AHC Media

April 15, 2016

Revised CMS Guidelines for Medical Staff & Board Changes

Speaker

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Objectives

- Describe the CMS change permitting hospitals to have a separate medical staff or an integrated medical staff.
- Interpret the CMS change allowing Medical Staff to credential qualified dieticians to order patient diets.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

History of Changes to the Hospital CoPs

- President Obama had issued an Executive Order 13563, January 18, 2011, entitled "Improving Regulation and Regulatory Review"
- This was implemented to **reduce** the procedural burden on hospitals. Hospitals have been frustrated by the increasing number of federal laws and regulations
- CMS says these changes will save hospitals and healthcare providers $676 million dollars a year and $3.4 billion over five years

CMS History of Changes

- First, CMS issues 114 pages of proposed changes to the CMS CoPs on February 4, 2013 called phase 1
- This comes on the heels of more than two dozen changes that were effective June 7, 2013
  - Changes to standing orders, verbal orders, IV medication and blood transfusions, medical staff, board etc.
- For more than 2 years, hospitals have seen a increasing number of new changes and additions to the hospital CoP manual
- A new twist was to actually eliminate ones that were out of date or no longer needed

Feb 4, 2013 History of Proposed Changes

CMS-3267-P

This document is scheduled to be published in the Federal Register on 02/07/2013 and available online at http://federalregister.gov/a/2013-02421, and on FDsys.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

www.ofr.gov/inspection.aspx

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

[CMS-3267-P]

RIN 0938-AR49

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would reform 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).

CMS Publishes Final Changes

- CMS published the final changes in the Federal Register (FR) on May 12, 2014 and effective on July 11, 2014
- CMS took the final regulatory changes and added interpretive guidelines
  - Advance copy IGs issued Sept 15, 2014 and final Sept 26, 2014 and the rest were final in April of 2015
- CMS published the memo on the **CMS survey and certification website**
- Reserves the right to tinker with the language and when final will publish in a **transmitta**l and put the final section in the CMS CoP manual

CMS Publishes Final Changes

- In final rule, CMS estimates cost safety to be nearly $660 million annually or $3.2 billion over five years
- The name of the federal rule was “Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II”
  - The final rule is 201 pages long
- The final changes are located at the end of the document
- The rule explains the decision making process and addresses comments sent

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Press releases

Return to Newsroom Center

Press release: Reforms of regulatory requirements to save health care providers $660 million annually

Date	2014-05-07
Title	Reforms of regulatory requirements to save health care providers $660 million annually
For Immediate Release	Wednesday, May 07, 2014
Contact	press@cms.hhs.gov

Reforms to Medicare regulations identified as unnecessary, obsolete, or excessively burdensome on hospitals and other health care providers will save nearly $660 million annually, and $3.2 billion over five years, through a rule issued today by the Centers for Medicare & Medicaid services (CMS).

Together with another rule finalized in 2012, this rule is estimated to save heath care providers more than $8 billion over the next five years. This final rule supports President Obama's unprecedented regulatory retrospective review—or "regulatory lookback"— initiative, where federal agencies are modifying, streamlining or eliminating excessively burdensome and unnecessary regulations on business.

"By eliminating stumbling blocks and red tape we can assure that the health care that reaches patients is more timely, that it's the right treatment for the right patient, and greater efficiency improves patient care across the board," said CMS Administrator Marilyn Tavenner.

This rule helps health care providers to operate more efficiently by getting rid of regulations that are out of date or no longer needed. Many of the rule's provisions streamline health and safety standards health care providers must meet in order to participate in Medicare and Medicaid.

Final Regulation 201 Pages

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

Federal Register Effective July 11, 2014

www.gpo.gov/fdsys/pkg/FR-2014-05-12/pdf/2014-10687.pdf

FEDERAL REGISTER

Vol. 79 Monday,
No. 91 May 12, 2014

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, 440 et al.
Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II; Final Rule

CMS Issues Advance Copy and Now Final

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-45-Hospital

DATE: **September 15, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Guidance Related to New & Revised Hospital Governing Body and Medical Staff Regulations

Memorandum Summary

- ***Guidance Updated:*** The Centers for Medicare & Medicaid Services (CMS) has updated its Hospital interpretive guidelines in State Operations Manual (SOM) Appendix A to reflect recent amendments to the Governing Body and Medical Staff Conditions of Participation (CoPs) as well as to make technical corrections, and clarify and update selected portions of the guidance.
- ***Effective Dates:*** The revised regulations were effective July 11, 2014.

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.p

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

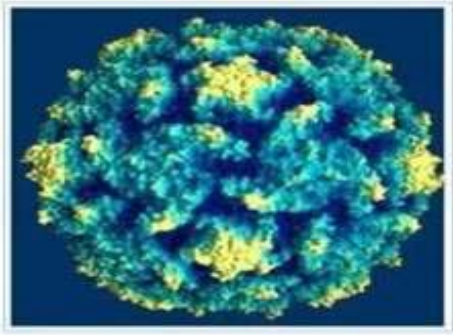
Rehabilitation Hospital Survey Module

Inpatient Rehabilitation Unit Survey Module

Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines

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



How to Keep Up with Changes

- First, periodically check to see you have the most current CoP manual[1]
- Once a month go out and check the survey and certification website [2]
- Once a month check the CMS transmittal page [3]
- Have one person in your facility who has this responsibility

