CMS Medical Records Standards: Moving Toward an Integrated EMR

Monday, September 29th, 2014
Speaker

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- Board Member
  Emergency Medicine Patient Safety Foundation
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- sdill1@columbus.rr.com
Learning Objectives

1. Identify the CMS informed consent requirements.
2. Discuss standards on verbal orders.
4. Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
5. Evaluate compliance requirements and penalties.
Hospitals Do Not Want One of These
The Conditions of Participation (CoPs)

- Regulations first published in 1986
  - Many revisions in the past to IV medication and Blood, Anesthesia, Pharmacy, medications, rehab orders, privacy, telemedicine, standing orders, luer misconnections, PI reporting, single dose vials, insulin pens, hospitals out of compliance, discharge planning etc.

- Manual updated more frequently now and MR section is tags 431 to 469

- First regulations are published in the Federal Register then CMS publishes the Interpretive Guidelines and some have survey procedures

- Hospitals should check this website once a month for changes

# Policy & Memos to States and Regions

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

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<tr>
<th>Title</th>
<th>Memo #</th>
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<td><strong>Focused Quality Assessment and Performance Improvement (F-QAPI) Surveys for Organ Transplant Programs – Informational Only</strong></td>
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Location of CMS Hospital CoP Manual

Medicare State Operations Manual
Appendix

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.

- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the 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.


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<tr>
<td>AA</td>
<td>Psychiatric Hospitals</td>
<td>606 KB</td>
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CMS Issues Final Regulation

- CMS publishes 165 page final regulations changing the CMS CoP and 3 changes to MR chapter
- Published in the May 16, 2012 Federal Register
  - CMS publishes to reduce the regulatory burden on hospitals-more than two dozen changes
- FR effective on July 16, 2012 and IGs issued March 15, 2013 and IGs effective **June 7, 2013** and now in current manual
  - Dec 12, 2013 transmittal combines 442 and 443 into 441
  - Changes to **verbal order section (454)**, **new standing order section (457)** and **H&P update (458)**
- Available at [www.ofr.gov/inspection.aspx](http://www.ofr.gov/inspection.aspx)
Combines 442 and 443 into Tag 441

**CMS Manual System**
**Pub. 100-07 State Operations**
**Provider Certification**

Transmittal 95

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

Date: December 12, 2013

Transmittal 84, dated June 7, 2013, is being rescinded and replaced by Transmittal 95, dated December 12, 2013, to reflect the deletion of Tags A-0442 and A-0443 on the transmittal page as this information has been incorporated into Tag A-0441. All other information remains the same.

**SUBJECT:** Revised Appendix A, Interpretive Guidelines for Hospitals, Appendix L, Interpretive Guidelines for Ambulatory Surgical Centers and Appendix W, Interpretive Guidelines for Critical Access Hospitals

**I. SUMMARY OF CHANGES:** Changes are made to reflect revised regulations adopted for hospitals in 42 CFR Part 482, ambulatory surgical centers in 42 CFR Part 416, and critical access hospitals in 42 CFR Part 485, Subpart F.

**NOTES:**

Appendix A

§482.23(c) Standard: Nursing Services/Tag A-0404 deleted
(content combined with Tag A-0405)

§482.24(b) Standard: Medical Records/Tag A-0442 deleted
(content combined with Tag A-0441)

§482.24(b) Standard: Medical Records/Tag A-0443 deleted
(content combined with Tag A-0441)

§482.42(a) Standard: Infection Control/Tag A-0750 deleted
(content removed through regulation)
Access to Hospital Complaint Data

- CMS issued Survey and Certification memo on March 22, 2013 regarding access to hospital complaint data and updated quarterly
- Includes acute care and CAH hospitals
  - Does not include the plan of correction but can request
  - Questions to bettercare@cms.hhs.com
- This is the CMS 2567 deficiency data and lists the tag numbers
- Will update quarterly
  - Available under downloads on the hospital website at www.cms.gov
Access to Hospital Complaint Data

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

Center for Clinical Standards and Quality/Survey & Certification Group

DATE: March 22, 2013
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group


Memorandum Summary

- **Survey Findings Posted on [http://www.cms.gov](http://www.cms.gov):** In July 2012, the Centers for Medicare & Medicaid Services (CMS) began posting redacted Statements of Deficiencies (CMS-2567s) for skilled nursing facilities and nursing facilities on **Nursing Home Compare**. In March 2013, CMS began posting CMS-2567s for short-term acute care hospitals and critical access hospitals (CAHs) for surveys based on complaint investigations. This memorandum describes the contents and location of these files.

- **Other Web-based Tools Based on These Data:** At least two additional websites, provided by private parties (ProPublica and the Association for Health Care Journalists), publish information based on the CMS-2567 data. These websites are independent of CMS. CMS does not endorse or sponsor any particular private party application.

