicidal Patients - Office Template

Post in a visible or accessible place for key office staff.

If a patient presents with suicidal ideation or suicidal ideation is suspected and detected with screening questions ...

✓ _____ should be called/paged to assist with suicide risk assessment (e.g., physician, mental health professional, telemedicine consult etc.).

✓ Identify and call emergency support person in the community (e.g., family member, pastor, mental health provider, other support person).

If a patient requires hospitalization ...

✓ Our nearest Emergency Department or psychiatric emergency center is _____ _____. Phone # _____.

www.sprc.org/sites/sprc.org/files/OfficeProtocolDevelopmentGuide.pdf

WHO Best Practice Protocols

World Health Organization

Best Practice Protocols
Clinical Procedures Safety

List of Contents

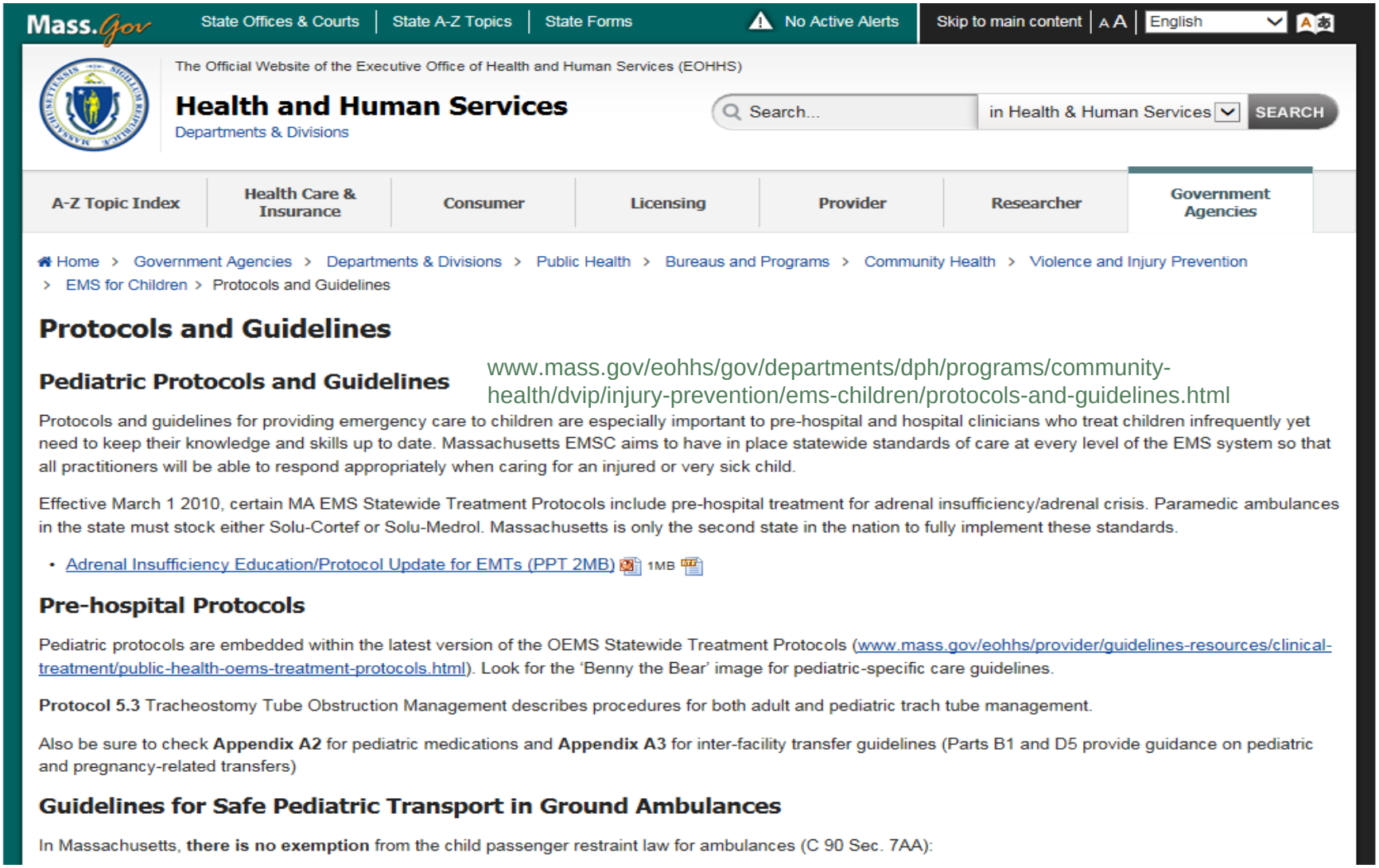
1. Ethics- Patient Consent
2. Record keeping
3. Operating Room (O.R.)
4. Hand Washing Techniques
5. Scrubbing and gowning
6. Prevention of Transmission of HIV
7. Infection Prevention and Universal Precautions
8. Waste disposal in clinical procedures at resource limited health care facility
9. Diagnosis of Labour
10. Diagnosis of vaginal bleeding in early pregnancy
11. Severe Pre-Eclampsia and Eclampsia
12. Eclampsia Management
13. Urinary Retention: Emergency Drainage
14. Caesarean Section
15. Check List Prior to inducing anaesthesia
16. Managing unexpected effects of a spinal anaesthetic
17. Postoperative management
18. Postoperative pain relief