1 http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf

2 http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

3 http://www.cms.gov/Transmittals

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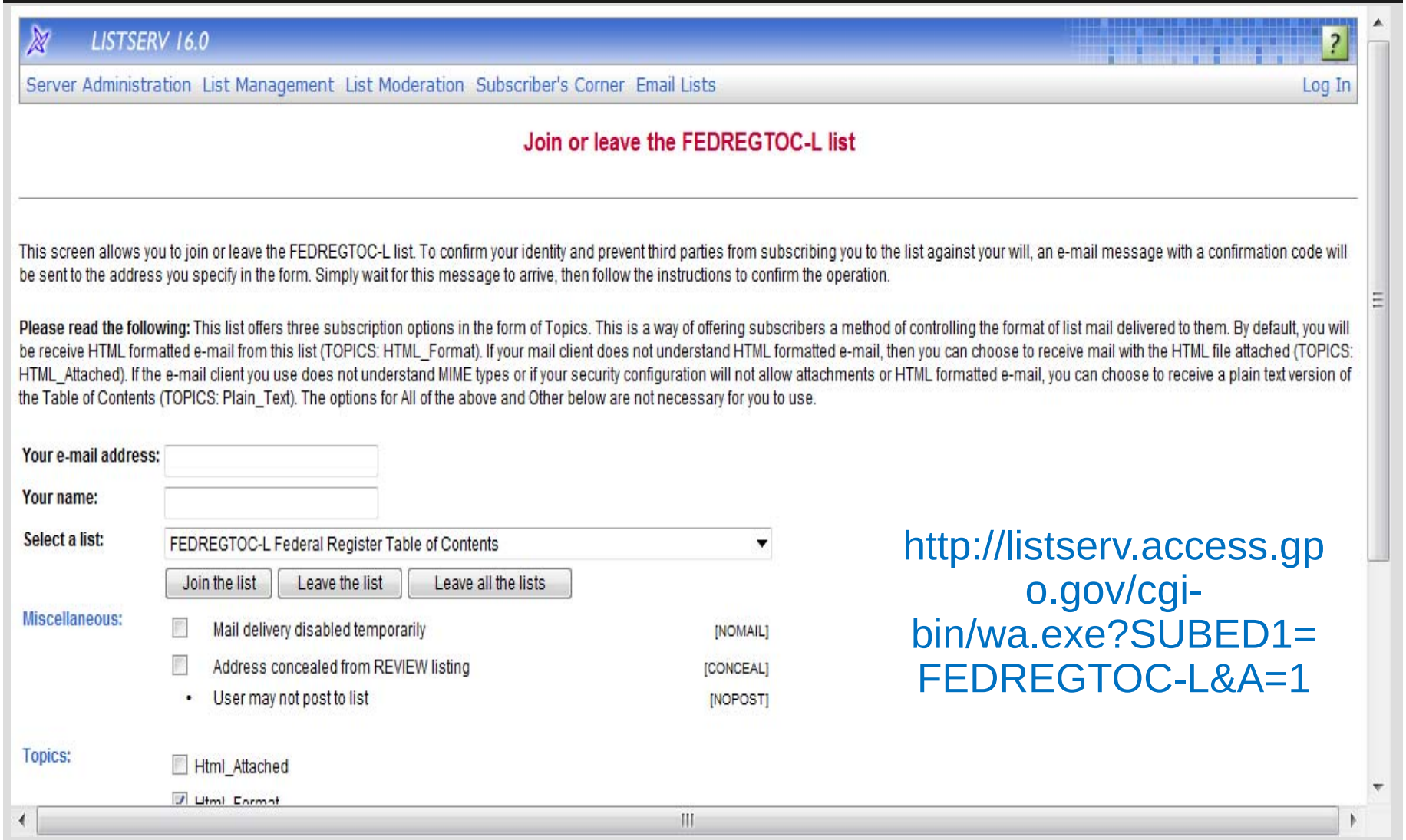
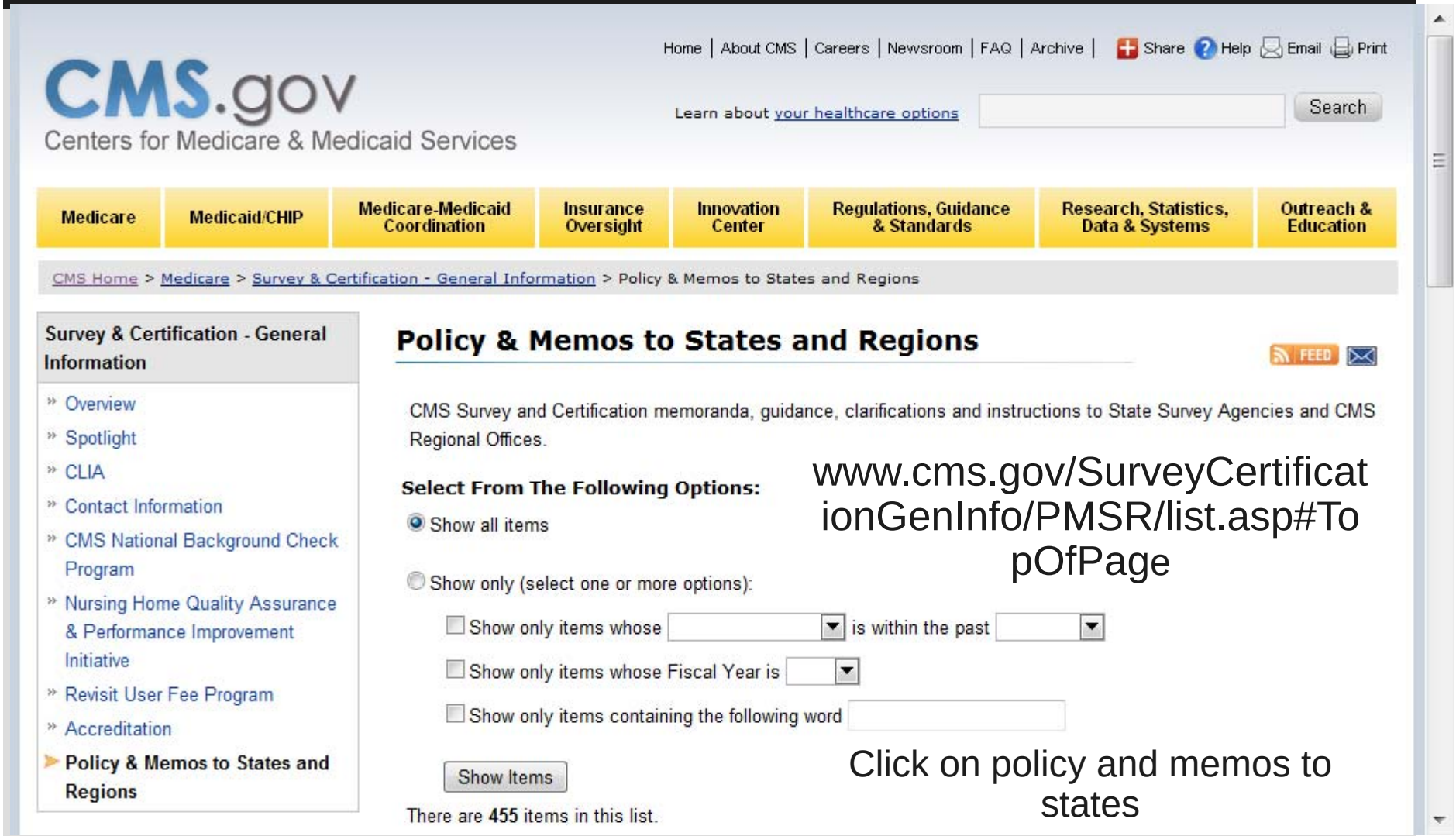


http://listserv.access.gpo.gov/cgi-bin/wa.exe?SUBED1=FEDREGTOC-L&A=1

CMS Survey and Certification Website



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

Click on policy and memos to states

CMS Policy & Memo to States

Policy & Memos to States and Regions

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

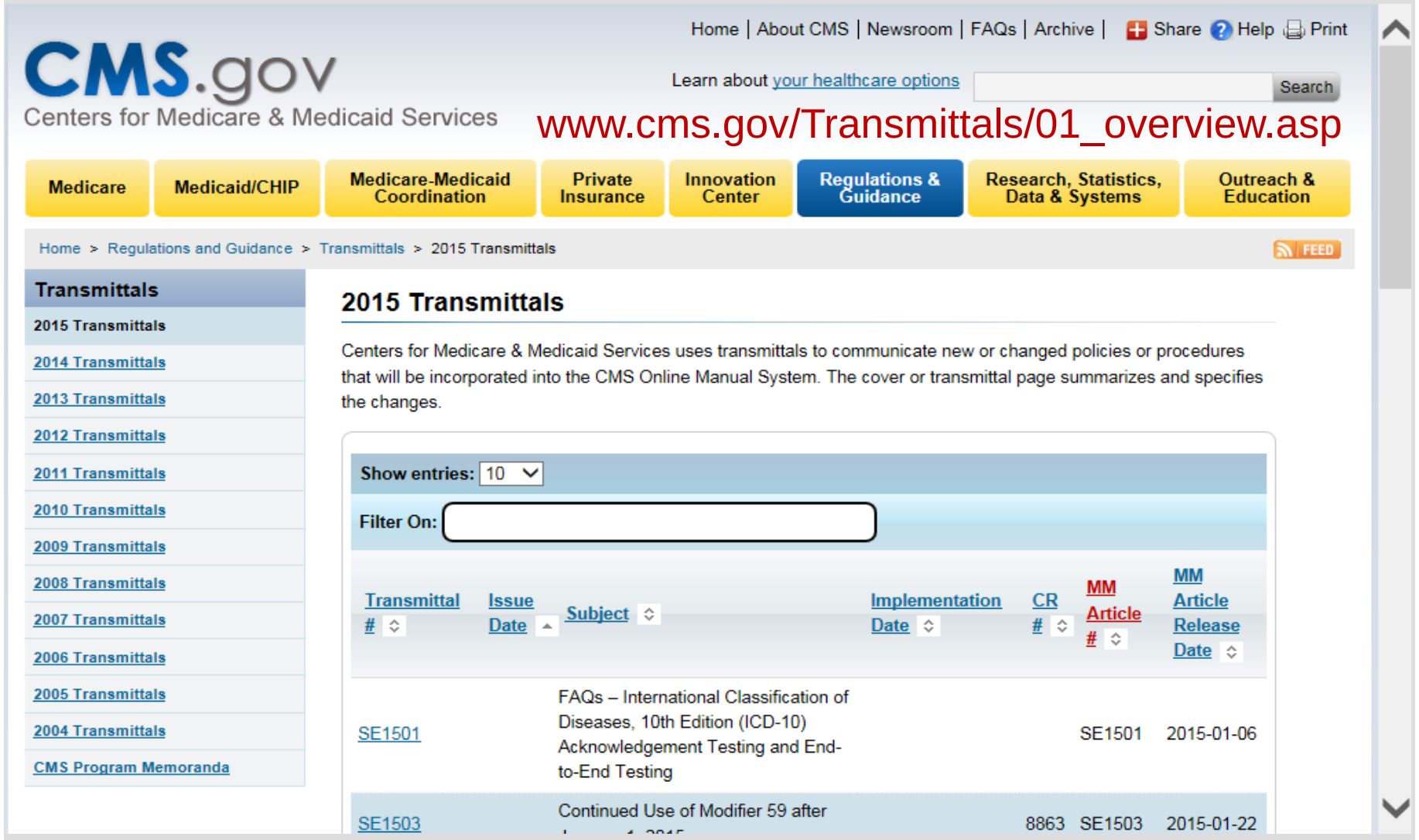
www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

Show entries: 10

Filter On:

Title	Memo #	Posting Date	Fiscal Year
Final Rule: SNF Medicare FY 2016 Payments, Quality Reporting, Value-Based Purchasing and Staffing Data Collection Requirements – Informational Only	15-49-NH	2015-08-07	2015
Publication of Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Proposed Rule (CMS-3260-P) – Informational Only	15-46-NHs	2015-07-17	2015
Medication-Related Adverse Events in Nursing Homes	15-47-NH	2015-07-17	2015
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) Appendix J, Part II - Clarifications to the Interpretive Guidance at Tag W187 for §483.430(d)(3)	15-48-ICF/IID	2015-07-17	2015
Advanced Copy - Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)	15-43-ASC	2015-06-26	2015
Use of Portable Reverse Osmosis (RO) Units and Block Carbon	15-44-ESRD	2015-06-26	2015