- **Plans of Correction (POC):** The posted CMS data do not contain any POC information. State Survey Agencies (SAAs) and CMS Regional Offices (ROs) may see an increase in requests for both the CMS-2567 and any associated POCs.

- **Question & Answers:** We plan to issue an update to this memorandum that will include an attachment of frequently asked questions; in order to provide answers to other queries that may arise.

Background – Nursing Home Survey Findings

In July 2012, CMS began posting nursing home statements of deficiencies, derived from the Farm
Updated Deficiency Data Reports

Hospitals

This page provides basic information about being certified as a Medicare and/or Medicaid hospital provider and includes links to applicable laws, regulations, and compliance information.

A hospital is an institution primarily engaged in providing, by or under the supervision of physicians, inpatient diagnostic and therapeutic services or rehabilitation services. Critical access hospitals are certified under separate standards. Psychiatric hospitals are subject to additional regulations beyond basic hospital conditions of participation. The State Survey Agency evaluates and certifies each participating hospital as a whole for compliance with the Medicare requirements and certifies it as a single provider institution.

Under the Medicare provider-based rules it is possible for one hospital to have multiple inpatient campuses and outpatient locations. It is not permissible to certify only part of a participating hospital. Psychiatric hospitals that participate in Medicare as a Distinct Part Psychiatric hospital are not required to participate in their entirety.

However, the following are not considered parts of the hospital and are not to be included in the evaluation of the hospital’s compliance:

- Components appropriately certified as other kinds of providers or suppliers, i.e., a distinct part Skilled Nursing Facility and/or distinct part Nursing Facility, Home Health Agency, Rural Health Clinic, or Hospice. Excluded are residential, custodial, and non-service units not meeting certain definitions in the Social Security Act; and,
- Physician offices located in space owned by the hospital but not functioning as hospital outpatient services departments.

Accredited Hospitals - A hospital accredited by a CMS-approved accreditation program may substitute accreditation under that program for survey by the State Survey Agency. Surveyors assess the hospital’s compliance with the Medicare Conditions of Participation (CoP) for all services, areas and locations covered by the hospital’s provider agreement under its CMS Certification Number (CCN).

Although the survey generally occurs during daytime working hours (Monday through Friday), surveyors may conduct...
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## MR Chapter Deficiencies

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<tr>
<td>466 955</td>
<td>Consent Consent (surgery)</td>
<td>14 12</td>
<td>25 22</td>
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<td>Final Diagnosis</td>
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</table>
Hospitals that participate in Medicare or Medicaid must meet the COPs for all patients in the facilities

- Not just those patients who are Medicare or Medicaid

Hospitals accredited by TJC, AOA, CIHQ, or DNV Healthcare have what is called deemed status

- CIHQ Center for Improvement in Healthcare Quality

This means you can get reimbursed without going through a state agency survey

Can still get complaint or validation survey
Joint Commission has two chapters that impact the area of Health Information Management (HIM) or Medical Records

- RC or Record of Care chapter
- IM or Information Management chapter

Recently, Joint Commission has made many changes over the past two years

- These bring the Joint Commission (TJC) standards closer into alignment
  - No longer called JCAHO
Joint Commission RC Standards

- Has a Record of Care chapter which has 10 standards
  - Clinical Record Components (RC.01.01.01)
  - Authentication (RC.01.02.01)
  - Timeliness (RC.01.03.01)
  - Audit (RC.01.04.01)
  - Retention (RC.01.05.01)
  - Care and Treatment (RC.02.01.01-RC.02.01.07)
  - Verbal Orders (RC.02.03.07)
  - Discharge Information (RC.02.04.01)
Joint Commission IM Standards

- TJC has a chapter on Information Management with 8 standards

- Planning for Management of Information IM.01.01.01 and IM.01.01.03

- Protecting the Privacy of Health Information IM.02.01.01 and IM.02.01.03

- Capturing Storing, and Retrieving Data IM.02.02.01 and IM.02.02.03
  - Changed 02.02.02 EP 2 January 2011 to conform with CMS standard
Joint Commission IM Standards

- Revised standard reads as follows:
  - The hospital’s storage and retrieval systems make health information accessible when needed for patient care and treatment
  - For hospitals that use TJC for deemed status “The medical records system allows for timely retrieval of patient information by diagnosis and procedure
- Knowledge-Based Information IM.03.01.01
- Monitoring Data and Health Information Management Processes IM.04.01.01
Standards of Care and Practice

- CMS incorporates standard of care and practice into the regulations
- AHIMA is a good source of standards
- Their practice briefs and practice tools cover some of the CMS requirements
- Including practice brief on privacy, confidentiality, and security
- Electronic signature, attestation, and authorship
- These are available at www.ahima.org/infocenter/practice_tools.asp
Practice Briefs

One of the resources in the BoK is AHIMA Practice Briefs. These Briefs provide practical and consensus-based guidance on traditional health information management (HIM) principles and evolving e-HIM® functions. Through research and professional volunteer efforts this best practice guidance is offered to AHIMA members and the healthcare industry as a resource for achieving our vision for quality healthcare through quality information. The practice briefs are organized by the topics below to help you more easily identify useful guidance.

