AHC Media

CMS CoPs
PART 3

Tuesday, April 21st, 2015

Speaker

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Objectives

- Discuss the many pharmacy policies required by government bodies.
- Explain why care plans and protocols must be maintained in the medical record.
- Verify why hospitals must have approved policies and related staff education in place.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

Hospital CoPs for QI

- CMS issued new hospital COPs for QA and Performance Improvement in 2014
- CMS issues Memo March 15, 2013 on AHRQ Common Formats
  - Hospitals are required to track adverse events for PI
- Starts with tag number 0263
- Short section because the hospital compare program is not part of the CMS CoP
  - Hospital compare is the indicators that must be sent to CMS to receive full reimbursement rates

Adverse Event Reporting

- Hospitals are required to track AE
- Several reports show that nurses and others were not reporting adverse events and not getting into the PI system
- OIG recommends using the AHRQ common formats to help with the tracking
- States could help hospitals improve the reporting process
- Encouraged all surveyors to develop an understanding of this tool

Report Adverse Events to PI

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: 13-19-HOSPITALS

DATE: **March 15, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: AHRQ Common Formats - Information for Hospitals and State Survey Agencies (SAs) - Comprehensive Patient Safety Reporting Using AHRQ Common Formats

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

Memorandum Summary

Hospitals are Required to Track Adverse Events: The Condition of Participation (CoP) for Quality Assessment and Performance Improvement (QAPI) at 42 CFR 482.21(a)(2) requires hospitals to track adverse patient events. However, several recent reports completed by the Department of Health and Human Services Office of the Inspector General (OIG) indicated that hospitals fail to identify most adverse events.

Use of the Common Formats May Help Hospitals Improve Tracking. The OIG suggested staff failure to understand what events need to be reported to the hospital's QAPI program contributes to the problems with internal tracking systems. The OIG recommended that the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS) could help hospitals improve their ability to track adverse patient safety events by disseminating information on AHRQ's Common Formats. The Common Formats define a systematic process for reporting adverse events, near misses, and unsafe conditions, and allow a hospital to report harm from all causes. Hospital use of the AHRQ Common Formats is voluntary, but a hospital that uses them and is adept at the analysis that they permit will be in a better position

PSO Privacy Protection Center

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Welcome to the PSO Privacy Protection Center

The Patient Safety Organization Privacy Protection Center (PSOPPC) was created by the Agency for Healthcare Research and Quality (AHRQ) to support the implementation of the Patient Safety and Quality Improvement Act (PL-109-41), passed by the United States Congress in July, 2005. The PPC provides technical assistance to PSOs by ensuring patient safety event data is nonidentifiable for data submission and reporting to the NPSD, and provides technical assistance on use of Common Formats. Read more about the PPC.

hwww.psoppc.org/web/patient safety

Common Formats

General Information

» About AHRQ Common Formats

Active for Reporting

Hospital Common Formats - v1.2

» Event Descriptions, Sample Reports, Forms and Users Guide
» Technical Specifications

Hospital Common Formats - v1.1

» Event Descriptions, Sample Reports, Forms and Users Guide
» Technical Specifications

Open for Public Review/Comment

Readmissions Common Format - v0.1 Beta

» Event Description, Sample Report, Form and Users Guide

Skilled Nursing Facility Common Formats - v0.1 Beta

» Event Descriptions, Sample Reports, Forms and Users Guide

PSOPPC Services

Services Available to PSOs

» Patient Safety Resources
» PSO Resource List
» PPC Connect

Common Formats Support

» Frequently Asked Questions
» Release Schedule

Submitting Data

» PSO Data Submission to the PSOPPC

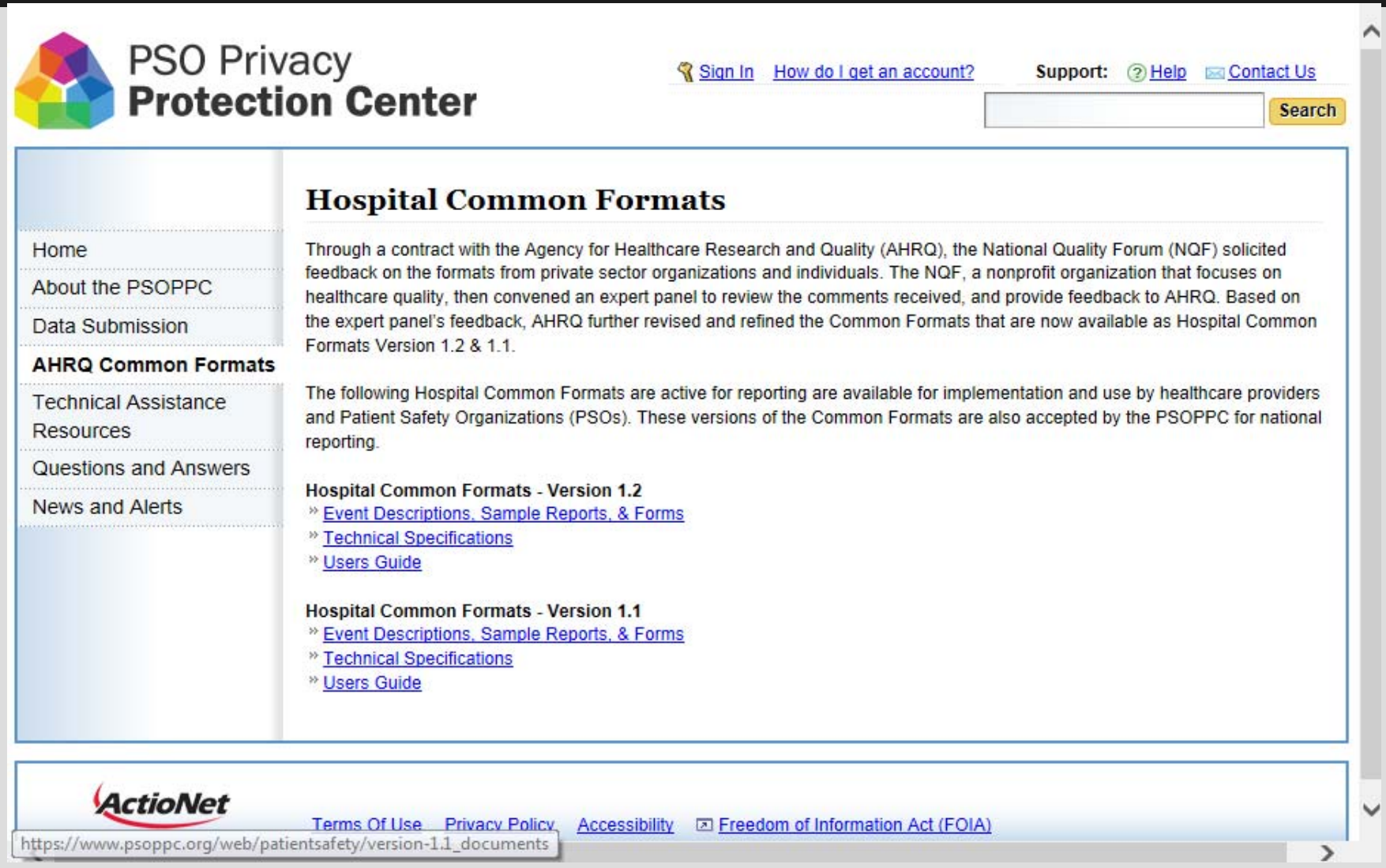
Spotlight

» New PPC Connect: Hospital Common Formats 09/18/12

» Hospital Common Formats Version 1.2 Now Available 04/03/2012

» To provide feedback on the Common Formats, go to the: National Quality Forum (NQF).