www.who.int/surgery/publications/BestPracticeProtocolsCPSafety07.pdf

15. Check List Prior to inducing anaesthesia
16. Managing unexpected effects of a spinal anaesthetic
17. Postoperative management
18. Postoperative pain relief
19. Cardiac life support
20. Airway Management
21. Surgical Cricothyroidotomy
22. Cast Application
23. Splint application
24. Caring for a cast or splint
25. Removing a cast
26. Hand lacerations
27. Disaster Planning
28. Trauma Team Leader Responsibilities
29. Abdominal Trauma
30. Burns Management: adults and children
31. War-related Trauma
32. Transportation of critically ill patients

Clinical Procedures Unit
Department of Essential Health Technologies
World Health Organization,
20 Avenue Appia, 1211, Geneva 27, Switzerland
Fax: 41 22 791 4836
Internet: www.who.int/surgery

Mass State Pediatric Protocols



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Home > Government Agencies > Departments & Divisions > Public Health > Bureaus and Programs > Community Health > Violence and Injury Prevention > EMS for Children > Protocols and Guidelines

Protocols and Guidelines

Pediatric Protocols and Guidelines

www.mass.gov/eohhs/gov/departments/dph/programs/community-health/dvip/injury-prevention/ems-children/protocols-and-guidelines.html

Protocols and guidelines for providing emergency care to children are especially important to pre-hospital and hospital clinicians who treat children infrequently yet need to keep their knowledge and skills up to date. Massachusetts EMSC aims to have in place statewide standards of care at every level of the EMS system so that all practitioners will be able to respond appropriately when caring for an injured or very sick child.

Effective March 1 2010, certain MA EMS Statewide Treatment Protocols include pre-hospital treatment for adrenal insufficiency/adrenal crisis. Paramedic ambulances in the state must stock either Solu-Cortef or Solu-Medrol. Massachusetts is only the second state in the nation to fully implement these standards.

- Adrenal Insufficiency Education/Protocol Update for EMTs (PPT 2MB) 1MB

Pre-hospital Protocols

Pediatric protocols are embedded within the latest version of the OEMS Statewide Treatment Protocols (www.mass.gov/eohhs/provider/guidelines-resources/clinical-treatment/public-health-oems-treatment-protocols.html). Look for the 'Benny the Bear' image for pediatric-specific care guidelines.