- Career Management, Education, and Schools
- Clinical Terminologies and Vocabularies
- Coding and Reimbursement
- Compliance, Regulations, and Accreditation
- Data Quality and Data Content Standards
- E-HIM® and Electronic Records
- Health Information Exchange
- Health Information Management Operations
- Personal Health Records
- Privacy, Confidentiality, and Security
- All Current Practice Briefs in chronological order by publication date

Tool Kits

The BoK contains a wealth of resources, not only practice briefs, but also toolkits and a multitude of articles. Search the BoK to find the resource you need. Examples of toolkits include the following.
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<td><strong>Managing Copy Functionality and Information Integrity in the EHR</strong></td>
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<td><strong>Appendix A: Authorization Checklist—Required Elements</strong></td>
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Privacy & Confidentiality Memo 3-2-12

- Discusses privacy & confidentiality consistent with HIPAA
- Discusses incidental uses and disclosures
- Combines tag 441, 442, and 442 and amends 143 and 147
  - Allows name on spine of chart
  - Allows name on outside of patient room
  - Allows signs such as fall risk or diabetic diet
- Important in light of HIPAA changes effective Sept 23, 2013
DEPARTMENT OF HEALTH & HUMAN SERVICES  
Center for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-21-16  
Baltimore, Maryland 21244-1850  

Office of Clinical Standards and Quality/Survey & Certification Group  

DATE: March 2, 2012  
TO: State Survey Agency Directors  
FROM: Director  
Survey and Certification Group  

SUBJECT: Hospital Patient Privacy and Medical Record Confidentiality  

Memorandum Summary  

- **Hospital Patient Privacy and Medical Record Confidentiality**: Guidance concerning the protection of patient privacy and medical record information is clarified. This guidance is consistent with the standards under the Federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.  
- **Incidental Uses and Disclosures**: Guidance concerning permitted incidental uses and disclosures is clarified and includes reasonable safeguards that must be in place to ensure patient privacy.  
- **Automated Survey Processing Environment (ASPEN) Changes**: Tags A-0441, A-0442 and A-0443 have been combined. It will take time for this guidance to be incorporated into a future ASPEN release. Prior to this conversion, citations should be made only to Tag A-0441.  

Patient Rights to Privacy and Medical Record Confidentiality  

We are taking this opportunity to clarify our guidance for the hospital requirements governing
Effective September 23, 2013

Medical Record Services 0431

- Starts with Tag number 431
- Standard: Hospital must have a MR service that has administrative responsibility for MR. A medical record must be maintained for every individual treated or evaluated in the hospital.
  - One unified MR service responsible for all MR, both inpatient and outpatient
  - An administrator responsible for MR such as the Director of Health Information Management
  - Surveyors will sample 10% of daily census and at least 30 records
§482.24 Condition of Participation: Medical Record Services

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

Interpretive Guidelines §482.24

The term “hospital” includes all locations of the hospital.

The hospital must have one unified medical record service that has administrative responsibility for all medical records, both inpatient and outpatient records. The hospital must create and maintain a medical record for every individual, both inpatient and outpatient evaluated or treated in the hospital.

The term “medical records” includes at least written documents, computerized electronic information, radiology film and scans, laboratory reports and pathology slides, videos, audio recordings, and other forms of information regarding the condition of a patient.

Survey Procedures §482.24

- Review the organizational structure and policy statements and interview the person responsible for the medical records service to ascertain that the service is
Medical Record Services 0431

- Keep MR on every patient
- Even if request not to bill patient must still maintain a medical record
- If leaves AMA or before being seen by the ED physician still need to maintain the medical record
- MR chapter standards apply to radiology films and scans, pathology slides, computerized information, etc.
- HIM department needs to be structured to meet the needs of the hospital and patients
Staffing of Medical Records 432

- Standard: Organization must be appropriate for size and complexity of services performed and must employ adequate personnel to ensure prompt completion, filing, and retrieval

- Must have proper education, skills, qualifications and experience to meet state and federal law

- Staffing to ensure proper coding, retrieval, and indexing of records and collect data for PI

- MR personnel must be employees of the hospital

- Surveyor will look at job descriptions and staffing schedules
Retention of Record A-438

- Standard: Must maintain a MR on each patient
  - Both inpatients and outpatients
- MR must be accurately written, promptly completed and filed, retained and accessible
  - Contains all orders, test results, care plans
  - Contain evaluations and interventions
  - Treatment and patient response to treatment
Retention of Record A-438

- MR must be complete, retained and accessible 24 hours a day
  - So if emergency department physician needs to see old records of a patient at 3 am then someone, such as the nursing supervisor, can access those records

- Must contain all documentation such as diagnosis, test results, consult reports, discharge summary and care provided

- MR must be properly filed and retained
MEDICAL RECORD RETENTION POLICY

IN ACCORDANCE WITH SB17, PASSED DURING THE 2009 LEGISLATIVE SESSION, THE NEVADA STATE HEALTH DIVISION SHALL NOT DESTROY THE HEALTH CARE RECORDS OF A PERSON WHO IS LESS THAN 23 YEARS OF AGE ON THE DATE OF PROPOSED DESTRUCTION OF THE RECORDS. DESTRUCTION OF RECORDS IS IN ACCORDANCE WITH THE RECORD RETENTION SCHEDULE MAINTAINED BY THE STATE RECORDS MANAGEMENT PROGRAM.