Hospital Common Formats



9 Modules in the Common Formats

1. Blood or Blood Product
2. Device or Medical/Surgical Supply, including Health Information Technology (HIT)
3. Fall
4. Healthcare-associated Infection
5. Medication or Other Substance
6. Perinatal
7. Pressure Ulcer
8. Surgery or Anesthesia
9. Venous Thromboembolism
10. Other (allows collection of information on all other types of events)

Hospital CoPs for QAPI

- Must have PI program that is ongoing and shows measurable improvements, that identifies and reduces medical errors
- Diagnostic errors, equipment failures, blood transfusion injuries, or medication errors
- Medical errors may be difficult to detect in hospitals and are under reported
- Make sure incident reports filled out for errors and near misses
- Remember the final QAPI Worksheet

CMS QAPI Worksheet

PART 2: DATA COLLECTION AND ANALYSIS - QUALITY INDICATOR TRACERS			
Instructions for Part #2 Questions: **Select 3 distinct quality indicators (not patient safety analyses) and trace them answering the following multipart question. Focus on indicators with related QAPI activities or projects. At least one of the indicators must have been in place long enough for most questions to be applicable.**			
Elements to be Assessed	**Indicator #1**	**Indicator #2**	**Indicator #3**
Write in indicator selected:			
2.1.a Can the hospital provide evidence that each quality indicator selected is related to improved health outcomes? (e.g., based on QIO, guidelines from a nationally recognized organization, hospital specific evidence, peer-reviewed research, etc.)	○ YES ○ NO	○ YES ○ NO	○ YES ○ NO
2.1.b Is the scope of data collection appropriate to the indicator, e.g., an indicator related to labor and delivery might be appropriate to all areas of that unit and the ED, but indicators related to hand hygiene would require data from multiple parts of the hospital.	○ YES ○ NO	○ YES ○ NO	○ YES ○ NO
2.1.c Is the method (e.g., chart reviews, monthly observations, etc.) and frequency of data collection specified?	○ YES ○ NO	○ YES ○ NO	○ YES ○ NO

CMS Hospital CoPs

- Triggers can help hospitals find errors
- Trigger tools available on IHI website[1]
- Program must incorporate quality indicator data including patient data (274)
- Look at information submitted to or from QIO

[1]www.ihi.org

CMS CoP PI Section Starts at Tag 263

A-0263
(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

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

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

A-0273
(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)

Data Collection & Analysis

§§482.21(a), 482.21(b)(1), 482.21(b)(2)(i), & 482.21(b)(3)

§482.21(a) Standard: Program Scope

(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes….

(2) The hospital must measure, analyze, and track quality indicators…and other aspects of performance that assess processes of care, hospital service and operations.

March 21, 2014 Manual Rewrites 7 Tags

A-0283

(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)

Quality Improvement Activities

§§482.21(b)(2)(ii), 482.21(c)(1) & 482.21 (c)(3)
§482.21(b)(2) Standard: Program Data

The hospital must use the data collected to--...

(ii) Identify opportunities for improvement and changes that will lead to improvement.

§482.21(c) Standard: Program Activities

(1) The hospital must set priorities for its performance improvement activities that--

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

A-0286

(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)

Changes to the Tag Numbers

- Old Tag Numbers:
  - 263, 264, 265, 266, 267, 273, 274, 275, 276, 277, 283, 285, 286, 287, 288, 289, 290, 291, 297, 298, 299, 300, 301, 302, 303, 309, 310, 311, 312, 313, 314, 315, 316, and 317
  - 34 tag numbers and 7 pages
- Tag Numbers changes in March 21, 2014 manual:
  - Revised tag numbers: **263, 273, 283, 286, 297, 308, 309 and 315**
  - 8 tag numbers and 4 pages
  - 34 tags to 8 with no change in actual process

2014 Changes to QAPI

- CMS issues a revised manual on March 21, 2014
- Rewrites 7 Tags;
  - 273, 283, 286, 297, 308, 309, and 315
- Remember that QAPI is important to both CMS and TJC
- Recall that one of the three CMS worksheets is on QAPI
- QAPI starts at tag 263

Hospital CoPs for QAPI 263

- Standard: Must have PI program that is ongoing, data driven, and effective,
- Board must make sure that PI program reflects the complexity of the hospital's organization and services
- Must involve all departments including contracted services
- Focus on indicators to improve health outcomes

Program Scope 273

- Standard: PI program needs to be ongoing and show measurable improvements to improve health outcomes
- Must measure, analyze and track the quality indicators
- Must incorporate data to measure the effectiveness and safety of services and the quality of care
- How often the data is collected must be specified by the board

CMS Hospital CoPs 2014

- Triggers can help hospitals find errors
- Look at information submitted to or from QIO
- Use data to identify opportunities for improvement (283)
  - Focus on high risk, high volume, or problem prone areas
  - Consider the incidence, severity, and severity of problems in those areas
  - Take action to improve and track the improvements made

[1]www.ihi.org

Patient Safety, Medical Errors, AE 286

- Standard: PI program must include indicators to identify and reduce medical errors
  - Track medical errors and ADE
- Analyze their causes and implement preventive actions
  - Example would be a RCA or root cause analysis
- Board is responsible for the operations of the hospital
- Medical staff and administrative staff are accountable to make sure clear expectations for safety

QAPI Program 2014

- So does the program show measurable improvements, that identifies and reduces medical errors
- Diagnostic errors, equipment failures, blood transfusion injuries, or medication errors
- Medical errors may be difficult to detect in hospitals and are under reported
- Make sure incident reports filled out for errors and near misses
- Make sure RCA done when indicated

PI Projects 297

- Standard: Hospital must conduct PI projects
- How many the hospital does depends on how big they are and what types of services are provided
- May develop an information technology system to improve patient safety and quality
- Document the projects and reasons for doing
- Can participate in a QIO project or do one that is of comparable effort

CMS Hospital CoPs QAPI

- QIO to advance quality of care for Medicare patients
- Every state has a QIO or Quality Improvement Organization under contract by CMS
- Sign up with your state QIO to get newsletters and other information
- CMS has a website on information about QIOs
- CMS has the mission to improve services provided to Medicare patients

Quality Improvement Organizations

- Spotlight
- How to Become a QIO-like Entity
- Future Work
- Current Work
- Past Work
- Resources for Quality Improvement

Quality Improvement Organizations

What are QIOs?

CMS contracts with one organization in each state, as well as the District of Columbia, Puerto Rico, and the U.S. Virgin Islands to serve as that state/jurisdiction's Quality Improvement Organization (QIO) contractor. QIOs are private, mostly not-for-profit organizations, which are staffed by professionals, mostly doctors and other health care professionals, who are trained to review medical care and help beneficiaries with complaints about the quality of care and to implement improvements in the quality of care available throughout the spectrum of care. QIO contracts are 3 years in length, with each 3-year cycle referenced as an ordinal "SOW."

What do QIOs do?

By law, the mission of the QIO Program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. Based on this statutory charge, and CMS' Program experience, CMS identifies the core functions of the QIO Program as:

- Improving quality of care for beneficiaries;
- Protecting the integrity of the Medicare Trust Fund by ensuring that Medicare pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting; and
- Protecting beneficiaries by expeditiously addressing individual complaints, such as beneficiary complaints; provider-based notice appeals; violations of the Emergency Medical Treatment and Labor Act (EMTALA); and other related responsibilities as articulated in QIO-related law.

Why does CMS have QIOs?

CMS relies on QIOs to improve the quality of health care for all Medicare beneficiaries. Furthermore, QIOs are required under Sections 1152-1154 of the Social Security Act. CMS views the QIO Program as an important resource in its effort

Executive Responsibilities 309

- Standard: Board assumes full legal authority and responsibility for the operations of the hospital
- Medical Staff and Administrative officials are responsible and accountable for the following:
  - Ongoing PI program that includes patient safety including reducing medical errors
  - Hospital wide PI and patient safety program
  - A determination of the number of PI projects that is conducted annually

Adequate Resources 315

- Standard: The board, Medical Staff, and Administrative Officials are accountable for measuring, assessing, improving and sustaining the hospital's performance
- This also requires reducing risk to patients
- Example; hospitals created a process to ensure MI patients got their thrombolytics timely, that PCI was done before 90 minutes and pneumonia patients got their antibiotics and blood culture timely
- Process to make sure the improvements continue

QAPI Patient Safety

- This means people who can attend meetings, data so analysis can be made and other resources
- Safer IV pumps, new anticoagulant program, implement central line bundle, sepsis, and VAP bundle, preventing inpatient suicides, wrong site surgery, retained FB, new processes for neuromuscular blocker agents, implement policy on Phenergan administration and Fentanyl patches
- So what's in your PI and Safety Plans?