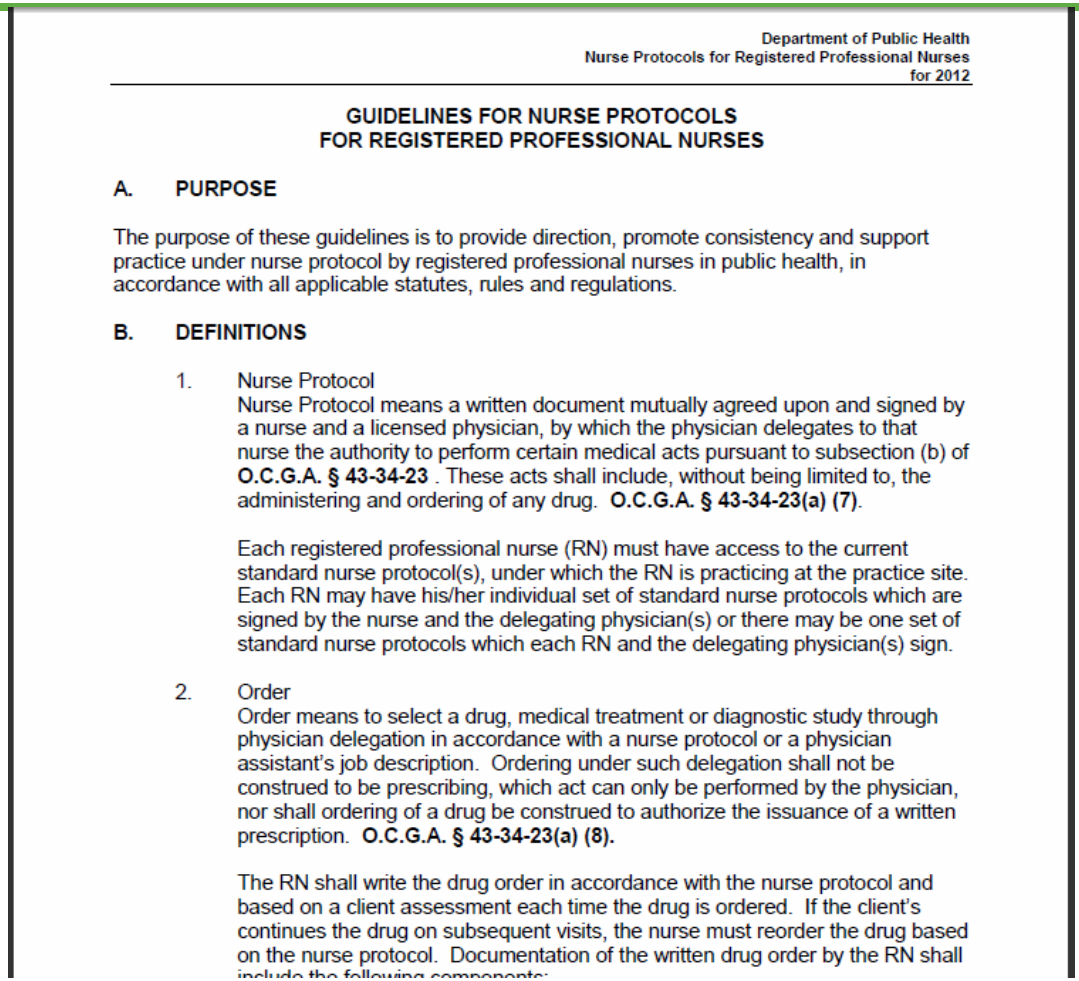
Protocol 5.3 Tracheostomy Tube Obstruction Management describes procedures for both adult and pediatric trach tube management.

Also be sure to check **Appendix A2** for pediatric medications and **Appendix A3** for inter-facility transfer guidelines (Parts B1 and D5 provide guidance on pediatric and pregnancy-related transfers)

Guidelines for Safe Pediatric Transport in Ground Ambulances

In Massachusetts, **there is no exemption** from the child passenger restraint law for ambulances (C 90 Sec. 7AA):

Georgia Has Guidelines for Protocols



Department of Public Health
Nurse Protocols for Registered Professional Nurses
for 2012

GUIDELINES FOR NURSE PROTOCOLS
FOR REGISTERED PROFESSIONAL NURSES

A. PURPOSE

The purpose of these guidelines is to provide direction, promote consistency and support practice under nurse protocol by registered professional nurses in public health, in accordance with all applicable statutes, rules and regulations.

B. DEFINITIONS

1. Nurse Protocol
Nurse Protocol means a written document mutually agreed upon and signed by a nurse and a licensed physician, by which the physician delegates to that nurse the authority to perform certain medical acts pursuant to subsection (b) of **O.C.G.A. § 43-34-23** . These acts shall include, without being limited to, the administering and ordering of any drug. **O.C.G.A. § 43-34-23(a) (7)**.

Each registered professional nurse (RN) must have access to the current standard nurse protocol(s), under which the RN is practicing at the practice site. Each RN may have his/her individual set of standard nurse protocols which are signed by the nurse and the delegating physician(s) or there may be one set of standard nurse protocols which each RN and the delegating physician(s) sign.