THE HEALTH CARE RECORDS OF A PERSON WHO HAS ATTAINED THE AGE OF 23 YEARS MAY BE DESTROYED IF THOSE RECORDS HAVE BEEN RETAINED FOR AT LEAST 5 YEARS IN ACCORDANCE WITH SB17.

TO ACCESS THE PROPOSED REGULATION, CLICK HERE: SB 17
Medical Records 438

- Standard: Hospital must use a system of author identification and protect security of all records
  - Many hospitals have signature cards
  - This would include a method to identify the author of each entry including verification of the author on faxes (AHIMA brief)
  - From patient safety perspective important that physician or LIP signature is legible when signing orders on paper records
  - Standards apply to paper and electronic records
Electronic Signature, Attestation, and Authorship (Updated)

Editor’s note: This update supersedes the November 2009 practice brief “Implementing Electronic Signatures.”

Electronic health record (EHR) systems provide the ability to sign entries electronically; however, implementing and using electronic signatures (e-signatures) is complex. This practice brief provides insight into the technology used to implement e-signatures, the related health IT standards, the regulatory environment, and recommendations on best practices.

This practice brief provides additional e-signature resources, tools, a glossary, and best practices to assist HIM professionals with EHR implementation and policy development.

While this practice brief addresses an organization’s internal approach to determining e-signature policy and procedures, the foundational principles should extend beyond an organization’s operations to external health information exchange efforts and participation agreements with HIE partners. As the healthcare industry evolves, an HIE’s business plan and supporting functions must include valid, legal, consistent, and agreed-upon e-signature methods of nonrepudiation for use by all participants.

An Evolving Definition of E-Signature

The EHR has changed certain concepts and terms related to signatures. In the past, HIM professionals identified the act of signing an entry as authentication. However, this definition has evolved.

In EHRs, authentication is the security process of verifying a user’s identity that authorizes the individual to access the system (e.g., the sign-on process). Authentication is important because it assigns responsibility to the user for entries he or she creates, modifies, or views. Attestation, on the other hand, is the act of applying an e-signature to the content, showing authorship and legal responsibility for a particular unit of information.

Signatures, like medical records, can be either analog (e.g., stored on paper and unable to be read by a computer) or digital (e.g., stored on electronic media such as disks that can be read by a computer). The term electronic...
Electronic Signature, Attestation, and Authorship.

Appendix C: Electronic Signature Model Policy
This template document is not intended for adoption as a substitute for a customized organizational policy of specificity and action steps appropriate to local factors.

Advancing technology and changing surveillance criteria make any technology adaptation an evolution. An applied and reputable approach will balance front-end technology capabilities against back-end administrative controls to measure compliance.

Development of an electronic signature policy is an important aspect of a healthcare organization’s legal electronic health record definition. AHIMA recommends legal counsel review the policy during the approval process. If technology limitations preclude implementation of optimal electronic signature approaches, organizations should identify gaps for future technology acquisitions and workflow improvements.

This model policy template recommends important legal and compliance considerations for healthcare organizations’ electronic signature policy and procedures. An appropriate organizational policy reflects best practices along with germane international, federal, and state laws and regulations, accreditation standards, payer requirements, documentation requirements for clinical services offered, and technology functionalities.

Term definitions in this document are taken from the glossary in appendix D. They are intended to be used together.

Subject/Title Electronic Signature, Attestation, and Authorship for Medical Record Documentation
Page 1 of X

Revision History
Effective Date: xx-xx-xx
Departments Affected
Information Security—An Overview (Updated)

Editor’s note: This practice brief supersedes the December 2010 publication with the same name that combined and replaced two previously-published practice briefs: “Information Security—An Overview (Updated)” (November 2013) and “Information Security: A Checklist for Healthcare Professionals (Updated)” (January 2009).

This practice brief provides an overview of information security, including some of the background and basic concepts involved in securing the privacy of health information. Included are key roles and responsibilities as well as a list of specific policies and procedures that should be considered when developing an organizational security program. References, a checklist (see Appendix A), and assistance in developing policies and procedure (see Appendix B) are also provided to assist readers in the actual development of a security program.

Background

In the past, maintaining the security of health information was fairly straightforward. When most clinical information systems were introduced, they were implemented using limited-function workstations that were physically attached to a designated processor. This meant that end users were limited to specific applications. Unauthorized user access to protected health information (PHI) was generally prevented using the security administration available in most health information applications.