Nursing Services 0385

- Must have an organized nursing service that provide 24 hour nursing services
- Must have at least one RN furnishing or supervising 24 hours
  - SSA at 1861 (b) states you must have a RN on duty at all times (except small rural hospitals under a waiver)
- Survey procedures-determine nursing services is integrated into hospital PI
- Make sure there is adequate staffing
- Surveyor will look for job descriptions including director of nursing

Director of Nursing Service

- DON must be RN, A-386
  - Often referred to as chief nursing officer or CNO
- CNO responsible for determining types and numbers of nursing personnel
- CNO responsible for operation of nursing service
- May read job description of DON to make sure it provides for this responsibility
- May verify DON approves patient care P&P's

Nurse Staffing 392

- Nursing service must have adequate number of nurses and personnel to care for patients
  - Answer call lights timely and check on patient if cardiac monitor alarms
- Must have nursing supervisor
- Every department or unit must have a RN present (not available if working on two units at same time)
- Survey procedure-look at staffing schedules that correlate number and acuity of patients

Nurse Staffing 392

- There are 3 recent evidenced based studies that show the importance of having adequate staffing which results in better outcomes
- Study said patients who want to survive their new hospital visit should look for low nurse-patient ratio
- Nurse Staffing and Quality of Patient Care, AHRQ, Evidence Report/Technology Report Number 151, March 2007, AHRQ Publication No. 07-E005[1]

[1]http://www.ahrq.gov/downloads/pub/ evidence/pdf/nursestaff/nursestaff.pdf

Nursing Linked to Safety

- IOM study also linked adequate staffing levels to patient outcomes
- Limits to number of hours worked to prevent fatigue
- Suggests no mandatory overtime for nurses
- Never work a nurse over 12 hours or 60 hours in one week (or will have 3 times the error)

Nursing Linked to Safety

- Also showed medication error rate, falls, pressure ulcers, UTI, surgery site infections, gastric ulcers, codes, LOS, increased unnecessary readmissions, patient experience or satisfaction rates etc. linked to staffing
  - Important in value based purchasing
- Redesigning the work force
- See Keeping Patients Safe: Transforming the Work Environment of Nurses 2004[1]

[1]www.nap.edu/openbook/0309090679/html/23/html

Nursing Staffing Linked to Safety

- AHRQ 2008 has published 3 volume, 51 chapter handbook for nurses at no cost
- Great resource that every hospital should have
- Nurse Staffing and Patient Care Quality and Safety
- Again shows that patient safety and quality is affected by short staffing
- Patient Safety and Quality: An Evidence-Based Handbook for Nurses, 2008[1]

[1] http://www.ahrq.gov/qual/nurseshdbk

Verify Licensure 394

- Must have procedure to ensure nursing personnel have valid and current license
- Survey procedure-review licensure verification P&P
- Can verify licensure on line by most state boards of nursing online
  - Considered primary source verification
  - Can print out information for employee file

RN for Every Patient 395

- A RN must supervise and evaluate the nursing care for every patient
- RN must do admission assessment
- Must use acceptable standard of care
- Evaluation would include assessing each patient's needs, health status and response to interventions

Nursing Care Plan 396 2013

- Hospital must ensure that nursing staff develop and keeps a current, nursing care plan for each patient
  - If nursing participates in interdisciplinary care plan then do not have to have separate nursing plan of care
- Starts upon admission, includes discharge planning, physiological and psychosocial factors
- Based on assessing the patient's needs
- Care plan is part of the patient's medical records and must be initiated soon after admission, revised and implemented

Agency Nurses 398

- Agency nurses or traveling nurses (CMS calls them non-employee nurses) must adhere to P&P's
- CNO must provide adequate supervision and evaluate (once a year) activities of agency nurses
- Includes other personnel such as volunteers
- Orientation must include to hospital and to specific unit, emergency procedures, nursing P&P, and safety P&P's

Preparation/Admin of Drugs 405 2014

- Drugs must be prepared and administered according to state and federal law
  - 404 deleted and combined with 405
- Need an practitioner's **order**
  - CMS changes to allow other practitioners who are allowed to order to sign off order such as PharmD as allowed by P&P and state scope of practice and MS bylaws/RR
- Surveyor will observe nurse prepare and pass medications
- Medications must be prepared and administered with acceptable national standards of practice (TJC MM chapter), manufacturer's directions and hospital policy

CMS Changes to Medication Administration

- CMS issued a survey and certification memo dated 11-18-11, 6-7-13 and March 14, 2014 which was effective June 6, 2014
  - Tag 405 use to say that all medications must be given within 30 minutes of the scheduled time
  - Now three blocks of time to give medications
  - Included section on standing orders but most sections moved to tag 457

March 14, 2014 Memo Amends Tag 405

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 post-operative care, to emphasize the need for post-operative monitoring of patients

CMS Changes to CoPs 6-6-2014

- Changed tag 405 which deals with orders of drugs and biologicals and **safe opioid use**
- Most sections on standing orders section was moved to 457
- Added information on age and weight of patient especially weight based doses for children
- All drugs are administered under the supervision of nursing or other personnel
- Five rights of medication administration: right patient, medication, dose, route and time and references nine rights

Pharmacy Should Prepare Piggybacks & IVs

For Information – Not Required/Not to be Cited

Although the regulation addresses both preparation and administration of drugs and biologicals and does not prohibit preparation of drugs by nursing staff, to improve patient safety it is generally preferable for hospitals to avoid nurse preparation of drugs in patient care areas, and instead rely upon pharmacy IV admixture systems and/or commercially available unit dose products.

Administration of Meds 0405 2014

- Medication management is a hot topic with CMS and TJC
- All drugs administered under the supervision of nursing or other personnel if permitted by law
- In accordance with approved medical staff P&P's, state & federal laws, MS bylaws and R/R and scope of practice
- Surveyor will review sample of medication records to ensure it conforms to physician's order

Administration of Meds 405

- Need to have an **order**, make sure compliant with state and federal laws, and acceptable standards of practice
- Need to have a P&P with three time frames on timing of medications
- Must educate staff and policy must comply with the 10 page memo issued
- Include medications not eligible for scheduled dosing such as stat drugs, PRN, loading doses, drugs for scheduled procedure etc.

Administration of Meds 405

- Medications that are eligible for scheduled times
- P&P to include time-critical scheduled medications given in 30 minutes with one hour window
- P&P that are non-time-critical scheduled medications
  - 2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours and
  - 4 hours for medications prescribed for daily or longer administration intervals
- P&P on missed or late medications

Assessment & Monitoring of Patients 2014

- Patients on medications needed to be carefully monitored
  - May need clinical and lab data to evaluate medication
  - Monitor respiratory status, pulse ox, BP, end tidal CO2 with patients on **opioids**
  - Evaluate clinical signs such as confusion, agitation, unsteady gait, itching etc.
  - Know high risk medications policy and safe practices
  - Know risk factors for ADE such as patient has liver or kidney failure, history of sleep apnea, obesity, smoking, drug-drug interaction and first time medication use

ISMP List of High Alert Medication

ISMP's List of *High-Alert* Medications

Printer friendly version

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

Classes/Categories of Medications	Specific Medications
adrenergic agonists, IV (e.g., **EPINEPH**rine, phenylephrine, norepinephrine)	epoprostenol (Flolan), IV
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)	magnesium sulfate injection
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)	methotrexate, oral, non-oncologic use
antiarrhythmics, IV (e.g., lidocaine, amiodarone)	opium tincture
antithrombotic agents, including: ■ anticoagulants (e.g., warfarin, low-molecular-weight heparin, IV unfractionated heparin) ■ Factor Xa inhibitors (e.g., fondaparinux) ■ direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran etexilate, lepirudin)	oxytocin, IV nitroprusside sodium for injection potassium chloride for injection concentrate potassium phosphates injection promethazine, IV vasopressin, IV or intraosseous

Assessment & Monitoring of Patients

- ADE, such as anaphylaxis or opioid-induced respiratory depression may require timely and appropriate
- Post-medication monitoring in case of a high alert medication may include regular assessment of VS, pulse ox, and sedation levels of post surgery patient on PCA
- Such as Richmond agitation sedation scale (RASS) or the Pasero Opioid-Induced sedation scale (POSS), Inova Sedation Scale (ISS), Ramsey scale, Aldrete Scoring system

Assessment & Monitoring of Patients

- Staff are expected to include patient reports of his experience with medication's effect
- Patient should be instructed to notify nurse if there is difficulty breathing or a reaction to the medication
- Hospital needs P&P to address the manner and frequency of monitoring
- P&P should include information to be communicated at shift change
- Should include patient's risk factors
- **Document** after medication administered

9 Rights of Medication Administration

For Information – Not Required/Not to be Cited

Recent literature identifies up to nine "rights" of medication administration including:*

- ☐ *Right patient*
- ☐ *Right drug*
- ☐ *Right route*
- ☐ *Right time*
- ☐ *Right dose*
- ☐ *Right documentation*
- ☐ *Right action (appropriate reason)*
- ☐ *Right form*
- ☐ *Right response*

However, other sources refer to 8 or 10 "rights, and some of these topics, such as right action, appear to involve prescribing and/or dispensing. Accordingly, there does not (yet) appear to be consensus about expanding beyond the 5 "rights."