Transmittals



Location of CMS Hospital CoP Manual

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

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

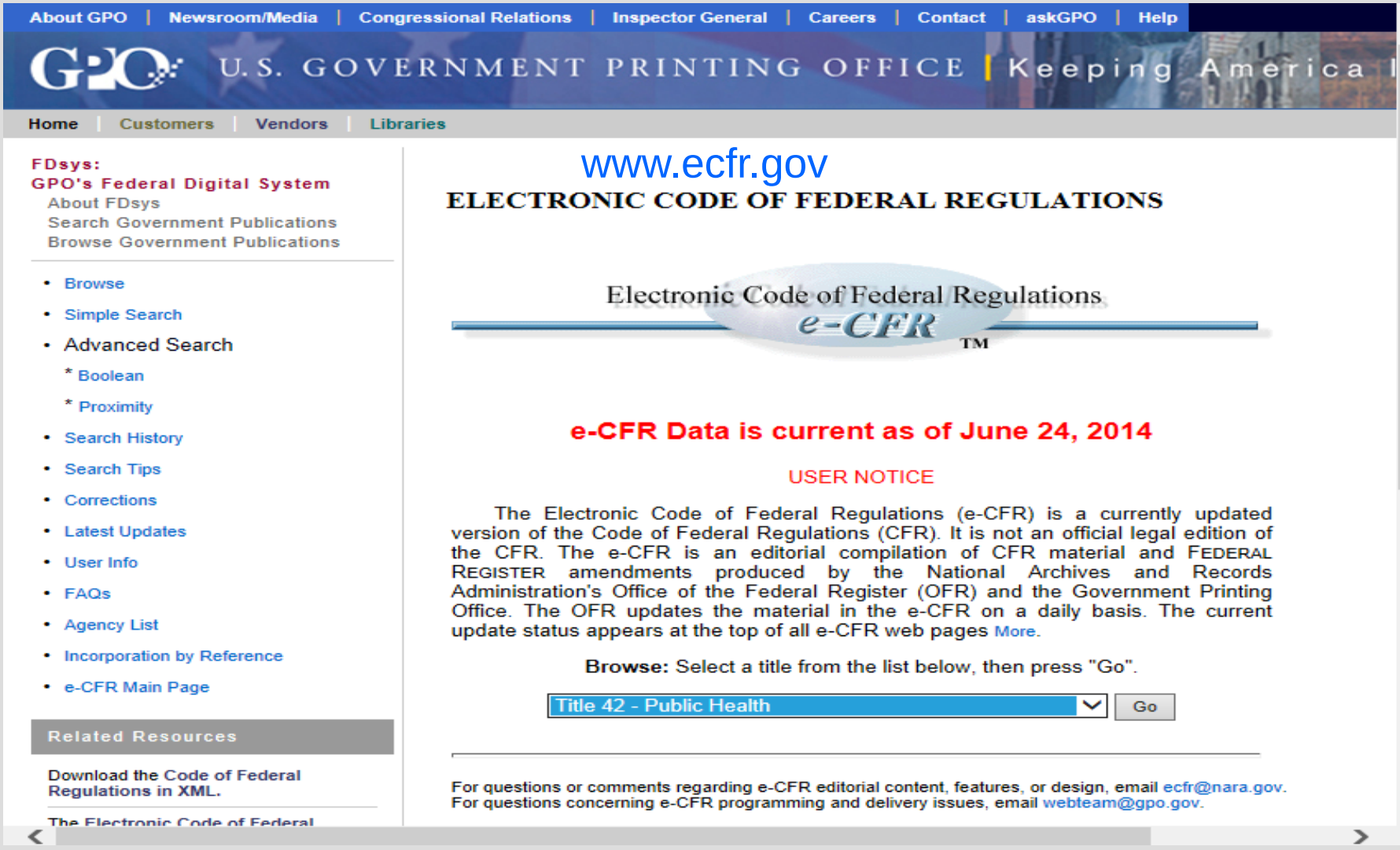
App. No.	Description	PDF File
A	Hospitals	2,185 KB
AA	Psychiatric Hospitals	606 KB

Overview of Changes in a Nutshell

Changes to Hospital Sections

- Governing Body (§ 482.12)
- Medical Staff (§ 482.22)
- Food and Dietetic Services (§ 482.28)
- Nuclear Medicine Services (§ 482.53) which CMS completely rewrites July 10, 2015
- Outpatient Services (§ 482.54)
- Special Requirements for Hospital Providers of Long-term Care Services (“swing-beds”) (§ 482.66)

Free Access to e-CFR



The CMS Conditions of Participation (CoPs) Changes for Dietary and Nutrition Services

CMS Final Interpretive Guidelines

- CMS issues survey memo dated January 30, 2015 to implement final dietary guidelines to the federal regulation and final April 1, 2015
- CMS rewrites tag number 628 (deleted), 629 and 630
- Explains process for hospitals that want to C&P their qualified dieticians or qualified nutritional specialist to order the patient's diet
- So diet can be ordered by practitioner responsible for the patient's care or a qualified dietician or nutritional specialist who is C&P

Dietary and Nutrition Services

- So the final changes allow the board and medical staff to allow registered dietitians (RDs) or nutritional specialist (QNS) to order patient diets independently in hospitals
- Which they are trained to do
- Without requiring the supervision or approval of a physician or other practitioner
- Can order lab tests to monitor effectiveness of the diet plan and modify diet based on lab tests

Dietary and Nutrition Services

- In the past the physician or LIP would order a consult with the dietician to make recommendations
  - Then the dietician or nurse would have to call the physician or LIP for the verbal order
  - If the staff waited until the next day to get the order when the physician came in the hospital was at risk for getting a deficiency
- The practitioners would have to be interupted
- The verbal order would have to be signed off which is another problematic standard
- When they adopted the recommendation anyway

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 qualified dietician 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)
- 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 and cannot just be done by policy

CMS Changes Food & Dietetic Services

- Must be consistent with state law as state can determine scope of practice
- State can determine the credentials and qualifications for dietitians and nutrition professionals
- MS could privilege speech-language pathologist who may order diet texture modification for patients with significant swallowing problems
- MS is not required to provide privileges but has the flexibility to do so if they choose

Ordering Privileges Resources

- The Academy of Nutrition and Dietetics has a 13 page resource on credentialing and privileging (C&P) so the dietician can order the patient's diet
- Also has a resource called "Practice Tip: Hospital Regulation-Ordering Privileges for the RDN"
- Privileging is optional- a hospital is not required to do but can if it wants to and must be consistent with state law
  - If the dietician is not C&P then cannot order the patient's diet which include therapeutic diet, TPN, or supplemental feedings
  - Can't just implement a P&P by the hospital

Ordering Privileges Resources

Academy of Nutrition and Dietetics

July 16, 2014

PRACTICE TIPS: Implementation Steps – Ordering Privileges for the RDN

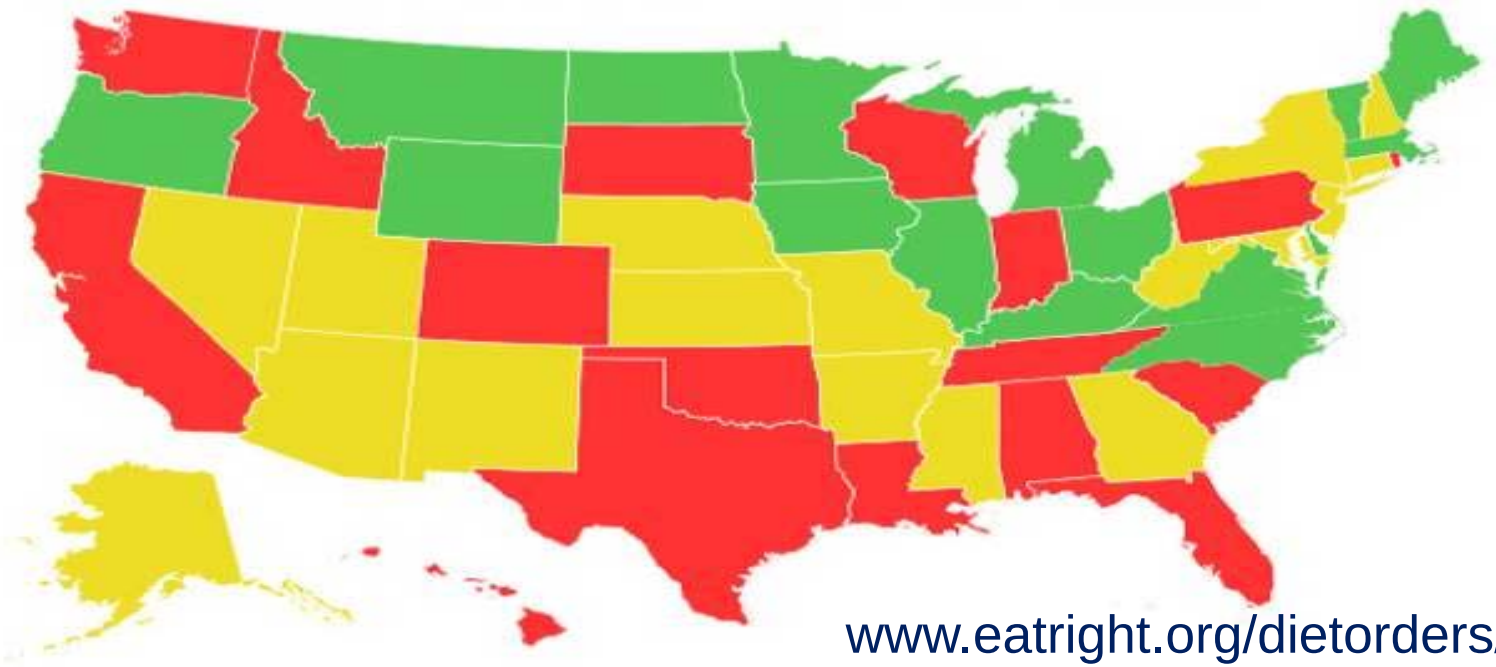
Table of Contents

Step 1: Review the May 12, 2014 Federal Register Final Rule effective July 11, 2014[1].