Today, powerful workstations are attached to networks on which multiple applications reside. End users are simply a password away from accessing a wide variety of information. Inappropriate access to information could occur if security is not monitored closely. Functionalities such as computerized physician order entry (CPOE) have increased the risks to healthcare organizations, their systems, and their patients. For example, computerized physician order entry increases risk because orders can be carried out on patients without alerts and safety checks, which will ultimately impact patient safety.

Interoperability and consolidation make information security even more challenging. Information systems that once resided in a single facility are expanding and integrating with other systems to serve the needs of hospitals, home health agencies, long-term care facilities, ambulatory care services, physicians, payers, employers, and others simultaneously. System boundaries now span multiple states or even nations. The Nationwide Health Information Network (NwHIN), an initiative developed by the Office of the National Coordinator for Health Information Technology (ONC), as well as other state and regional health information exchanges pose additional challenges.
OCR Has 6 Free Training Programs

Helping Entities Implement Privacy and Security Protections

Medscape Programs

OCR has six educational programs for health care providers on compliance with various aspects of the HIPAA Privacy and Security Rules. Each of these programs is available with free Continuing Medical Education (CME) credits for physicians and Continuing Education (CE) credits for health care professionals. They are available at Medscape.org and on OCR’s Medscape Destination page:

- EHRs and HIPAA: Steps for Maintaining the Privacy and Security of Patient Information
- Your Mobile Device and Health Information Privacy and Security
- Understanding the Basics of HIPAA Security Risk Analysis and Risk Management CME
- Patient Privacy: A Guide for Providers
- HIPAA and You: Building a Culture of Compliance
- Examining Compliance with the HIPAA Privacy Rule

www.hhs.gov/ocr/privacy/hipaa/understanding/training
Security Risk Assessment Tool

- Tool is available from Office of National Coordinator for Health IT (ONC) in collaboration with OCR and HHS Office of General Counsel

- Helps makes the security risk assessment (SRA) required under the HIPAA more understandable

- The tool lets users take a self-directed tour of the HIPAA standards and has a user guide

- Tool is not required

- SRA tool asks yes or no questions to show if you need to take corrective action
Security Risk Assessment

Security Risk Assessment Tool

Onc, in collaboration with the HHS Office for Civil Rights (OCR) and the HHS Office of the General Counsel (OGC), developed a downloadable Security Risk Assessment Tool (SRA Tool) to help guide you through the process.

SRA Tool Videos

Watch videos on what a risk assessment may involve, and learn how to use the SRA Tool by watching the SRA Tool Tutorial video.

We want to hear from you!

Share with us your thoughts and submit your comments on the SRA Tool by Monday, June 2nd.
Sanction Guidelines for Privacy and Security Violations

Editor's note: This practice brief supersedes the May 2009 and October 2011 practice brief "Sanction Guidelines for Privacy and Security Violations."

The HIPAA Breach Notification Rule requires healthcare providers, health plans, and other HIPAA covered entities (CEs) to notify individuals when their health information is breached. In addition, breaches that affect more than 500 individuals must be reported to the Secretary of Health and Human Services and the media. Under the Health Information Technology for Economic and Clinical Health Act (HITECH), the HHS secretary is required to post a list of these breaches on the department's website, which is available at www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/breachtool.html.

As a result of these regulations, media reports of healthcare privacy and security breaches continue to increase in number and scope. These reports threaten efforts to build consumer trust in electronic health records (EHR), health information exchange (HIE), and healthcare reform.

They also reveal a wide range of provider philosophies and responses regarding breaches. Healthcare organizations have differing access management controls, enforcement policies, and employee sanctions. For example, in one case, an employee reviewed a record they should not have and got fired. In another, a physician lost a USB device with 1,000 patients' information on it and underwent counseling. In addition, organizations caught in the media spotlight have shown varied readiness to address the press with a solid and serious message that embraces their privacy and security responsibilities.

The stakes are raised under HITECH enforcement and the potential for harm to an organization has increased greatly.

Organizations must ensure that workforce sanctions related to HIPAA privacy and security violations are relevant not only to the incident but also to the potential for compromise of the PHI that was breached. In addition, they must ensure sanctions are developed and standardized to complement and support all applicable organizational human resources and professional staff corrective action policies and processes.