**Reference: Elliott, M. and Lis, Y. (2010). The Nine Rights of Medication Administration: An Overview. British Journal of Nursing, Vol. 19, 5, 300-305.*

Physician Order 406 2013

- Standard: Drugs and biologicals must be prepared on the order contained within preprinted and electronic standing orders, order sets, and protocols if meet the standards in tag 457
- Orders for drugs can be documented and signed by other practices if acting in scope of practice, state law, P&P, and MS bylaws and R/R
- CMS issues standing order memo 10-24-08
- Also includes standing orders, preprinted orders and use of rubber stamps

Physician Order 406 2013

- Flu and pneumovax can be given by protocol approved by the MS after assessment of contraindications
- Orders for drugs must be documented and signed by practitioners allowed to write them
- Doctors and if allowed NP and PAs
- Rubber stamps - will not be paid for order for M/M patients and some insurance companies so many hospitals do not allow rubber stamps

Physician Order 406

- Order must have name of patient, age and weight (if applicable), date and TIME of order, drug name, strength, frequency, dose, route, quality and duration, and special instructions for use, and name of pre scriber
- Have a culture so can ask questions
- Now allowed to have written protocol or standing orders with drugs and biologicals that have been approved by MS
- Can implement them but be sure provider signs, dates, and times the order

Physician Order 406

- Chest pain protocol or asthma protocol with Albuterol and Atrovent are an example of initiation of orders
- Code teams gives ACLS drugs in an arrest
- Timing of orders should not be a barrier to effective emergency response
- Preprinted order - should send memo so doctors and providers are aware of new guidelines

Preprinted Order Sets

- Must date and time when the order set is signed
- Must indicate on last page the total number of pages in the order set
- If want to strike out something in the order sheet or delete it or add order on blank line then physician needs to initial each place
- Should add this to the MR audit sheet to make sure there is compliance with this guideline
- Standing orders must address well-defined clinical scenarios involving medication
- Refers to tag 457 and 450 for more information

Verbal Orders 407 and 408

- Verbal orders are a patient safety issue
- Have lead to many errors
- Hospital must describe situations in which they can be used as well as limitations
- Must establish the identity and author of all orders
- Rewrite your P&P and Medical staff by-laws to be consistent with these standards
- Repeated VO section in MR starting with tag 454 and reiterated area of verbal orders offer too much room for error

Verbal Orders 2013

- Must follow state law for time period to sign off such as 24 or 48 hours
  - If no state law do **not** have to sign off in 48 hours anymore
- Must sign off orders within time frame set by hospital policy
- Many hospitals **without** a state law can choose to have signed off but must be less than 30 days
  - But still try and get them signed off **ASAP**
- Must still sign name and date and time the order

CMS Verbal Orders 2013

- Emphasizes to be used infrequently and never for convenience of the physicians
- This means that physician should not give verbal orders in nursing station if he or she can write them
- Can be used in emergency or if surgeon is scrubbed in during surgery
- Regulation broadens category of practitioners who can sign orders off such as PA or NP
- Renewed any physician can sign off for any other physician on the case

Verbal Orders P&P Should Include

- Limitations or situation on not using VO such as not for chemotherapy
- List the elements for a complete VO (such as patient name, drug, dose, frequency, name of person giving and taking order, et al.)
- Define who can receive VO and the method to ensure authentication
- Provide guidelines for clear and effective communications

Signing Off Verbal Orders

- Person taking VO must document it in the chart
- Physician must sign off a verbal order, **date,** and **time** it when signed off
- Any physician on the case can sign off any VO
- This practice must be addressed in the hospital's P&P
- Now a NP or PA may sign off a verbal order, if within their scope (where they had authority to write order) and allowed by state law, hospital policy and delegated to this by the physician

Verbal Orders

- Regulation states that verbal orders should be authenticated based on state law
- Some states require order to be signed off in 24 hours or 48 hour and if no state law then no longer a set 48 hours but what your hospital P&P dictates
- Need hospital P&P to reflect these guidelines
- Write it down and repeat it back

Joint Commission Verbal Orders

- RC.02.03.03 (IM 6.50) requires that qualified staff receive and record VO
- Define in writing who can receive and record VO
- Date and document identity of who gave, received, and implemented the order
- Authenticated within time frame law/regulation
- Write it down and read back the completed order or test result (NPSG 2009)

Blood Transfusions and IVs 409 2013 & 2014

- Standard: Blood transfusions and IV medications must be administered with state law and MS P&P
  - CMS previously issued a memo on May 13, 2011
- Use to require special training for this and there was a long list of things that nurses had to be trained on
- CMS eliminated the regulations mandating training for non-physicians who administer IV medication and blood and blood products
  - CMS says because this training is already standard practice but must still be competent in those areas
  - Must follow your P&P and state scope of practice

Blood and IV Medication Training 2013/14

- Must still follow **state law requirements**
  - In some states an LPN can not hang blood
  - Or the LPN can not push certain IV medications in some states
  - Must show they are competent
- Must still have approved **Medical Staff Policies** and Procedures in place
- Staff must follow these which have most of the things that were previously required

Blood Transfusions and IVs

- Hospital P&P for blood and IV medication must be based on state law and MS P&P and must address the following:
  - Vascular access route such as central line, peripheral or implanted port and what medications can be given IV and via what type of access devices
  - Basic safety practices for medication administration
    - Tracing line and tubes prior to administration to be sure proper route
    - Verify proper programming of infusion devices

Blood Transfusions and IVs

- Patient Monitoring
  - Monitor for the effects of the medication since IV medications have a more rapid effect
  - Monitoring to include assessment of risk factors that would influence type and frequency of monitoring
  - Such as patient with renal failure on Vancomycin and dose is based on lab test
- P&P expected to address
  - Monitoring for fluid and electrolyte balance
  - Monitor patients on high alert meds including **opioids** and evaluate for over-sedation and respiratory depression

Blood Transfusions and IVs

- Risk factors for patients receiving opioids include
  - Snoring or history of sleep apnea
  - No recent opioid use or first-time use of IV opioids
  - Increased opioid dose requirement or opioid habituation
  - Longer length of time receiving general anesthesia during surgery
  - Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other CNS depressants
  - Preexisting pulmonary or cardiac disease
  - Thoracic or other surgical incisions that may impair breathing

Blood Transfusions and IVs

- P&P must include who can conduct the assessments
- The frequency and duration of the assessments
- Under what circumstances practitioners prescribing IV opioids are allowed to establish protocols that differ from hospital P&P
- Assessment includes VS (TPR and BP), pain level, respiratory status, sedation level and $ETCO_2$
- Also mentions APSF monitoring of opioids including $ETCO_2$

For Information – Not Required/Not to be Cited

Institute for Safe Medication Practices Guidelines for PCA Monitoring

Assessment of Opioid Tolerance	*Vital Signs*	*Pain*	*Sedation*	*Respiratory*		
				Rate	*Quality*	*SPO_2* &/or $ETCO_2$***
Baseline Assessment before PCA	*X*	*X*	*X*	*X*	*X*	*X*
PCA Initiation or Change in Drug/Syringe *Q 15 minutes x 1 hour* *Q 1 hour x 4 hours* *Then Q 2 hours*	*X*	*X*	*X*	*X*	*X*	*X*
PCA Dose Change or Bolus *Q 1 hour x 4 hours* *Then Q 2 hours*	*X*	*X*	*X*	*X*	*X*	*X*
Adverse Event or Patient Deterioration (e.g., adverse change in sedation score) *Q 15 minutes x 1 hour* *Q 1 hour x 4 hours* *Then Q 2 hours*	*X*	*X*	*X*	*X*	*X*	*X*
Hand-offs/Shift Change	*X*	*X*	*X*	*X*	*X*	*X*

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013 ISMP adapted these recommendations from the San Diego Patient Safety Council

* *SPO_2: Saturation of peripheral oxygen via pulse oximetry*

Blood Transfusions

- Confirm correct patient
- Verify correct blood product
- Standard calls for two qualified persons, one who is administering the transfusion
- Document monitoring
- P&P include how frequent you monitor the patient and do vital signs
- How to identify and treat and report any adverse transfusion reaction

Blood Transfusions

- Staff must be competent in venipuncture
- Competent in using vascular access devices
- Trained in early detection and intervention for opioid over-sedation
- Must document competency
- So make sure nursing education is aware and staff trained in orientation periodically
- Make sure staff educated on P&P

Blood Transfusions and IVs 2013

- Is there evidence that staff competent in;
- Maintaining fluid and electrolyte balance
- Venipuncture techniques
- Blood transfusion: blood components, administration policy, national standards of practice, patient monitoring requirements including frequency, documentation, verifying correct blood and patient
- Transfusion reactions; Identification, treatment and reporting requirements

Incident Reports Transfusions 2013

- There must be procedure for reporting transfusion reactions, adverse drug reactions and errors in administration of drugs (410)
- Survey procedure - request procedure for reporting- they may review the incident reports or other documentation through QAPI program
  - But must have a hospital P&P for reporting transfusion reactions such as an incident reporting system
  - See tag number 508 which was updated May 20, 2011 on this issue

ADE and Drug Administration 410

- Mentions similar standard in pharmacy section which is in tag 508
- Want to be sure all drug errors and ADE are reported
- This includes any blood transfusions AE
- Discusses symptoms of a transfusion reaction
- Need P&P for internal reporting of transfusion reactions since be life threatening
- Must be immediately reported to the practitioner responsible for the patient's care and documented in the medical record and report to PI

Self Administration of Medication 412

- New tag number in 2013, Tag 412 and 413 and one addition in 2014 that PCA is self administered med
- Standard: Hospital may allow a patient or caregiver to self administer both hospital issued medication and the medication the patient brought from home
  - As specified in the hospital P&P
- Revise your policy to include this section
- Add this to the education of your nursing and pharmacy staff

Self Administration of Medication 412

- Must have an order, must make sure patient is competent to do, must educate the patient
- P&P must address security of medication for each patient
- Must document in the MR so patient must let nurse know
- Visually inspect medication for integrity
- Previously this section was in the pharmacy section 502

CMS Self Administered Drugs 412 and 413

A-0412
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§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.