1. Learn more: http://www.gpo.gov:80/fdsys/pkg/FR-2014-05-12/pdf/2014-10687.pdf
   a) Final Rule for Regulatory Reforms Impacting Hospital Conditions of Participation (CoPs)
   b) Agency: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS)

   Review the companion **Practice Tip: Hospital Regulation - Ordering Privileges for the RDN** that reviews the key elements of the Final Rule for Regulatory Reforms by the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS) which set the

Therapeutic Diet Orders: State Status and Regulation



www.eatright.org/dietorders/statestatus/

The below chart is a resource for Academy members considering seeking privileges to order therapeutic diets in the hospital setting. We have sought to identify all relevant statutes and regulations related to therapeutic diet ordering in each state and provide a brief analysis of each state's relevant law. In the event that state regulators perceive additional statutes or regulations to be relevant, we are available to work with affiliates. We encourage RDNs to become familiar with their relevant state regulations and statutes, including the interpretation of the extent of their scope of practice.

States are color coded in a stoplight fashion to indicate:

Green:
There do not appear to be statutory or regulatory impediments to qualified RDNs seeking hospital privileges to order therapeutic diets.

Yellow:
There are not definitive impediments to obtaining privileges. However, certain statutory or regulatory language exists leading us to recommend affiliates work with state regulators to ensure their interpretation of relevant statutes and regulations will enable qualified RDNs to see privileges for therapeutic diet.

Red:
Specific statutory or regulatory impediments exist that preclude RDNs from taking full advantage of the opportunities presented by the revised CMS rule.

Board and Medical Staff Changes

Medical Staff and Board Issues

- Addresses the following:
  - Medical staff on the board
  - Board consult with the President of the MS
  - Unified and integrated MS
  - Medical staff matters and having non-physician members on the medical staff

Medical Staff on the Board

- CMS initially said that there had to be a physician on the board
- This was rescinded and in the final regulation affirms this
  - Although hospitals are permitted to do so
  - Most hospitals have a physician on their board
- Comments included that some board members are elected
  - There was concern that if the physician was not elected the hospital would be out of compliance with the hospital CoPs
  - In some this was a state law conflict

Board Direct Consult with CMO

- What are the unique needs of the patient population
- So CMS requires instead for the board to directly consult with the individual responsible for the medical staff of the hospital who is responsible for the conduct of the medical staff
- It also states it can be their designee
- This confirms the proposed rule and make it final that the board needs to consult with the individual
  - Such as chief medical officer (CMO) or the president of the medical staff

Board Direct Consult

- This is done to ensure coordination and communication between the medical staff and the board so as to get the MS perspective on the quality of care
- The consultation would be of matters related to the quality of the medical care
- Board needs to determine the number of consultations based on factors specific to the hospital
  - Recommends at least **twice a year**
  - Factors include scope and complexity of services provided, issues of patient safety, QAPI program

Board Direct Consult

- CMS said would expect to see evidence that the board or governing body is appropriately responsive to any **periodic and/or urgent requests** from this person
  - Meaningful communication and direct communication as face to face meeting or via telecommunications
- If in a system, the board needs to consult with the person from **each** hospital
- CMS discusses the importance of medical staff input on the board is important to continuing quality of patient care

Board Direct Consult

- Just having a medical staff member on the board does not met this standard
- However, if the physician is the one responsible for the conduct of the medical staff it would meet the standard
- Board would also need to make sure it included on the agenda discussing matters quality of care issues related to the medical care
- CMS acknowledges many ways in which this can be met such as use of a committee structure or simultaneous conversations with the leader

Board Final New Language

- There must be an effective governing body that is legally responsible for the conduct of the hospital (Tag 43)
- If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body
- Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee

Board Meetings with CMO Final Language

- At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year
- It must include discussion of matters related to the quality of medical care provided to patients of the hospital.
- For a multi-hospital system using a single governing board, the single multi-hospital system, the Board must consult directly with the individual responsible for the organized MS (or his or her designee) of each hospital within its system in addition to the other requirements of this paragraph (a).
- * *

Composition of the Medical Staff

- Accomplished what CMS had been trying to do since 2013
- This section talks about who can be on the Medical Staff
  - It must be consistent with state law
- The MS can appoint non-physicians to be on the MS
- It would have to be approved by the board
  - APN, RD, PA, Pharm.D, qualified nutritional specialist, etc.

Composition of the Medical Staff

- Medical staff must consist of :
- Either MD or DOs
  - Although MS comprised predominately of physicians
- May include other categories of physicians
  - Such as dentists, podiatrists, clinical psychologists, optometrists and chiropractors
- And may include non-physicians
  - Such as advanced practice providers (APRN), physician assistants (PA), registered dietitians (RD), doctors of pharmacy (Pharm.D) etc.

Composition of the Medical Staff

- Such appointments must be within state regulatory boundaries and approved by the governing body
- CMS believes this provides for great flexibility to enlist the services of non-physician providers to carry out the patient care duties they are trained and licensed to do
- CMS changed the term “non-physician practitioners” to just “other practitioners”
  - Dentist, optometrists, podiatrist, or chiropractors are considered “doctors” under the broad term and they can be members of the medical staff

Composition of the Medical Staff

- CMS said that there is expectation is that all practitioners granted privileges are also members of the medical staff
- As long as state law allows
- However, there is nothing to prohibit medical staff from C&P them but excluding them from MS membership
- As long as state law allows and within their state scope of practice
- MS still needs to make sure they are competent

Medical Staff Final Language

- The hospital must have an organized MS that operates under bylaws, approved by the board, and which is responsible for the quality of medical care provided to patients by the hospital (Tag 338)
- MS must be composed of MDs and DOs
- The MS may also include other categories of physicians and non physicians who are deemed to be eligible to be on the MD
  - Must be consistent with their state scope of practice such as PAs, NPs, and PharmD

Medical Staff Final Language

- The medical staff may also include other categories of physicians (Tag 339)
  - Such as dentists, podiatrists, optometrists, or chiropractors
- The medical staff may include non-physicians determined to be eligible for appointment by the governing board
  - Such as physician assistants (PAs), Nurse Practitioner (NP), Clinical nurse specialist (CNS), Certified registered nurse anesthetist (CRNA), Registered dietician(RD) or nutrition professional, and PharmD

Unified and Integrated Medical Staff

- In a very surprising move, CMS said that a hospital could have a unified and integrated medical staff
- Previously, while CMS allowed hospitals in system to share a board, they required that every hospital had to have a separate medical staff
- This change gives hospitals flexibility and CMS does not mandated one way or the other
  - Some commentators felt that sharing a MS improves peer review process, patient safety through shared C&P, more efficient sharing of knowledge and innovation, consistency with ACO and modern delivery systems, and better on-call coverage

Unified and Integrated Medical Staff

- Option is open to multi-hospital systems
- CMS notes many hospitals have been doing this for years
- CMS looks at evidence to show hospitals with shared medical staff have had success in reducing HACs, HAIs, and improved patient safety and outcomes
- CMS did set some basic parameters
- Hospital must have an organized MS that operates under bylaws approved by the board

Unified and Integrated Medical Staff

- Would consist of MS from each hospital in the system
- Each member would be eligible to take on a leadership role on various committees just as if they are part of a single medical staff
- Neither board nor the MS can impose its will unilaterally and new provisions are aimed at:
  - First, every hospital MS in each certified hospital, must have voted by majority, to either accept or reject a shared medical staff

Unified and Integrated Medical Staff

- The shared MS has P&P to ensure that the needs of the separately certified hospitals are given due consideration and localized issues are discussed
- Second, the unified and integrated MS has bylaws, rules and requirements which describe the process for self governance, appointment, C&P, oversight and peer review
  - This must include a process for the MS at each hospital to be advised of their right to opt out of the structure by majority vote and return to a separate and distinct MS

Unified and Integrated Medical Staff

- Third, the need to share a medical staff takes into account each hospital's unique circumstances and differences in populations
  - Such as low income or minority populations, rural populations, etc.
- And services offered in each hospital
  - Such as emergency services, psychiatric services, pediatric care, long term acute care, organ transplant services, dialysis, etc.