This practice brief is intended to bring awareness for a united industry message of the seriousness regarding the handling of violations by workforce members. This brief offers methods for sanction management within organizational policies. This guidance mirrors the breach category approach now codified by HITECH, which
Medical Records 0438

- Protected from fire, water damage and other threats
  - HIPAA security rules also require this
- MR must be promptly completed and within 30 days
  - This means discharge summary dictated and on chart
  - Includes all evaluations, orders, treatments and results
- MR must be able to be retrieved within the last 5 years
Discharge Summary

- In October, 2013, any hospital with a higher than average readmission rate were financially penalized by CMS (hospitals forfeited 218 million dollars)

- Hospitals will need to reengineer the discharge process

- 78% of patients who went for their first visit after they got discharged the primary care physician (PCP) did not have a copy of the discharge summary

- Recommendation that this be dictated immediately when the patient is discharged

- Hospital needs to document that it got the discharge summary into the hands of the PCP before 1st appointment
Discharge Summary

- CMS rewrote all of the discharge summary and discharge planning standards July 19, 2013
- CMS has third revised worksheet on discharge planning
- So make sure medical record information or the discharge summary is in the hands of the PCP before the first hospital visit
- This is one of the most important things a hospital can do to reduce unnecessary readmission
Discharge Planning Revisions

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: 13-32- HOSPITAL

DATE: May 17, 2013
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Revision to State Operations Manual (SOM), Hospital Appendix A - Interpretive Guidelines for 42 CFR 482.43, Discharge Planning

Memorandum Summary

- **Discharge Planning Guidance Revised:** SOM Hospital Appendix A has been revised to update the guidance for the discharge planning Condition of Participation (CoP).

- **Advisory Boxes:** Included in the updated interpretive guidelines are “blue boxes,” to display advisory practices to promote better patient outcomes. The information found in these advisory boxes is not required for hospital compliance but only resource information or references for process improvement.

- **Automated Survey Processing Environment (ASPEN) Tags:** ASPEN Tags for discharge planning CoPs have been reorganized. A number of tags were eliminated. These changes were made in 2012.

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage
SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals, Condition of Participation: Discharge Planning.

I. SUMMARY OF CHANGES: Clarification is provided for the provisions of 42 CFR 482.43, concerning discharge planning. Several “Tags” within this CoP guidance have been consolidated, but there are no changes to the regulatory text.

NOTES:
- Tag A-0808 is deleted. Content combined with Tag A-0806
- Tag A-0809 is deleted. Content combined with Tag A-0806
- Tag A-0817 is deleted. Content combined with Tag A-0818
- Tag A-0822 is deleted. Content combined with Tag A-0820
- Tag A-0824 is deleted. Content combined with Tag A-0823
- Tag A-0825 is deleted. Content combined with Tag A-0823
- Tag A-0826 is deleted. Content combined with Tag A-0823
- Tag A-0827 is deleted. Content combined with Tag A-0823
- Tag A-0828 is deleted. Content combined with Tag A-0823
- Tag A-0829 is deleted. Content combined with Tag A-0823
- Tag A-0830 is deleted. Content combined with Tag A-0823
- Tag A-0831 is deleted. Content combined with Tag A-0823
- Exhibit XX is deleted, renamed Exhibit 353 and moved with other SOM Exhibits
Survey Procedure 820

- Send necessary medical information (like discharge summary) to providers that the patient was referred to prior to the first post-discharge appointment or within 7 days of discharge, whichever comes first.

- Surveyor will make sure referrals made to community based resources such as Departments of Aging, elder services, transportation services, Centers for Independent Living, Aging and Disability Resource Centers, etc.

- If transfer, will make sure medical record information sent along with patient.
Medical Records 439

- MR system must ensure that records are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner
  - Observe person who comes in from outside to review records such as patients or outside attorneys
- Standard: MR must be kept at least 5 years (439) in original, microfilm, computer memory or other electronic storage
Medical Records

- Certain medical records may be retained longer if required by state or federal law (OSHA, EPA, FDA)
  - CAH must be kept at least 6 years
  - See retention law memo from AHIMA at www.ahima.org
- Has state and federal law retention periods
- Has recommendation for longer retention periods for certain documents
- Surveyor will request records from 48-60 months ago
Retention and Destruction of Health Information

Editor's note: This update supersedes the August 2011 practice brief "Retention and Destruction of Health Information."

Health information management professionals traditionally have performed retention and destruction functions using all media, including paper, images, optical disk, microfilm, DVD, and CD-ROM. The warehouses or resources from which to retrieve, store, and maintain data and information include, but are not limited to, application-specific databases, diagnostic biomedical devices, master patient indexes, and patient medical records and health information. To ensure the availability of timely, relevant data and information for patient care purposes; to meet federal, state, and local legal requirements; and to reduce the risk of legal discovery, organizations must establish appropriate retention and destruction schedules. This practice brief provides guidance on record retention standards and destruction of health information for all healthcare settings.