(i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.
(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).
(C) Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s).
(D) Address the security of the medication(s) for each patient.
(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

Interpretative Guidelines §482.23(c)(6)(i)

Hospitals have the option of establishing a program for self-administration by patients, or, when applicable, patient caregivers or support persons, of hospital-issued medications. The existence of this regulatory option does not mean that a hospital must offer medication self-administration programs or that a patient has a right to self-administer their medications

See Tag 412 and 413 March 2013

* * *

A-0413

[§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.]

§482.23(c)(6)(ii) If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital.

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s) and also determine if the patient (or the patient's caregiver/supplier person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).

(C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity.

Pharmaceutical Services 490

- Hospital must have a pharmacy to meet the patient's needs and need to promote safe medication use process
- Must be directed by registered pharmacist or drug storage area under constant supervision
- MS is responsible for developing P&P to minimize drug error
- Function may be delegated to the pharmacy service

Pharmacy 490

- CMS allows radiopharmaceuticals to be given off shifts without physician or pharmacist being present in the hospital (2015)
- Provide medication related information to hospital personnel
  - Medication Management is important to CMS and TJC and TJC has a medication management chapter
- Contains list of functions of the pharmacist
  - Collect patient specific information, monitor effects, identify goals, implement monitoring plan with patient, et.al.
- Flag new types of mistakes

Pharmacy Policies Include:

- High alert medication-dosing limits-packaging, labeling and storage (policy at www.wpsi.org and ISMP (Institute for Safe Medication Practice) and USP have list of high alert medications)
- Limiting number of medication related devices and equipment-no more that **2 types** of infusion pumps (490)
- Availability of up to date medication information
- Pharmacist on call if not open 24 hours

Pharmacy Policies

- Avoid dangerous abbreviations
- All elements of order; dose, strength, route, units, rate, frequency
- Alert system for sound alike/look alike (LASA)
- Use of facility approved pre-printed order sheets whenever possible
- “Resume pre-op orders” is prohibited
- Voluntary, non-punitive reporting system to monitor and report adverse drug events

Pharmacy Policies

- Preparation, distribution, administration and disposal of hazardous medications (chemotherapy)
- Drug recall
- Patient specific information that should be readily available
  - TJC tells you exactly what this is, like age, sex, allergies, current medications, etc.
- Means to incorporate external alerts and recommendation from national associations and government for review and policy revision (Joint Commission, ISMP, FDA, IHI, AHRQ, Med Watch, NCCMER, MEDMARX)

Pharmacy Policies 490

- Identification of weight based dosing for pediatric populations (only weigh in kg)
- Requirements for review based on facility generated reports of adverse drug events and PI activities
- Policy to identify potential and actual adverse drug events (IHI trigger tool, concurrent review, observe med passes etc.)
- Must periodically review all P&P's

Pharmacy Policies Include

- Need a multidisciplinary committee - committee of medicine, nursing, administration, and pharmacy to develop P&P
- MS must develop P&P or have policy that this function is fulfilled by pharmacy
- Surveyors will make sure staff is familiar with all the medication P&P's
- Need policies to minimize drug error

Pharmacy Management 491

- Pharmacy or drug storage must be administered in accordance with professional principles (TJC 03.01.01 and problematic standard)
- This includes compliance with state laws (pharmacy laws), and federal regulations (USP 797), standards by nationally recognized organizations (ASHP, FDA, NIH, USP, ISMP, etc.)
- Pharmacy director must review P&P periodically and revise

Pharmacy Management 491

- Drugs stored as per manufacture's instructions; refrigerate, freeze, room temperature, keep out of light etc.
- Pharmacy employees provide services within the scope of their licensure and education
- Sufficient pharmacy records to follow flow from order to dispensing/administration
- Maintain control over floor stock

Pharmacist 491

- Ensure drugs are dispensed only by licensed pharmacist
- Must have pharmacist to develop, supervise, and coordinate activities of pharmacy
- Can be part time, full time or consulting
- Single pharmacist must be responsible for overall administration of pharmacy

Pharmacist 491

- Job description should define development, supervision, and coordination of all activities
- Must be knowledgeable about hospital pharmacy practice and management
- Must have adequate number of personnel to ensure quality pharmacy service, including emergency services
- Sufficient to provide services for 24 hours, 7 days a week

Pharmacy Delivery of Service 500

- Keep accurate records of all scheduled drugs
- Need policy to minimize drug diversion
- Drugs and biologicals must be controlled and distributed to ensure patient safety
- In accordance with state and federal law and applicable standards of practice
- Accounting of the receipt and disposition of drugs subject to COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

Delivery of Service 500

- Pharmacist and hospital staff and committee develop guidelines and P&P to ensure control and distribution of medications and medication devices
- System in place to minimize high alert medication (double checks, dose limits, pre-printed orders, double checks, special packaging, et.al.)
- And on high risk patients (pediatric, geriatric, renal or hepatic impairment)
- High alert meds may include investigational, controlled meds, medicines with narrow therapeutic range and sound alike/look alike

Delivery of Service 500

- All medication orders must be reviewed by a pharmacist before **first dose** is dispensed
- Includes review of therapeutic appropriateness of medication regime
- Therapeutic duplication
- Appropriateness of drug, dose, frequency, route and method of administration
- Real or potential med-med, med-food, med-lab test, and med-disease interactions
- Allergies or sensitivities and variation from organizational criteria for use

Delivery of Service 500

- Sterile products should be prepared and labeled in suitable environment
- Pharmacy should participate in decisions about emergency medication kits (such as crash carts)
- Medication stored should be consistent with age group and standards (such as pediatric doses for pediatric crash cart)
- Must have process to report serious adverse drug reactions to the FDA

Delivery of Service 500

- Policy to address **use of medications brought** in
- P&P to ensure investigational meds are safely controlled and administered
- Medications dispensed are retrieved when **recalled** or discontinued by manufacturer or FDA (eg. Darvocet N)
- System in place to **reconcile medication** that are not administered and that remain in medication drawer when pharmacy restocks
- Will ask why it was not used?
- Not the same as medication reconciliation as in the TJC NPSG which all hospitals should still do from a patient safety perspective although in worksheets mentions this

Compounding of Drugs 501

- All compounding, packaging, and disposal of drugs and biologicals must be under the supervision of pharmacist
- Must be performed as required by state of federal law & compounding law passed in 2013
- Staff ensure accuracy in medication preparation
- Staff uses appropriate technique to avoid contamination

Compounding of Drugs

- Use a laminar airflow hood to prepare any IV admixture, any sterile product made from non-sterile ingredients, or sterile product that will not be used within 24 hours (see USP 797)
- Meds should be dispensed in safe manner and to meet the needs of the patient
- Quantities are minimized to avoid diversion, dispensed timely, and if feasible in unit dose
- All concerns, issues, or questions are clarified with the individual prescriber before dispensing

Locked Storage Areas 502

- Drugs and biologicals must be kept in a secure and locked area
- Would be considered a secure area if staff actively providing care but not on a weekend when no one is around
- Schedule II, III, IV, and V must be kept locked within a secure area (see also 503)
- Only authorized person can get access to locked areas

Locked Storage Areas 502

- Persons without legal access to drugs and biologicals can have not have unmonitored access
- They can not have keys to storage rooms, carts, cabinets or containers with unsecured medications (housekeeping, maintenance, security)
- Critical care and L&D area staffed and actively providing care are considered secure
- Setting up for patients on OR is considered secure such as the anesthesia carts but after case or when OR is closed need to lock cart

Securing Medications

- So all **controlled substances must be locked**
- Hospitals have greater flexibility in determining which **non controlled drugs** and biologicals must be kept locked
- Medications should not be stored in areas readily accessible to unauthorized persons such in a private office unless visitors are not allowed without supervision of staff
- P&P need to address security of any carts containing drugs

Securing Medications

- CMS made changes in the FR effective June 2013 to match the interpretive guidelines (See 412 & 413)
- May allow patients to have access to urgently needed drugs such as Nitro and inhalers
- Need P&P on competence of patient, patient education and must meet elements in TJC MM standard on self administration
- Measures to secure bedside medications
- Document when patient reports the medication was taken
- Inspect the integrity of the medication