Unified and Integrated Medical Staff

- Fourth, The unified and integrated MS gives due consideration to the needs and concerns of members of the medical staff,
- Regardless of practice or location,
- The MS have mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed
  - Note that each hospital must still comply independently with all of the hospital Cops such as the QAPI requirements and infection control requirements

Unified and Integrated MS Final Language

- If a hospital is part of a hospital system consisting of multiple separately certified hospitals
- And the system elects to have a unified and integrated medical staff for its member hospitals,
- After determining that such a decision is in accordance with all applicable State and local laws,
- Each separately certified hospital must demonstrate that:

Unified and Integrated MS Final Language

- The MS members of each separately certified hospital in the system
- That is, all MS members who hold specific privileges to practice at that hospital
- Have voted by majority, either to accept a unified and integrated medical staff structure
- Or have voted to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital
  - In accordance with MS bylaws,

Unified and Integrated MS Final Language

- The unified and integrated MS has bylaws, R&R that describe its processes for self-governance, appointment, credentialing, privileging, and oversight,
- As well as its peer review policies and due process rights guarantees,
- And which include a process for the members of the MS each separately certified hospital to be advised of their rights to opt out of the unified and integrated MS structure after a majority vote by the members

Unified and Integrated MS Final Language

- That is, all MS members who hold specific privileges to practice at that hospital
- The unified and integrated MS is established in a manner that takes into account each member hospital's unique circumstances
- And any significant differences in patient populations and services offered in each hospital and

Unified and Integrated MS Final Language

- The unified and integrated MS establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the MS
- At each of its separately certified hospitals, regardless of practice or location,
- Are given due consideration, and that the unified and integrated MS has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed

CMS Issues Advance Copy

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-45-Hospital

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- ***Effective Dates:*** The revised regulations were effective July 11, 2014.

Added or Amended Sept 2014 Memo

- MS must examine the credentials of all eligible candidates for MS membership and make recommendations to the board on the appointment of the candidates in accordance with
  - State law, including scope-of-practice laws, and the MS bylaws, rules, and regulations
- A candidate who has been recommended by the MS and who has been appointed by the board is subject to all MS bylaws, rules, and regulations, in addition to the requirements contained in this section

Added or Amended Sept 2014 Memo

- Hospitals and their MS have flexibility to determine which categories of MS members have voting rights and what constitutes a “majority” for purposes of voting whether to accept or opt out of a unified MS
  - MS must not set up bylaws that are unduly restrictive of the MS’s rights
- To opt out of whether to have a unified MS, a majority of the entire MS must be more than 50%
  - Vote cannot be limited only to the MS executive committee but must be available to all members of the staff who hold specific privileges to practice at the hospital and who have voting rights

Added or Amended Sept 2014 Memo

- Some hospitals thought you could have a shared MS prior to July 11, 2014
- It is not necessary for hospitals who have been doing this before July 11, 2014 to hold a MS vote
- However, hospital does need to formally notify the MS of the board's desire to continue this as well as the right of the staff to vote on whether to opt out and have a separate MS
- CMS provided an advance copy of the interpretive guidelines but reserve the right to make changes which are now final as published in the CoP manual

Blue Box Advisory

For Information Only – Not Required/ Not to be Cited

CMS expects that all practitioners granted privileges are also appointed as members of the medical staff. However, if State law limits the composition of the hospital's medical staff to certain categories of practitioners, e.g., only physician practitioners, there is nothing in the CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for those specific categories of non-physician practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with State law. (79 FR 27114 - 27115, May 12, 2014)

For non-physician practitioners granted privileges only, the hospital's governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those non-physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

Added or Amended Sept 2014 Memo

- Practitioners generally C&P:
  - PA, NP, CNS (clinical nurse specialist), CRNA, CNM (midwife), clinical SW, AA (anesthesiology assistant), RD or nutrition specialist
- Practitioners generally not C&P:
  - Physical therapist, occupational therapist, and speech language therapist
- Must follow state scope of practice for pharmacists who provide patient care
- May be granted active, courtesy, emergency, temporary, etc as per MS bylaws and state law

Outpatient Services

Outpatient Services

- The CMS Outpatient section starts at Tag Number 1076
- It is important to note that the outpatient section also underwent changes on June 7, 2013 to Tag 1079 and 1080
- The issue regards who can order outpatient tests and services
- The person does not have to be a member of the Medical Staff
- CMS has added a new standard

Outpatient Services Tag 1079

A-1079
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§482.54(b) Standard: Personnel

The hospital must --

(1) Assign one or more individuals to be responsible for outpatient services.

(2) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

Interpretive Guidelines §482.54(b)

The hospital's outpatient services may be directed by one or more individuals. Hospitals have the flexibility to determine how best to organize their outpatient services, including how direction will be provided. As services offered in outpatient departments become more varied, complex and technologically advanced, hospitals may find it better to have individuals with more specialized expertise providing direction for a specific type of outpatient services.

Hospitals should define in writing the qualifications and competencies necessary for their outpatient services department leader(s). These qualifications should include items such as education, experience, and specialized training consistent with State law and acceptable standards of practice.

The hospital should define in writing the qualifications and competencies necessary to direct each outpatient service for which there is a separate director. Qualifications

Tag 1080 Outpatient Services

Orders for outpatient services may be made by any practitioner who is:

- Responsible for the care of the patient;
- Licensed in, or holds a license recognized in, the jurisdiction where he/she sees the patient;
- Acting within his/her scope of practice under State law; and
- Authorized by the medical staff to order the applicable outpatient services under a written hospital policy that is approved by the governing body. This includes both practitioners who are on the hospital medical staff and who hold medical staff privileges that include ordering the services, as well as other practitioners who are not on the hospital medical staff, but who satisfy the hospital's policies for ordering applicable outpatient services.

The hospital's medical staff policy for authorizing practitioners to refer patients to the hospital with orders for specific outpatient services must address how the hospital verifies that the referring/ordering practitioner who is responsible for the patient's care is appropriately licensed and acting within his/her scope of practice. The policy must also make clear whether the policy applies to all hospital outpatient services, or whether there are specific services for which orders may only be accepted from practitioners with

Orders for Outpatient Services

- This standard codifies the interpretive guidelines that were recently made
  - Allowed practitioners to order outpatient rehab without requiring them to be a member of the hospital's medical staff as discussed in a CMS memo in 2011
  - CMS received feedback to expand the categories of practitioners who could order outpatient rehab and respiratory therapy services beyond physicians
  - As discussed, CMS made two changes to the outpatient standards on June 7, 2013 which clarified that outpatient services can be provided by any practitioner responsible for the patient's care as long as within state law and scope of practice and approved by the MS and board

Previous CMS Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 02-02-38
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-28-Hospitals
REVISED 05.20.11

DATE: **May 13, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: State Operations Manual (SOM) Hospital Appendix A Update

***** In the attached SOM Transmittal, the reference to 484.24 is changed to 482.24 for Tag A-1164. The change is highlighted in yellow color*****

Memorandum Summary

SOM Hospital Appendix A Updated

- Revisions have been made to reflect regulation changes governing orders for rehabilitation (42 CFR 482.56) and respiratory care services (42 CFR 482.57)
- Clarifications have been made for provisions related to:
  - Nursing requirements related to blood transfusions and intravenous medications (42 CFR 482.23(c)(3))
  - Immediate reporting of medication administration errors, adverse events, and incompatibilities (42 CFR 482.25(b)(6))

Background

The final FY 2011 Inpatient Prospective Payment System (IPPS) rule was published on August 16, 2010 (*75 FR 50042*) and effective on October 1, 2010. The FY 2011 IPPS final rule

Outpatient Services

- Wanted to clarify who may order such services
- Allows any practitioner to order outpatient services who is responsible for the patient's care
  - Must be licensed in the state and
  - Person must be within their scope of practice under state law
    - For example, the nursing board in each state generally determines the scope of practice for an APN while the medical board determines the scope for a PA

Orders for Outpatient Services

- Must be authorized to order the outpatient test by the MS and approved by the board
- Practitioner does **not** have to be credentialed and privileged by the hospital
- Must be in accordance with P&P approved by the MS and board
- Residents and interns can order as part of their training program

- Unless there is a more strict standard such as nuclear med can only be ordered by practitioner whose scope of licensure allows

Orders for Outpatient Services

- Hospital would need to verify the practitioner's licensure before providing the outpatient service
- Most medical boards you can check online for verification
- Most state boards of nursing have online verification process for APN
  - Considered primary source verification
  - Can print out information for employee file
- Note don't forget to check the OIG list of excluded individuals (LEIE) and document it

Verification of Nursing License

- Most state boards of nursing have online verification process
  - Considered primary source verification
  - Can print out information for employee file
  - Don’t forget to check the OIG list of excluded individuals (LEIE) and document it in the HR file for nurses