Records Retention

The life cycle of records management begins when information is created and ends when the information is destroyed. The picture below provides a simple reflection of the entire records retention process. The goal for organizations is to manage each step in the record life cycle to ensure record availability. The creation of information is easy to establish, and most organizations do not have concerns when creating or using information. However, when maintaining information, various issues may arise.
Retention and Destruction of Health Information (Updated 2011)

Appendix C: AHIMA's Recommended Retention Standards

<table>
<thead>
<tr>
<th>Health Information</th>
<th>Recommended Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic images (such as x-ray film) (adults)</td>
<td>5 years</td>
</tr>
<tr>
<td>Diagnostic images (such as x-ray film) (minors)</td>
<td>5 years after the age of majority</td>
</tr>
<tr>
<td>Disease index</td>
<td>10 years</td>
</tr>
<tr>
<td>Fetal heart monitor records</td>
<td>10 years after the age of majority</td>
</tr>
<tr>
<td>Master patient/person index</td>
<td>Permanently</td>
</tr>
<tr>
<td>Operative index</td>
<td>10 years</td>
</tr>
<tr>
<td>Patient health/medical records (adults)</td>
<td>10 years after the most recent encounter</td>
</tr>
<tr>
<td>Patient health/medical records (minors)</td>
<td>Age of majority plus statute of limitations</td>
</tr>
<tr>
<td>Physician index</td>
<td>10 years</td>
</tr>
<tr>
<td>Register of births</td>
<td>Permanently</td>
</tr>
<tr>
<td>Register of deaths</td>
<td>Permanently</td>
</tr>
<tr>
<td>Register of surgical procedures</td>
<td>Permanently</td>
</tr>
</tbody>
</table>
# Federal Law Retention Periods

## Appendix A: Federal Record Retention Requirements

<table>
<thead>
<tr>
<th>Type of Documentation</th>
<th>Retention Period</th>
<th>Citation/Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abortions and related medical services documentation</td>
<td>Maintain for three years.</td>
<td>42 CFR 50.309</td>
</tr>
<tr>
<td>Ambulatory surgical services</td>
<td>Retention periods are not specified</td>
<td>42 CFR 416.47</td>
</tr>
<tr>
<td>Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services</td>
<td>As determined by the respective state statute, or the statute of limitations in the state. In the absence of a state statute, five years after the date of discharge; or in the case of a minor, three years after the patient becomes of age under the state law or five years after the date of discharge, whichever is longer.</td>
<td>42 CFR 485.721(d)</td>
</tr>
<tr>
<td>Clinics, rural health</td>
<td>Six years from date of last entry and longer if required by state statute.</td>
<td>42 CFR 491.10 (c)</td>
</tr>
<tr>
<td>Competitive medical plans (See HMOs, competitive medical plans, healthcare prepayment plans)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comprehensive outpatient rehabilitation facilities (CORFs)</td>
<td>Five years after patient discharge.</td>
<td>42 CFR 485.60 (c)</td>
</tr>
<tr>
<td>Critical access hospitals (CAHs)</td>
<td>Six years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.</td>
<td>42 CFR 485.628 (c)</td>
</tr>
</tbody>
</table>
Have A Destruction Policy

Destruction of Patient Health Information

Destruction of patient health information by an organization or provider must be carried out in accordance with federal and state law pursuant to a proper written retention schedule and destruction policy approved by appropriate organizational parties. Records involved in any open investigation, audit, or litigation must not be destroyed until the litigation case has been closed.

As with record retention, there is no single standard destruction requirement. Some states require organizations create an abstract of the destroyed patient information, notify patients when destroying patient information, or specify the method of destruction used to render the information unreadable. Organizations should reassess the method of destruction annually based on current technology, accepted practices, and availability of timely and cost-effective destruction services.

In the absence of any state law to the contrary, organizations must ensure paper and electronic records are destroyed with a method that provides for no possibility of reconstruction of information.

Examples of destruction methods are provided below:

- Paper record methods of destruction include burning, shredding, pulping, and pulverizing.
- Microfilm or microfiche methods of destruction include recycling and pulverizing.
- Laser discs used in write once-read many document-imaging applications are destroyed by pulverizing.
- Computerized data are destroyed by magnetic degaussing.
- DVDs are destroyed by shredding or cutting.
- Magnetic tapes are destroyed by demagnetizing.

Organizations must maintain documentation of the destruction of health records permanently and include the following (see appendix D for a sample form):

- Date of destruction
- Method of destruction
- Description of the disposed records
- Inclusive dates
- A statement that the records were destroyed in the normal course of business
- The signatures of the individuals supervising and witnessing the destruction

Under the HIPAA Privacy Rule (45 CFR, Part 160 and 164), the destruction of paper records must be in a manner so that no identifiable patient health information may be retrieved from the destroyed records.
Coding and Retrieval 440

- Standard: Must have a system of coding and indexing that allows timely retrieval of MR
- Must be able to retrieve by diagnosis and procedure to support medical care studies
  - Important for obtaining records for PI studies
- MR have to be accessible for departments that need them like the emergency department
Automated Coding Workflow and CAC Practice Guidance (Update)

Editor’s Note: This update supersedes the July 2010 practice brief “Automated Coding Workflow and CAC Practice Guidance.”