Locked Storage Areas

- Saline flushes need to be secure to prevent tampering (FDA does not consider a medication now)
  - Consider having safe injection practices P&P and follow CDC 10 guidelines such as one needle, one syringe
- If medication cart is in use and unlocked, then someone with legal access must be close by and directing monitoring the cart, like when the nurse is passing meds
- Need policy for safeguarding, transferring and availability of keys

Policy and Procedure

- CMS states that they expect hospital P&P to address
- The security and monitoring of any carts including whether locked or unlocked if contains drugs and biologicals
- In all patient care areas to ensure safe storage and patient safety
- P&P to keep drugs secure, prevent tampering, and diversion

TJC Self Administered Meds

- Self administered medications are safely and accurately administered
- If you allow self administration, need procedure to manage, train, supervise, and document process
- TJC MM stands for medication management standard MM 5.20 or MM.06.01.03
- CMS mentions this standard in the FR when changes were made and said to follow

TJC Self Administered Meds

- If non-staff member administers (patient or family) must train and make sure competent to do so (give info on nature of med, how to administer, side effects, and how to monitor effects)
- Patient has to be determined to be competent before allowed to self administer
- Mentioned TJC in Federal Register but not in IG

Outdated or Mislabeled Drugs 505

- Outdated, mislabeled or otherwise unusable drugs and biologicals must not be available for patient use
- Hospital has a system to prevent outdated or mislabeled drugs
- Surveyor will spot check individual drug containers to make sure have all the required information including lot and control number, expiration date, strength, etc.

No Pharmacist on Duty 506

- If no pharmacist on duty, drugs removed from storage area are allowed only by personnel designated in policies of MS and pharmacy service
- Must be in accordance with state and federal law
- Routine access to pharmacy by non-pharmacist for access should be minimized and eliminated as much as possible
- E.g. night cabinet for use by nurse supervisor
- Need process to get meds to patient if urgent or emergent need

No Pharmacist on Duty 506

- TJC does not allow nurse supervisor in pharmacy so would need to call the on call pharmacist
- Access is limited to set of medications that has been approved by the hospital and only trained prescribers and nurses are permitted access
- Quality control procedures are in place like second check by another or secondary verification like bar coding
- Pharmacist reviews all medications removed and correlates with order first thing in the morning

Medications Errors 508 5-20-11

- Drug errors, adverse drug reaction, and drug incompatibilities must be immediately reported to the attending physician and to the hospital PI program
- Definition of med error or ADE should be broad enough to include NEAR MISSES
- Recommend use of the broad definition by National coordinating council medication error reporting and prevention definition and ASHP definition of ADR
  - Will make sure definition is based on national standards
- Must have a P&P for reporting

Medications Errors 508 2013

- Must be documented in the medical record and reported to QAPI program
- CMS encourages non-punitive approach
- Hospital can not just rely on incident reports but must take step to identify these events
- Need to measure the effectiveness of systems to identify and report to the PI program which includes benchmarks and RCA when indicated
- Encouraged to externally report to FDA MedWatch program, ISMP medication error reporting program etc.

Medications Errors 509

- Hospital must proactively identify med errors and ADE and can not rely solely on incident reports
- Proactive includes observation of med passes, concurrent and retrospective review of patient's clinical record, ADR surveillance, evaluation of high alert drugs and indicator drugs (Narcan, Romazicon, Benadryl, Digibind, et al) or generate a review for potential ADE
- Remember FMEA (failure mode and effect analysis) and IHI adverse event trigger tool is great

Abuses and Losses 509

- Abuses and losses of controlled substances must be reported pharmacist and CEO and in accordance with any state or federal laws
- Surveyor will interview pharmacist to determine their understanding of controlled substances policies
- What is procedure for discovering drug discrepancies?

Drug Interaction Information 510

- Information on drug interactions and information on drug side effects, toxicology, dosage, indication for use and routes of administration must be available to staff
- Texts and other resources must be available for staff at nursing stations and drug storage areas
- Staff development programs on new drugs added to the formulary and how to resolve drug therapy problems

Formulary 511

- Formulary system must be established by the MS to ensure quality pharmaceuticals at reasonable cost
- Formulary lists the drugs that are available
- Processes to monitor patient responses to newly added medication
- Process to approve and procure meds not on the list
- Process to address shortages and outages including communication with staff, approving substitution and educating everyone on this, and how to obtain medications in a disaster

Radiology 529

- Hospital has radiology services to meet needs of patients
- Radiology services should be provided in accordance with accepted standards of practice
- Radiology, especially ionizing procedures, must be free from hazards for patients and personnel
- Must have policy that provides for safety of both

Safety

- Proper safety precautions maintained against radiology hazards (535)
- Including shielding for patients and personnel as well as storage, use, and disposal of radioactive materials (536)
- Need order of practitioner with privileges or practitioners outside the hospital who have been authorized by MS to order as allowed by state law
- Period inspection of equipment and fix any hazard (537)
- Check radiation workers by use of badge tests or exposure meters (538)

Personnel 545

- Qualified radiologist must supervise ionizing radiology services (546)
- Must interpret those tests that are determined by the MS to require a radiologist's specialized knowledge
- Written policy approved by MS to designate which tests require interpretation by radiologist
- If telemedicine is used, radiologist interpreting must be licensed and meet state law requirements (state medical board requirements), (546, see Tag 23)

Personnel 546

- Supervision of radiology by radiologist who is member of the MS, Supervision should include the following
- Ensure reports are signed by the practitioner who interpreted them
- Assign duties to personnel based on their level of training, experience and licensure
- **Enforce infection control standards**
- Ensure emergency care if patient experience ADR to diagnostic agent

Radiology 547

- Ensure files, records are kept in secure area and retrievable, train staff on how to operate equipment safely
- Written policy, approved by the MS on who can use radiology equipment and administer procedures
- Only qualified personnel may use radiology equipment
- Surveyor will review personnel folders to make sure they are qualified as established by the MS for the tasks they perform

Radiology Records

- Radiology records must be maintained for all procedures performed (553)
- Must contain copies of all reports and printouts and any films, scans, or other image records
- Must have written P&P that ensure the integrity of authentication and protect privacy of radiology records - must be secure and retrievable for five years (555)
- Radiologist or other practitioner who performs radiology services must sign the report of his or her interpretation
- They have to be signed by the one who read and evaluated the x-ray (not the partner who is reviewing the dictated report), A-0554

Laboratory Services 576

- Must have adequate lab services to meet the needs of the patient
- All lab services must in any hospital department has to meet these guidelines
- All services must be provided in accordance with CLIA requirements (Clinical Laboratory Improvement Act) and have CLIA certificate
- Can provide lab services directly or as contracted service

Lab Services

- All lab services, including contracted services, must be integrated into hospital wide PI
- Lab results are considered medical records and must meet all MR CoPs
- Must have lab services available either directly or indirectly
- Must meet needs of its patients and in each location of the hospital
- TJC has lab standards also

Emergency Lab-Services Available 583

- Must provide emergency lab services 24 hours a day, 7 days a week - directly or indirectly (contracted)
- Hospital with multiple campuses must have available 24/7 at each campus
- MS must determine what lab tests will be immediately available
- Should reflect the scope and complexity of the hospital's operations
- Written description of emergency lab services available
- Written description of test available are provided to MS on routine and stat basis

Tissue Specimens 584

- Written instructions for the collection, preservation, transportation, receipts, and reporting of tissue specimen results
- MS and pathologist determine when tissue specimens need macroscopic (gross) and microscopic examination
- Need written policy on this
- TJC has a chapter on transplant safety and FAQs

Blood Banks 592

- Potentially infectious blood and blood components
- This section completely rewritten so have person in charge of P&P in this area and the look back program to review these changes
- Will need to update P&Ps
- TJC has similar sections in transplant safety chapter starting with TS.01.01.01 through TS.03.03.01 and PC chapter for blood and blood components

Blood and Blood Components

- Potentially HIV infectious blood and hepatitis C virus (HCV) and blood products are collected from a donor who tests negative
- If on a later donation tests positive then more specific test or follow up testing is done as required by FDA
- If services provided by outside blood collecting establishment (blood bank) then need agreement to govern procurement, transfer and availability of blood and blood products
- Agreement with blood bank must require blood bank to notify hospital promptly (HIV and added HCV)

Blood Banks 592

- Time depends on if tested positive on this unit or tested negative but on later donation tested positive
- Within 3 calendar days if blood tested is positive later
- Follow up of notification within 45 calendar days after reactive screening test was positive for additional tests
- See look back procedures required by 21 CFR 610.45 et seq. and FDA regulations
- Hospital will dispose any contaminated blood from donor if not given (TJC PC.05.01.01)