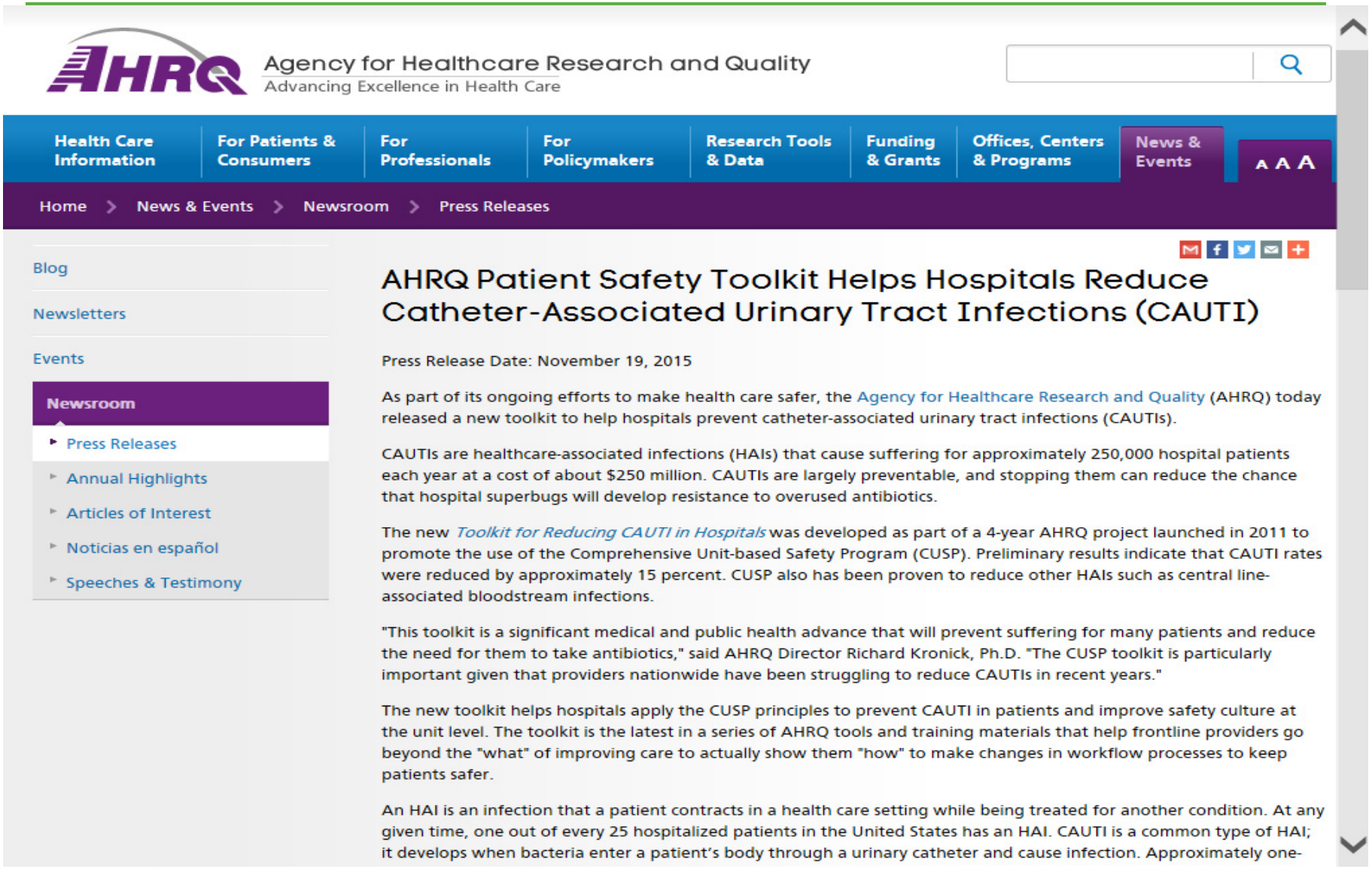
2. Order
Order means to select a drug, medical treatment or diagnostic study through physician delegation in accordance with a nurse protocol or a physician assistant's job description. Ordering under such delegation shall not be construed to be prescribing, which act can only be performed by the physician, nor shall ordering of a drug be construed to authorize the issuance of a written prescription. **O.C.G.A. § 43-34-23(a) (8).**

The RN shall write the drug order in accordance with the nurse protocol and based on a client assessment each time the drug is ordered. If the client's continues the drug on subsequent visits, the nurse must reorder the drug based on the nurse protocol. Documentation of the written drug order by the RN shall include the following components:

http://dph.georgia.gov/sites/dph.georgia.gov/files/related_files/site_page/Guidelines%20for%20Nurse%20Protocols.pdf

Protocols to Prevent DVTs

CaUTI Protocols



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AHRQ Patient Safety Toolkit Helps Hospitals Reduce Catheter-Associated Urinary Tract Infections (CAUTI)

Press Release Date: November 19, 2015

As part of its ongoing efforts to make health care safer, the Agency for Healthcare Research and Quality (AHRQ) today released a new toolkit to help hospitals prevent catheter-associated urinary tract infections (CAUTIs).