LEIE Downloadable Database

Orders for Outpatient Services

- Allows a physician to order nuclear medicine tests without being C&P as long as MS P&P allow this
- CMS says not uncommon for physician not on the MS to refer their patients to the hospital for common outpatient nuclear medicine tests, such as myocardial perfusion scans used in conjunction with cardiac stress tests and hepatobiliary scans used in the detection of gallbladder disease
- Would allow other services by the physician without privileges such as outpatient chemo

Orders for Outpatient Services

- Bottom line is that the hospital gets to decide (MS and board) what type of outpatient services they are comfortable in providing based on an order or referral
- Hospitals now have flexibility to decide whether or not they will allow a practitioner who is not a member of the MS to order outpatient services
- If hospital unable or unwilling to verify the state scope of practice then hospital is not required to allow the practitioner to order the outpatient tests

Outpatient Final Language

- Standard: Orders for outpatient services. Outpatient services must be ordered by a practitioner who meets the following conditions:

(1) Is responsible for the care of the patient

(2) Is licensed in the State where he or she provides care to the patient

(3) Is acting within his or her scope of practice under State law

Outpatient Final Language

(4) Is authorized in accordance with State law and policies adopted by the MS, and approved by the governing body, to order the applicable outpatient services

- This applies to the following:
- (i) All practitioners who are appointed to the hospital's MS and who have been granted privileges to order the applicable outpatient services

Outpatient Final Language

- (ii) All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the MS and the hospital for ordering the applicable outpatient services for their patients
- Outpatient section starts at Tag 1079 and includes Tag 1080

Summary of Changes

- Medical Staff (MS) can grant hospital privileges for RD or nutrition specialist to write diet orders
  - Includes diet orders, TPN, or supplemental feeding
- Board must consult with and individual responsible for the MS for each individual hospital regarding quality of medical care provided in the hospital and suggest at least twice a year
  - Such as the chief medical officer or MS president
- Each hospital can have separate medical staff or shared which CMS calls a unified integrated medical staff with specific rules in a multi hospital system

Summary of Changes

- CMS revised the definition of physician in the rural health center (RHC)/federally qualified health center (FQHC) regulations to conform to the definition of a “physician” to be the same as the term used for M/M payments
- Medical Staff can include PharmD, registered dieticians, PA, NP, dentist, podiatrist, speech pathologist, etc.
  - Must be consistent with state scope of practice and state law

Summary of Changes

- No requirement for board to include MD/DO
- Allow in-house preparation of radiopharmaceuticals by trained nuclear medicine technicians in hospitals on off hours without a physician or a pharmacist being present
  - Removed the wording of direct supervision but still under their supervision
- Changes for hospitals that are transplant centers by eliminating a redundant data submission requirement and an unnecessary survey process while maintaining strong federal oversight

Summary of Changes

- Swing beds move to Part D so accreditation organizations
  - TJC, AOA HCFA, DNV Healthcare or CIHQ
- CAH P&P committee deleted requirement for non staff member requirement on P&P committee
- CMS removed the requirements that the CAH had to have a physician present once every two weeks
  - Includes RHC and FQHCs
  - Must still have a physician onsite for sufficient periods of time depending on the needs of both the patient and the facility

Summary of Changes

- Made a change to the CLIA law regarding proficiency testing referrals
- ASC change for radiology services incident to the surgery
  - ASC use to have to follow the radiology standard in the hospital manual which didn’t make any sense for an ASC
  - Reduces oversight and supervision requirements and allows individuals other than radiologist to provide supervision

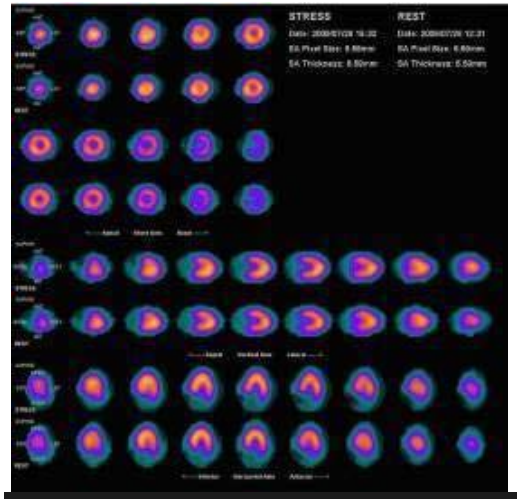
Summary of Changes

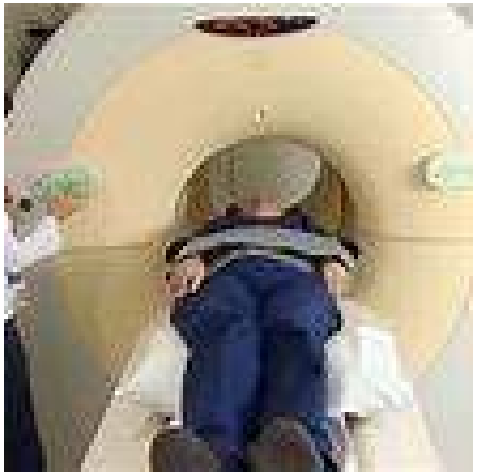
- Allow practitioners not on MS to order outpatient services
  - Must have policy to specify which tests can be ordered
  - Must be licensed in state where care is provided
  - Must be acting within scope of practice under state law
  - Must be allowed by the MS
  - Confirms its prior interpretation regarding who can order outpatient orders under tag 1079 and 1080
- Questions contact Lauren Oviatt at 410 786-4683 at CMS

The End! Questions???

- Sue Dill Calloway RN, Esq. CPHRM, CCMSCP
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Education Consulting
- 5447 Fawnbrook Lane
- Dublin, Ohio 43017
- 614 791-1468 (Call with questions, No emails)
- sdill1@columbus.rr.com
- Additional resources

Hospital Supervision of Radiopharmaceutical Preparation





Radiopharmaceuticals

- In nuclear medicine radioactive substances are used to diagnose and treat disease
  - The medical imaging use radioactive isotopes (radionuclides) to locate organs or cellular receptors
  - The radiopharmaceuticals are taken IV or orally
  - An example is a myocardial perfusion scan or pulmonary ventilation and perfusion (V/Q) scan
- CMS revised the nuclear medicine CoP to remove the requirement from “direct supervision” from the in-house preparation supervision requirement

Radiopharmaceuticals

- Direct supervision meant that the pharmacist or physician had to be physically located inside the hospital and immediately available during the preparation of the radiopharmaceutical
- This was extremely burdensome on off hours
- The rule adopted the proposed changes to revise to supervision instead of direct supervision so appropriately trained staff can prepare in-house pharmaceuticals under the oversight of a registered pharmacist or physician

Radiopharmaceuticals

- This means that now on off hours, such as evenings and weekends, a pharmacist or MD/DO does not have to be present to do nuclear medicine tests
- CMS received information that there is minimal in-house preparation required for radiopharmaceuticals
  - Many are batch prepared by the manufacturer
  - This was based on the recommendation of the Society of Nuclear Medicine and Molecular Imaging (SNMMI)

Radiopharmaceuticals

- Hospitals need to have a P&P on supervision of nuclear medicine personnel and in-house preparation
- CMS said they expect hospitals to follow the Society of Nuclear Medicine and Molecular Imaging recommendations on this issue
- This includes emergency performance of diagnostic procedures such as CAD, pulmonary emboli, stroke, and testicular torsion
  - All comments were supportive of this change
  - Note all NM was rewritten July 10, 2015 which includes this

SNMMI Website

In This Section

- Legislative Issues & Priorities
- Regulatory Issues & Priorities
- + Grassroots Issues
- Position Statements
- Coalition for PET Drug Approval
- HPRA Newsletter
- Government Relations News

Conditions of Participation

Background

Previously, section § 482.53(b)(1) required that the in-house preparation of radiopharmaceuticals be performed by, or under the direct supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy. Direct supervision means that one of these professionals must be physically present in the hospital and immediately available during the preparation of all radiopharmaceuticals.

In the past, hospitals had reported to CMS that the direct supervision requirement is extremely burdensome when the presence of a pharmacist or physician is required for the provision of off-hour nuclear medicine tests that require only minimal in-house preparation of radiopharmaceuticals.

On February 4, 2013, the Centers for Medicare and Medicaid Services (CMS) released the Proposed Rule for Part II Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction. This long awaited proposed rule was important to nuclear medicine and addressed the issue of direct supervision in the preparation of radiopharmaceuticals.

Following SNMMI's suggestions, CMS proposed removing the word "direct."

We propose to revise the current requirement at § 482.53(b)(1) by removing the term "direct." The revised requirement would then require that in-house preparation of radiopharmaceuticals be performed by, or under the supervision of, an appropriately trained registered pharmacist or doctor of medicine or osteopathy. The revision to "supervision" from "direct supervision" would allow for other appropriately trained hospital staff to prepare in-house radiopharmaceuticals under the oversight of a registered pharmacist or doctor of medicine or osteopathy, but it would not require that such oversight be exercised by the physical presence in the hospital at all times of one of these professionals, particularly during off-hours when such a professional would not be routinely present.