Patient Notification

- If administered potentially HIV/HCV infected blood hospital must make reasonable attempts to notify patient over period of 12 weeks unless patient already notified or unable to locate in 12 weeks
- Records of the source and disposition of all units of blood and blood components must keep records ten years

Patient Notification

- A fully funded plan to transfer these records to another hospital if the hospital closes (TJC PC.05.01.05 maintains records on receipt, testing and disposition of all blood and blood components and fully funded plan to transfer records to another organization if hospital ceases operation for any reason)
- Must have P&P that meet federal and state laws on notification of patients

Patient Notification

- Must document in MR
- Must conform to confidentiality requirements
- Must have 3 things in the content of the notice; explanation of need for HIV and HCV testing and counseling
- Enough written or oral information so can make an informed decision
- List of programs where can get counseled and tested
- If minor or incompetent or deceased then notify legal representative

Food and Dietetic Services 618

- Hospital must have organized dietary services
- Must be directed and staffed by qualified personnel
- If contract with outside company need to have dietician and maintain minimum standards and provide for liaison with MS on recommendations on dietary policies
- Dietary services must be organized to ensure nutritional needs of the patient are met in accordance with physician orders and acceptable standard of practice

CMS Changes

- CMS published some final changes to hospital CoP effective July 11, 2014
- Interpretive guidelines published January 30, 2015 with changes to 628 (deleted), 629 and 630
- Several are important to the CMS dietary CoPs
- Would permit registered dietitians or nutritional specialist to order patient diets independently, which they are trained to do, without requiring the supervision or approval of a physician or other practitioner when C&P

CMS Changes Food & Dietetic Services

- CMS said it came to their attention that CMS CoPs were too restrictive and lacked the flexibility to allow hospitals to extend privileges to RD (Registered Dietician) in accordance with state law
- CMS believes RD are best qualified to assess patient's nutritional treatment plan and design and implement a nutritional treatment plan in consult with the care team
- Used the term RD but noted that not all states call them RD and some states call them licensed dieticians (LD) and some states recognize other qualified nutrition specialists

CMS Changes Food & Dietetic Services

- CMS includes a qualified dieticians (such as a RD) as a practitioner who may be privileged to order patient diets (Enteral and parenteral nutrition, supplemental feedings and therapeutic diets) or order related lab tests
- CMS said this would free up time for physicians and other practitioners to care for patients
- Dietician or nutritional specialist can be granted nutrition ordering privileges by the Medical Staff (MS)
- This can be with or without appointment to the MS

Dietary Policies Required 618

- Need the following 7 policies:
  - Availability of diet manual and therapeutic diet menus
    - Sometimes called Nutrition Care Manual (NCM) or Pediatric Nutrition Care Manual (PNCM)
  - Frequency of meals served
  - System for diet ordering and patient tray delivery
  - Accommodation of non-routine occurrences
    - Parenteral nutrition (tube feeding), TPN, peripheral parenteral nutrition, changes in diet orders, early/late trays, nutritional supplements etc.

Seven Dietary Policies Required 618

- Integration of food and dietetic services into hospital wide QAPI and infection control programs
- Guidelines on acceptable hygiene practices of personnel
- Guidelines for kitchen sanitation
  - Important to protect against germs and bacteria that cause illness
- Compliance with state or federal laws

Organization 620

- Must have full time director who is responsible for daily management of dietary services
- Must be granted authority and delegation by the Board and MS for the operation of dietary services
- Job description should be position specific and clearly delineate authority for direction of food and dietary services
- Includes training programs for dietary staff and ensuring P&Ps are followed

Dietary Policies

- Safety practices for food handling
- Emergency food supplies
- Orientation, work assignment, supervision of work and personnel performance
- Menu planning
- Purchase of foods and supplies
- Retention of essential records (cost, menus, training records, QAPI reports)
- Service QAPI program

Dietitian 621

- Qualified dietician must supervise nutritional aspects of patient care and approve patient menus and nutritional supplements
- Patient and family dietary counseling
- Perform and document nutritional assessments
- Evaluate patient tolerance to therapeutic diets when appropriate
- Collaborate with other services (MS, nursing, pharmacy, social work)
- Maintain data to recommend, prescribe therapeutic diets

Personnel 622

- Must have administrative and technical personnel competent in their duties
- Menus must be nutritional, balanced, and meet special needs of patients
- Screening criteria should be developed to determine what patients are at risk
- Once patient is identified nutritional assessment should be done (TJC PC.01.02.01)
- Patient should be evaluated

Diets 628 Deleted 2015

- Menus must meet the needs of the patient
- Menus must be nutritional, balanced
- Menus must meet the special needs of patients
- Current menus should be posted in the kitchen
- Screening criteria should be developed to determine what patients are at risk
  - Once patient is identified nutritional assessment should be done (TJC PC.01.02.01)
  - Patient should be re-evaluated as necessary to ensure their nutritional needs are met

CMS Rewrites Tag 629

A-0629
(Rev.)

§482.28(b) Menus must meet the needs of patients.

(1) - *Individual patient nutritional needs must be met in accordance with recognized dietary practices.*

Interpretive Guidelines §482.28(b)(1)

Each hospital patient for whom the hospital is providing one or more meals or nutrition must have their nutritional needs met in a manner that is consistent with recognized dietary practices. Affected patients include all inpatients and those patients in observation status whose stay is sufficiently long that they must be fed. According to the U.S. Department of Agriculture's (USDA) Food and Nutrition Center the nationally recognized source for recommended dietary intakes allowances is the Institute of Medicine Food and Nutrition Board's Dietary Reference Intakes (DRIs), which are designed to provide recommended nutrient intakes for use in a variety of settings. The DRIs are a set of four reference values:

- *Recommended Dietary Allowance (RDA) is the average daily dietary intake of a nutrient that is sufficient to meet the requirement of nearly all (97-98%) healthy persons.*
- *Adequate Intake (AI) for a nutrient is similar to the Estimated Safe and Adequate Daily Dietary Intakes (ESADDI) and is only established when an RDA cannot be determined. Therefore a nutrient either has an RDA or an AI. The AI is based on observed intakes of the nutrient by a group of healthy persons.*
- *Tolerable Upper Intake Level (UL) is the highest daily intake of a nutrient that is likely to pose no risks of toxicity for almost all individuals. As intake above the UL increases, risk increases.*
- *Estimated Average Requirement (EAR) is the amount of a nutrient that is estimated to meet the requirement of half of all healthy individuals in the*

Dietary Services 2015

- The IOM's Food and Nutrition Board's DRI or Dietary Reference Intake 4 reference values includes:
  - RDA or the recommended dietary allowance is average dietary intake of a nutrition sufficient of healthy people
  - Adequate Intake (AI) for a nutrient is similar to the ESADDI and is only determine when an RDA can be determined
    - Estimated Safe and Adequate Daily Intake (ESADDI)
    - AI is based on observed intakes of the nutrient by a group of healthy persons

Dietary Services 2015

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

IOM DRI or Dietary Reference Intake

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

Dietary Reference Intakes (DRIs): Estimated Average Requirements

Food and Nutrition Board, Institute of Medicine, National Academies

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

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

Dietary Guidelines for Americans

Dietary Guidelines for Americans 2010

U.S. Department of Agriculture; Department of Health and Human Services.

Use this science-based nutrition guidance for Americans ages 2 and older to promote healthy lifestyles and dietary habits.

- Dietary Guidelines for Americans 2010. Also in PDF|3 MB.
- Executive Summary (Includes Key Recommendations). (PDF|227 KB)
- Backgrounder. (PDF|40 KB)
- Questions and Answers. (PDF|358 KB)
- Selected Messages for Consumers. (PDF|165 KB)
- Consumer Brochure. (PDF|397 KB)

Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010

U.S. Department of Agriculture; Department of Health and Human Services.

Read about the 2005 Dietary Guidelines for Americans and rationale for changes incorporated into the 2010 release of the Dietary Guidelines for Americans.

2010 Dietary Guidelines Backgrounder: History and Process (PDF | 40 KB)

USDA. Center for Nutrition Policy and Promotion.

Review the history of the Dietary Guidelines for Americans and process for developing the 2010 Dietary Guidelines.

USDA Nutrition Evidence Library (NEL)

USDA. Center for Nutrition Policy and Promotion.

Examine evidence-based systematic reviews which inform Federal nutrition policy and programs. The Library evaluates, synthesizes, and grades the strength of available scientific evidence to support dietary recommendation and guidance.