CAUTIs are healthcare-associated infections (HAIs) that cause suffering for approximately 250,000 hospital patients each year at a cost of about $250 million. CAUTIs are largely preventable, and stopping them can reduce the chance that hospital superbugs will develop resistance to overused antibiotics.

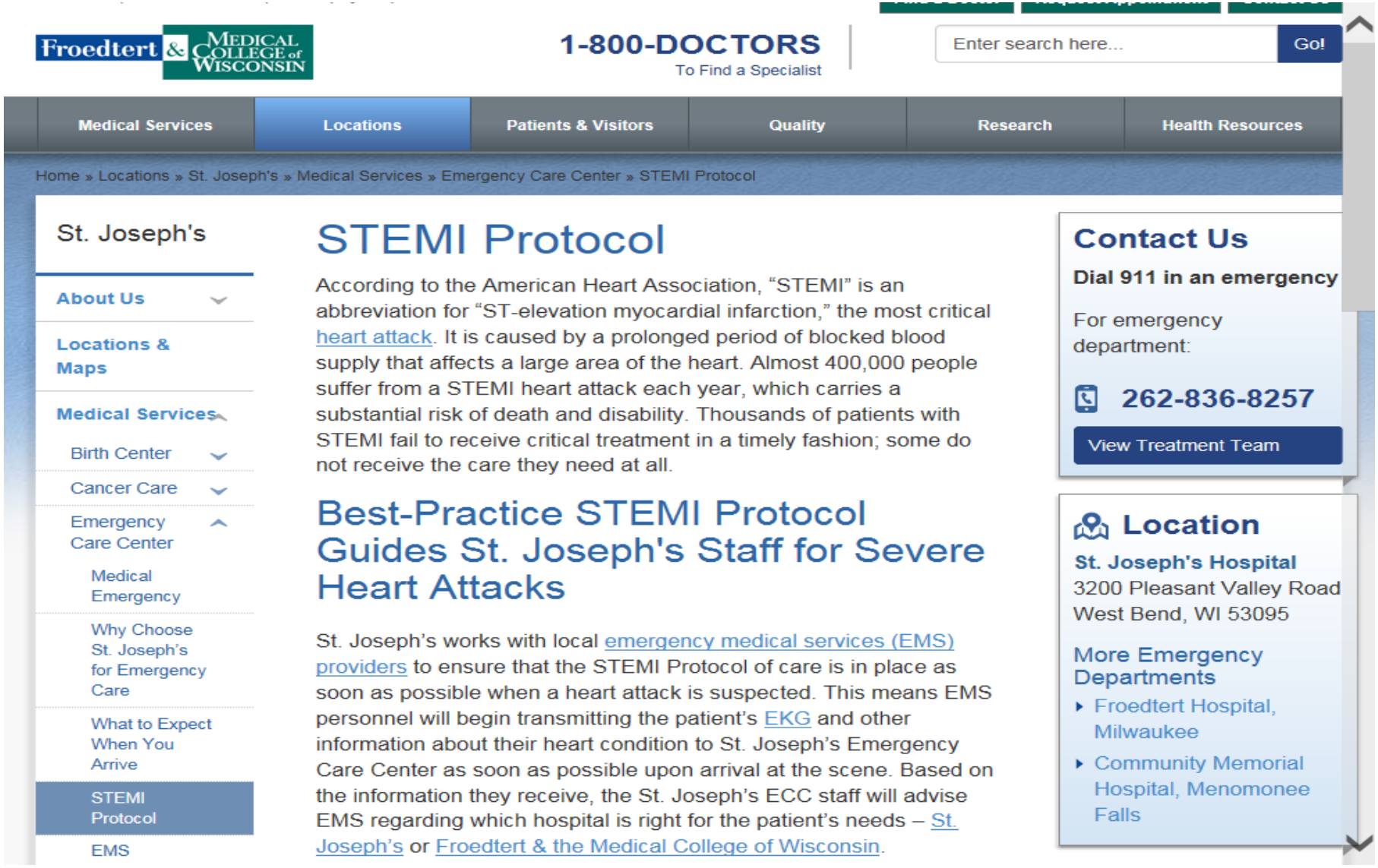
The new *Toolkit for Reducing CAUTI in Hospitals* was developed as part of a 4-year AHRQ project launched in 2011 to promote the use of the Comprehensive Unit-based Safety Program (CUSP). Preliminary results indicate that CAUTI rates were reduced by approximately 15 percent. CUSP also has been proven to reduce other HAIs such as central line-associated bloodstream infections.