Current Status

On May 7, 2014, the Centers for Medicare and Medicaid Services (CMS) released the Final Rule for Part II Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction. This new rule finalized the previously proposed change of removing the term "direct" from the current requirement at § 482.53(b)(1).

CMS stated: *We received several comments on our proposed change to §*

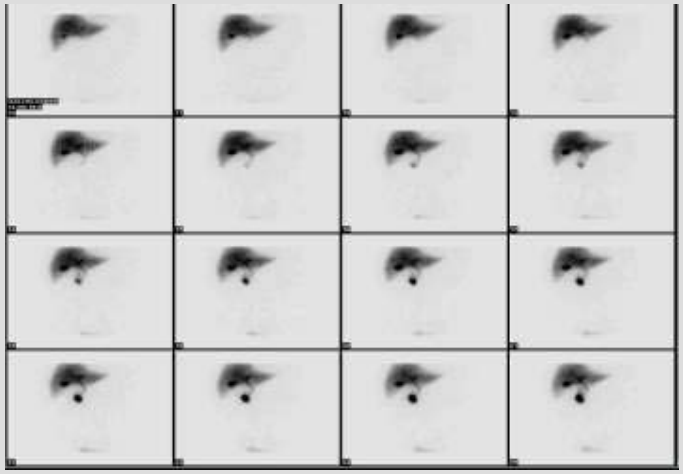
RELATED CONTENT

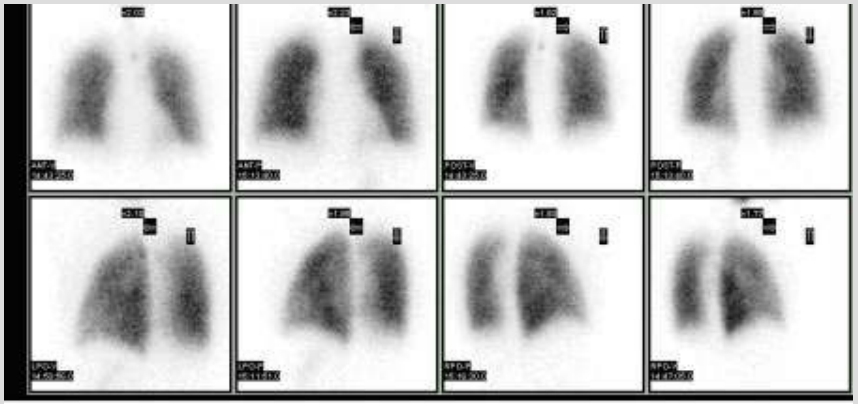
- 2013 Proposed Rule for Part II Regulatory Provisions to Promote Program Efficiency, Transparency, an - PDF document, 493 KB
- Comments to CMS Regarding the 2013 Proposed Rule for Part II Regulatory Provisions to Promote Progra - PDF document, 417 KB
- Comments to CMS Regarding the 2011 Proposed Rule for Medicare and Medicaid Programs; Reform of Hospi - PDF document, 852 KB
- Medicare Reimbusement Rates
- Coverage with Evidence Development
- Grants, Awards, and Scholarships
- Education Program
- Barry A. Siegel, MD, Receives 2014 Benedict Cassen Prize for Research in Nuclear Medicine

Nuclear Medicine Final Language

- In-house preparation of radiopharmaceuticals is by, or under the supervision of,
- An appropriately trained registered pharmacist or a doctor of medicine or osteopathy
- Nuclear Medicine starts at Tag 1026

Nuclear Medicine Tests





- Normal hepatobiliary scan (HIDA scan) used to detect gallbladder disease

- Normal pulmonary ventilation and perfusion V/Q scan

Radiology and Nuclear Medicine

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

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C-15-38-Hospitals

DATE: **May 15, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Hospital Radiologic and Nuclear Medicine Services Interpretive Guidelines—State Operations Manual (SOM) Appendix A

Memorandum Summary

Updated Guidance for Hospital Services: The Centers for Medicare & Medicaid Services (CMS) has updated the interpretive guidelines for the hospital Conditions of Participation (CoPs) for the below to reflect current accepted standards of practice:

- Radiologic Services at 42 CFR 482.26, and
- Nuclear Medicine Services at 42 CFR 482.53

Background

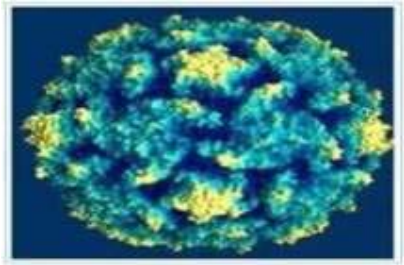
Radiologic and nuclear medicine services have improved the ability to detect and treat a wide variety of conditions and diseases, and advanced diagnostic and therapeutic procedures have become routine in many hospitals throughout the country. While these services provide

Radiology & NM Final 7-10-2015

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

Table of Contents
(Rev. 141, 07-10-15)

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



Changes to the CAH CoPs

Current CAH Manual

State Operations Manual

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

(Rev. 143, 07-31-15)

Transmittals for Appendix W

INDEX

Survey Protocol

www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_Appendixtoc.pdf

April 7, 2015 Changes

- Note major changes to pharmacy, dietary, infection control, drugs, and nursing standards and adds rehab April 7, 2015
- CMS now has an email address that questions can be addressed
  - **CAHSCG@cms.hhs.gov**
- Amends **31 tag numbers**
  - 211, 260, 261, 270-284, 286-299

CAH Staffing & Staff Responsibilities Final

- The final rules removed the requirement that a physician must be present at least once every two weeks in a CAH, RHC or FQHC facility
- Some of these facilities in remote area or areas with geographic barriers have indicated it is difficult to comply with the biweekly schedule requirement
- Many rural populations have limited access to care based on a shortage of healthcare professions, especially physicians
- Improvements in telemedicine services allow physicians to provide care in remote areas

CAH Staffing & Staff Responsibilities Final

- CMS requires physician involvement as appropriate and necessary given the services provided at the facility
- A final rule which was not previously covered in the proposed rules discuss the interval for physician review and co-signing a sample of mid-level provider outpatient records
- These facilities will continue to be required to have a physician onsite for sufficient periods of time depending on the needs of the facility and its patients

CAH Staffing & Staff Responsibilities Final

- This was changed to require only a sample of outpatient medical records be reviewed "periodically,"
  - so long as there are no specific timeframe requirements set by state law for such review and co-signature
  - And there is no state law requiring this type of oversight
- This will allow more flexibility to manage patient care

CAH Staffing & Staff Responsibilities Final

- Starts at Tag 250
- **Periodically** reviews and signs a sample of **outpatient** records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants (Tag 259)
- **Only** to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician

CAH Staffing & Staff Responsibilities Final

- A doctor of medicine or osteopathy is present for sufficient periods of time to provide medical direction, consultation,
- And supervision for the services provided in the CAH,
- And is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

CAH Policy Committee Final

- The policies are developed with the advice of members of the CAH's professional healthcare staff
- Including one or more doctors of medicine or osteopathy
- And one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff
- Note: Removed requirement in Tag 271 requiring a person to be on the P&P who is not a member of the staff

CAH Policy Committee

- CMS said this provision is no longer necessary and that the original reasons for including this requirement
- For example, lack of local resources and in-house expertise have been effectively addressed
- It has always been a challenge for hospitals to comply with this requirement
- It took an amount of time to familiarize the non-staff member with the process and they had high turnover

Swing Beds Can Be Surveyed by AO

- Addresses swing beds by providers of LTC services known as swing beds
  - Previously the regulations were found in Subpart E of Part 482, Requirements for specialty hospitals
  - Many AOs were already surveying CAH but also applies to other hospitals with swing beds
- As such, the accreditation organizations could not survey the swing beds
  - Such as TJC, CIHQ, DNV Healthcare and AOA HFAP
  - Moved it to Subpart D of Part 482, optional hospital services, since swing-bed services are optional hospital services for eligible rural hospitals and CAH

Swing Beds Can Be Surveyed by AO

- So final rule change will allow the Accreditation Organizations to survey compliance with the swing bed requirements
- So no longer a separate survey by the state agency such as the state department of health
- Final language reads
  - **§ 482.66 [Redesignated as § 482.58]** Redesignate § 482.66 as § 482.58 and transfer the section from Subpart E to SubpartD.

Laboratories and CLIA

Laboratories and CLIA

- Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed
- Final regs published on February 28, 1992
- CDC and CMS published final CLIA lab regulations that became effective April 24, 2003
- Addresses proficiency testing or PT and cannot send PT samples out of the lab for any reason

Laboratories and CLIA

- Hospital is never permitted to send the proficiency testing samples to another lab even if you would send patient specimens to another lab for confirmation
- Would select box that says would refer or test not performed
  - Sending PT samples to another lab for testing is considered PT Referral and will cause serious actions to be taken against the lab, the lab director, and the owner of the lab
  - Could loss CLIA certificate for 1 year or lab director cannot direct a lab for 2 years or owner not operate lab for 2 years

IMPORTANT INFORMATION FOR LABORATORIES PERFORMING NON-WAIVED TESTS

Frequently Asked Questions about CLIA Requirements for Proficiency Testing (PT)

NOTE: This brochure information applies to CMS inspected laboratories. If your laboratory is accredited, you MUST follow the proficiency testing requirements of your accreditation organization. This does not apply to cytology PT.

www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf

What is proficiency testing?