Watch for Changes in 2015

Menu | Our Work | Dietary Guidelines

http://www.health.gov/dietaryguidelines/

Announcement

Now Available

Scientific Report of the 2015 Dietary Guidelines Advisory Committee

As to be announced in the *Federal Register*, the "Scientific Report of the 2015 Dietary Guidelines Advisory Committee" is now available. Individuals are encouraged to submit written comments to the federal government on the Advisory Report. Written comments will be accepted online through midnight E.D.T. on April 8, 2015.

HHS and USDA will host a public oral comment meeting on March 24, 2015. Meeting registration will open on or around March 9, 2015.

Please direct all media inquiries to ASHMedia@hhs.gov or call (202) 205-0143.

Scientific Report of the 2015 Dietary Guidelines Advisory Committee

Each section of the Advisory Report below links to text for that section. A printable PDF is also provided. *The PDF provides page and line numbers that the public can use when submitting written comments.*

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Letter to the Secretaries – [Download as a PDF - 422KB]

Dietary Guidelines Advisory Committee Membership – [Download as a PDF - 114KB]

Part A: Executive Summary – [Download as a PDF - 283KB]

Part B: Setting the Stage and Integrating the Evidence

- Chapter 1: Introduction – [Download as a PDF - 505KB]
- Chapter 2: 2015 DGAC Themes and Recommendations: Integrating the Evidence – [Download as a PDF - 89KB]

Part C: Methodology – [Download as a PDF - 143KB]

Part D: Science Base

- Chapter 1: Food and Nutrient Intakes, and Health: Current Status and Trends – [Download as a PDF - 5.6MB]
- Chapter 2: Dietary Patterns, Foods and Nutrients, and Health Outcomes – [Download as a PDF - 952KB]
- Chapter 3: Individual Diet and Physical Activity Behavior Change – [Download as a PDF - 276KB]
- Chapter 4: Food Environment and Settings – [Download as a PDF - 607KB]
- Chapter 5: Food Sustainability and Safety – [Download as a PDF - 837KB]
- Chapter 6: Cross-Cutting Topics of Public Health Importance – [Download as a PDF - 305KB]
- Chapter 7: Physical Activity – [Download as a PDF - 603KB]

Interactive DRI Tool and Tables

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- Food Composition
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- Weight and Obesity
- Food Labeling
- Dietary Supplements
- Nutrition Assistance Programs
- Surveys, Reports and Research

Dietary Guidance >

Dietary Reference Intakes

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

Dietary Reference Intake Calculator for Healthcare Professionals

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

DRI Tables

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

DRI Reports

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

Resources on Individual Macronutrients, Phytonutrients, Vitamins and Minerals

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

Dietary Guidance

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

Therapeutic Diet 629 2015

- Therapeutic diets may help meet the patient's nutritional needs
- Assess patients for risk of nutritional deficiencies
- Therapeutic diets refer to a diet ordered as part of the patient's treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet(e.g., sodium or potassium), or to provide mechanically altered food when indicated

Therapeutic Diet 629 2015

- Patients must be assessed to determine if they need a therapeutic diet for other nutritional deficiencies
  - Include in patient's care plan
  - Include the need to monitor intake
  - Include if need daily weights, I&O, or lab values
- Nursing does an admission assessment which includes a nutritional screen
  - These are good things to determine the patient's risk and if a dietary consult is needed

Nutritional Assessment Includes

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

Dietary 2015

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

Therapeutic Diet 629 2015

- Patients who refuse food should be offered substitutes of equal nutritional value in order to meet their basic nutritional needs
- Surveyor will ask dietician how the menus and nutritional needs of patient are being met such as rely on DRIs, including RDA, in developing menus
  - Will ask how patients are monitored who are identified as having specialized needs
  - Will look for order for therapeutic diet
- Will look at sample of patient records of patients identified with special nutritional needs

Diet Order Needed 630 2015

- Standard: Need an order for all patient diets including therapeutic diets
- Must be by practitioner responsible for care (doctor, PA, NP) or qualified dietician or qualified nutritional professional
- Must be authorized in the medical staff bylaws
- Must be consistent with state law
  - A few states hold it against state law for a dietician to prescribe a therapeutic diet

Patient Diets New Tag 630 2015

A-0630
(Rev.)

§482.28(b)(2) - ***All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.***

Interpretive Guidelines §482.28(b)(2)

Patient diets, including therapeutic diets, must be provided in accordance with orders from a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional who is permitted to order diets under State law and authorized to do so by the medical staff.

Diets must be based on an assessment of the patient's nutritional and therapeutic needs and documented in the patient's medical record (including documentation about the patient's tolerance to any therapeutic diet ordered).

The hospital's governing body may choose, when permitted under State law and upon recommendation of the medical staff, to grant qualified dietitians or qualified nutrition professionals diet-ordering privileges. In many cases State law determines what criteria an individual must satisfy in order to be a "qualified dietician;" State law may define the term to mean a "registered dietician" registered with a private organization, such as the Commission on Dietetic Registration, or State law may impose different or additional requirements. Terms such as "nutritionists," "nutrition professionals," "certified clinical nutritionists," and "certified nutrition specialists" are also used to refer to individuals who are not dieticians, but who may also be qualified under State law to order patient diets. It is the responsibility of the hospital to ensure that individuals are qualified under State law before appointing them to the medical staff or granting them

Diet Order Needed 630 2015

- Diets must be based on an assessment of the patient's nutritional and therapeutic needs
- Must be documented in the medical record
- Including patient's tolerance to the therapeutic diet
  - Patient has a new diagnosis of CHF and put on a 2 gram low sodium diet and losses weight because she does not like the taste of the food without salt
- Board may permit the medical staff to grant privileges to dieticians or nutritional professionals

Diet Order Needed 630 2015

- Many states have a specific statute that determines when someone is a qualified dietician
- Registered dietician may be defined to include one who is registered with Commission on Dietetic Registration or state law
- Terms such as “nutritionists,” “nutrition professionals,” “certified clinical nutritionists,” and “certified nutrition specialists” are also used to refer to individuals who are not dieticians, but who may also be qualified under State law to order patient diets.

Diet Order Needed 630 2015

- Hospital must make sure person is qualified before appointing them to the medical staff or C&P
- If the hospital decides not to **C&P,** even if that state's law allows it, the patient must have a diet ordered by the practitioner responsible for the patient's care
- If not C&P the person can still do a nutritional assessment and make recommendations
- Surveyor will make sure diet is ordered and if dietician writes orders is C&P whether appointed to the medical staff or not

Nutritional Needs Survey Procedure 630

- Surveyor is suppose to ask the hospital to show them what national standard they are using
- Surveyor to view patient medical records to verify diet orders are provided as prescribed by the practitioner
- Surveyor is to determine if patient's nutritional needs have been met
- Will determine if dietary intake and nutritional status is being monitored

UR 2015

- There were no changes to this regulation,
- But corrected a guidance to reflect statutory changes to SSA Section 1865
- Based on these statutory changes, any AO seeking CMS approval of its hospital accreditation program must demonstrate that it has standards for UR and that its standards meet or exceed the Medicare standards.
  - Thus, we are removing language indicating that UR CoP compliance must always be assessed by State Survey Agencies since this is no longer the case for deemed status hospitals.

Utilization Review 652

- Hospital must have a UR plan that provides for review of services furnished by the institution and the members of the MS to Medicare and Medicaid beneficiaries
- UR plan should state responsibility and authority of those involved in the UR process
- Surveyor will make sure activities performed as in UR plan
- UR important to determine medical necessity especially with increased RACs
- CMS issue UR CoP Memo June 22, 2007

Composition of UR Committee 654

- Consists of 2 or more practitioners who carry out UR function
- At least 2 members must be doctors
- The UR committee must be either a staff committee of the hospital or an group outside that has been established by the local medical society for hospitals in that locale and established in a manner approved by CMS

UR Committee 654

- A committee may not be conducted by an individual who has a direct financial or ownership interest (5% or more)
- Who was professionally involved in the care of the patient whose case is being reviewed
- Surveyor will look to see if the governing board has delegated UR function to a outside group if impracticable to have a staff committee

Scope of Reviews 655

- Reviews may be on a sample basis except for reviews of cases assumed to outlier cases because of extended stay cases or high costs
- Surveyor will examine UR plan to determine if medical necessity is reviewed for admission, duration of stay and services provided
- If IPPS hospital there should be a review of the duration of stay in cases assumed to be outlier

Admissions or Continued Stay

- Before determination not medically necessary, UR committee must consult the MD responsible for the care and afford opportunity to present their views
- Then committee must provide written notification no later than two days after determination to the hospital, patient and practitioner responsible for care
- Document medical necessity and compliance with the 2 midnight rule

This presentation is intended solely to provide general information and does not constitute legal advice. Attendance at the presentation or later review of these printed materials does not create an attorney-client relationship with the presenter(s). You should not take any action based upon any information in this presentation without first consulting legal counsel familiar with your particular circumstances.

The End! Questions???

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