"This toolkit is a significant medical and public health advance that will prevent suffering for many patients and reduce the need for them to take antibiotics," said AHRQ Director Richard Kronick, Ph.D. "The CUSP toolkit is particularly important given that providers nationwide have been struggling to reduce CAUTIs in recent years."

The new toolkit helps hospitals apply the CUSP principles to prevent CAUTI in patients and improve safety culture at the unit level. The toolkit is the latest in a series of AHRQ tools and training materials that help frontline providers go beyond the "what" of improving care to actually show them "how" to make changes in workflow processes to keep patients safer.

An HAI is an infection that a patient contracts in a health care setting while being treated for another condition. At any given time, one out of every 25 hospitalized patients in the United States has an HAI. CAUTI is a common type of HAI; it develops when bacteria enter a patient's body through a urinary catheter and cause infection. Approximately one-

STEMI Protocol is a Common One



TKA Is a Common Protocol

BRIGHAM AND WOMEN'S HOSPITAL
A Teaching Affiliate of Harvard Medical School
75 Francis St., Boston, Massachusetts 02115

Department of Rehabilitation Services

www.brighamandwomens.org/Patients_Visitors/pcs/rehabilitationservices/Physical%20Therapy%20Standards%20of%20Care%20and%20Protocols/Knee%20-%20TKR%20protocol.pdf

Total Knee Arthroplasty Protocol:

The intent of this physical therapy protocol is to provide the clinician with a guideline of the post-operative rehabilitation course of a patient who has undergone a total knee arthroplasty (TKA) at Brigham and Women's Hospital (BWH). It is by no means intended to be a substitute for one's clinical decision making regarding the progression of a patient's post-operative course based on their physical exam/findings, individual progress, and/or the presence of post-operative complications. If a clinician requires assistance in the progression of a post-operative patient, the clinician should consult with the referring surgeon.

This physical therapy protocol applies to primary total knee arthroplasty. In a revision total knee arthroplasty, or in cases where there is more connective tissue involvement, Phase I and II should be progressed with more caution to ensure adequate healing.

Progression to the next phase is based on Clinical Criteria and/or Time Frames as appropriate.

Pain Management
Adequate pain control after TKA is important in expediting patient progress with mobility and range of motion after surgery. This in turn may result in a shorter hospital stay and improved patient satisfaction.

Pain management following TKA at Brigham and Women's Hospital (BWH) is multimodal and may include:

- *Pre-operative dose of medications* including Acetaminophen and/or Celebrex.

The End! Questions???

- Sue Dill Calloway RN Esq.
  CPHRM, CCMSCP, AD, BA, BSN, MSN, JD
- President Patient Safety and Healthcare Consulting
- 5447 Fawnbrook Lane
  Dublin, Ohio 43017
- 614 791-1468
  (Call with questions, no emails)
- sdill1@columbus.rr.com
- Email questions to CMS at hospitalscg@cms.hhs.gov

THANK YOU

RELIAS | LEARNING

Additional Resources

Resources

- July 16, 2012 section, in the Federal Register, Vol. 77, No. 95, Page 29034,on standing orders, order sets, and protocols is published at www.federalregister.gov/articles/2012/05/16
- CMS Survey Memo, October 24, 2008, “Standing Orders in Hospitals” Revisions to S&C Memoranda, at www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

Resources

- See also www.guidelines.org
- See tag number 405, 407, and 450 in the CMS Hospital CoP, Appendix A, which is located at www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf
- Institute for Clinical Systems Improvement (ICSI) website has order sets and guidelines at https://www.icsi.org/
  - Has updated monthly list of guidelines, orders sets, protocols etc.

Resources

- Promoting Best Practice and Safety Through Preprinted Orders at www.ahrq.gov/downloads/pub/advances2/vol2/Advances-Ehringer_17.pdf
- ISMP Standard Order Sets at www.ismp.org/newsletters/acutecare/articles/20100311.asp
- Preprinted Order Sets as a Safety Intervention in Pediatric Sedation, J Pediatrics 2009, June:154(6):865-8 at http://www.ncbi.nlm.nih.gov/pubmed/19181332