Proficiency testing or PT is the testing of unknown samples sent to a laboratory by a CMS approved PT program. Most sets of PT samples are sent to participating laboratories three times per year. After testing the PT samples in the same manner as its patient specimens, the laboratory reports its sample results back to their PT program. The program grades the results using the CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed the testing. CMS and accreditation organizations routinely monitor their laboratories' performance.

Why is PT important?

PT is important because it is a tool the laboratory can use to verify the accuracy and reliability of its testing. Routine reviews of PT reports by the laboratory staff and director will alert them to areas of testing that are not performing as expected and also indicate subtle shifts and trends that, over time, would affect their patient results.

If I only perform waived testing, am I required to perform PT?

PT is not required for any test that is waived. (Check the FDA web site to determine whether your test(s) are waived: *www.FDA.gov/cdrh/CLIA*) However, enrolling in a PT program and performing PT on your waived test(s) will provide you with an excellent indication of the accuracy of the waived test(s) and thus improve the quality of testing you provide to your patients. It also serves to demonstrate the accuracy of your testing if it is ever questioned.

Never Send PT Samples to Another Lab

May I discuss my PT results with another laboratory?

NEVER discuss your PT results with another laboratory and **NEVER** enter into discussion with another laboratory about their PT results before the PT event cut-off date. This activity may cause you to lose your CLIA certificate.

May I send my PT samples to another laboratory to see if they get the same results as I do?

NEVER send your PT samples to another laboratory even if you send your patient specimens to another laboratory for confirmation or identification testing. (Please read the PT results sheet carefully and select "Would refer" or "Test not performed" in these instances.) Sending PT samples to another laboratory for testing is considered PT referral and will cause serious actions to be taken against your laboratory, your laboratory director, and the laboratory owner. The penalties include loss of your laboratory's CLIA certificate for at least one year, your director cannot direct a laboratory for two years, and your laboratory owner may not own or operate a laboratory for two years.

Your laboratory's name will be listed on the CMS Laboratory Registry on the CMS web site.

Laboratories and CLIA

- Final rule makes a number of clarifications and changes regarding proficiency testing that is done under CLIA
- Need to establish P&Ps under which certain proficiency testing (PT) referrals by laboratories may not generally be subject to revocation of a CLIA certificate
- Provides for a narrow, one-time exception to the prohibition on sending proficiency testing samples to other laboratories for additional or confirmatory testing

Laboratories and CLIA

Treatment of Proficiency Testing Samples:

- Clarified that the requirement to test PT samples in the same manner as patient specimens does not mean that it is acceptable to refer PT samples to another laboratory for testing
- Even if that is the protocol for patient specimens

Treatment of proficiency testing samples:

- Created a narrow exception of what constitutes an intentional referral of PT samples
- In this instance lab will be subject to alternate sanctions

Laboratories and CLIA

New definitions*:*

- Added the following terms, with their definitions, to the regulation:
- Reflex testing, Confirmatory testing, and Distributive testing
  - Adds a definition of “distributive testing” to address concerns about how testing performed by multiple laboratories on the same specimen would be handled
  - Note: Lab is not to send PT samples out for a reflex test which is a test procedure routinely added-on to a patient specimen when the test results are at a level that meets the clinician’s threshold to automatically add specific tests. This is usually done by a “standing” order.

Laboratories and CLIA

- Repeat issues within a certain survey timeframe will otherwise be deemed “intentional” and subject to sanctions
- Alternative sanctions could include money penalty, directed plan of correction, state monitoring or a suspension of Medicare payments

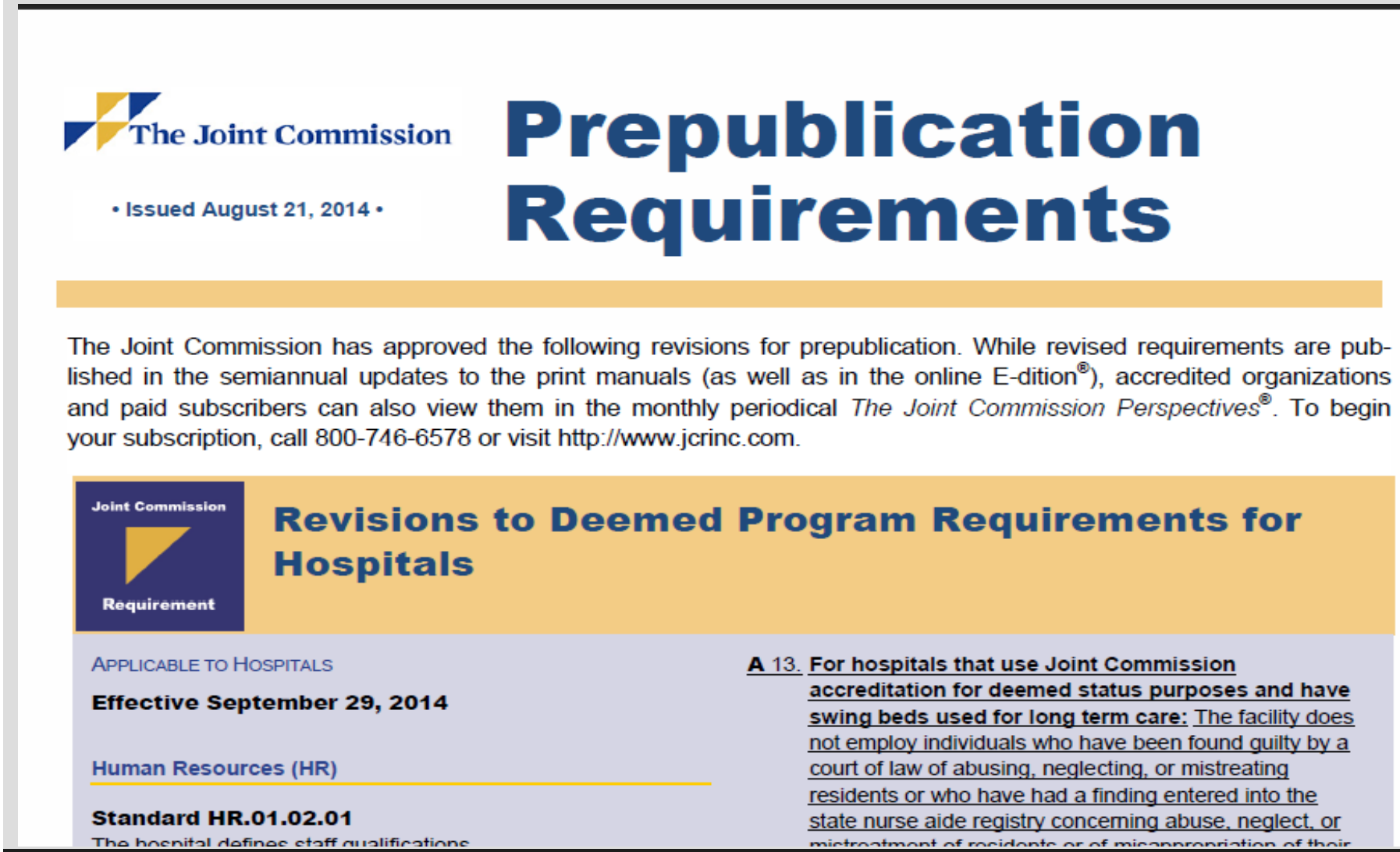
Application of TEST Act:

- This will acknowledge CMS’s ability to substitute alternative sanctions in lieu of the two-year prohibition for the owner or operator when a CLIA certificate is revoked

Joint Commission Hospitals

- TJC has issued prepublication standards to comply with the CMS new regulations
- Effective September 29, 2014
- Has list for hospitals and CAH
- Added to HR, LD, MS, PC, RC and RI chapters
- Available at www.jointcommission.org/assets/1/6/HAP_Burden_Reduction_Aug2014.pdf

Published in August 2014 Perspective



The Joint Commission

• Issued August 21, 2014 •

Prepublication Requirements

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online E-dition®), accredited organizations and paid subscribers can also view them in the monthly periodical *The Joint Commission Perspectives®*. To begin your subscription, call 800-746-6578 or visit http://www.jcrinc.com.

Joint Commission Requirement

Revisions to Deemed Program Requirements for Hospitals

APPLICABLE TO HOSPITALS

Effective September 29, 2014

Human Resources (HR)

Standard HR.01.02.01

The hospital defines staff qualifications

A 13. **For hospitals that use Joint Commission accreditation for deemed status purposes and have swing beds used for long term care:** The facility does not employ individuals who have been found guilty by a court of law of abusing, neglecting, or mistreating residents or who have had a finding entered into the state nurse aide registry concerning abuse, neglect, or mistreatment of residents or of misappropriation of their

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Thanks for attending!

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