Over the past decade, clinical coding has become more complex due to:

- The expansion of prospective payment systems to multiple healthcare settings, each with specific reporting requirements
- Expanded coding rules due to new reporting requirements, such as the Health Information Technology for Economic and Clinical Health Act (HITECH), Correct Coding Initiative, and payer-specific coverage policies
- The increased need for improved data collection and data maintenance as organizations integrate, use, and rely upon more data from disparate data sources
- Increased scrutiny for erroneous or fraudulent claims, leaving little tolerance for coding or billing errors
- The financial pressure to send (or “drop”) a bill or claim to an insurance company as efficiently as possible due to the impact on an organization’s accounts receivable
- Advancements in medical care, which require that coding professionals continuously advance their understanding of various clinical subjects such as anatomy, physiology, pathophysiology, and pharmacology
- The imminent transition from the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) to ICD-10-CM and the ICD-10 Procedure Coding System (ICD-10-PCS).

This climate requires coders to have a robust clinical understanding and code with greater accuracy and speed than ever before. These factors create a stronger impetus to improve coding and documentation processes.

Clinical coding departments and healthcare organizations now use multiple forms of computer technology to address these issues. Some organizations have begun deploying computer-assisted coding (CAC) applications. Many more organizations have begun to consider CAC as a means to help optimize coder productivity with the impending transition from ICD-9-CM to ICD-10-CM/PCS, which has multiple impacts to coding processes.

This practice brief explores CAC technology in the current healthcare environment and outlines considerations for automating the coding process.

The CAC Process and Benefits
Confidentiality 441

- Standard: Must have a procedure for ensuring confidentiality of MR

- Copies may only be released to authorized individuals and written authorization by proper person, DPOA, guardian, etc.

- Hospital must make sure unauthorized people do not get access to medical record information
  - Significant issue under HIPAA

- 442 and 443 were combined into tag 441
What’s in Your P&P?

Vermont State Hospital Policy

Medical Records Policy

<table>
<thead>
<tr>
<th>Replaces version dated: 11/12/00</th>
<th>New</th>
<th>Effective date: 12/17/00</th>
</tr>
</thead>
<tbody>
<tr>
<td>If title changed, previous title: Same title - Interim</td>
<td>Revised</td>
<td>Effective Dates</td>
</tr>
<tr>
<td>Approved by the Governing Body</td>
<td>Updated</td>
<td>Date: 12/17/00</td>
</tr>
</tbody>
</table>

Policy Statement:

The Vermont State Hospital (VSH) creates and maintains a medical record for every individual evaluated or treated at the hospital in accordance with state and federal law and regulations.

VSH has a Medical Record Service that has administrative responsibility for medical records.

The Medical Record Service is organized, equipped, and staffed to ensure completion, filing, and retrieval of medical records.

Each patient’s medical record contains information sufficient to determine the degree and intensity of treatment provided, including: history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized; complete psychiatric evaluation; individualized treatment plan based on an inventory of the patient’s strengths and disabilities; progress notes at regular intervals written by professionals significantly involved in the patient’s treatment; and a discharge summary.

Authority:

42 CFR Sec. 482.24 Condition of participation for hospitals: Medical record services
42 CFR Sec. 482.61 Condition of participation for specialty hospitals: Special medical record requirements for psychiatric hospitals

Procedures:

1. Medical records will be accurately written, promptly completed, properly filed, and retained and accessible.
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Office of Clinical Standards and Quality/Survey & Certification Group

DATE: March 2, 2012
TO: State Survey Agency Directors
FROM: Director Survey and Certification Group
SUBJECT: Hospital Patient Privacy and Medical Record Confidentiality

Memorandum Summary

- **Hospital Patient Privacy and Medical Record Confidentiality**: Guidance concerning the protection of patient privacy and medical record information is clarified. This guidance is consistent with the standards under the Federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

- **Incidental Uses and Disclosures**: Guidance concerning permitted incidental uses and disclosures is clarified and includes reasonable safeguards that must be in place to ensure patient privacy.
CMS Memo on Confidentiality

- CMS issues guidance on patient privacy and confidentiality of medical record information
- The guidance is consistent with the federal HIPAA Privacy Rule
- Discusses incidental uses and disclosures and includes reasonable safeguards that must be put in place for patient privacy
- Incidental use or disclosure is disclosure of patient information that cannot be reasonably prevented and is limited in nature
CMS Memo on Confidentiality

- Hospital is not required to eliminate all risk of incidental use so long as reasonable safeguards are put into place

- Also limit disclosure to the minimum amount necessary

- The Office of Civil Rights (OCR) enforces the HIPAA privacy standards

- Questions may be addressed to Survey & Certification department at hospitalscg@cms.hhs.gov.
Amends Tag 143 in Patient Right’s Section

- This memo amends tag 143 on the patient’s right to personal privacy
- Right to privacy during personal hygiene
- Can have audio and video of patients as long as clinical need and patient is aware of monitoring
- Need the consent of the patient so can get separate consent or put it in the general consent form signed by the patient
- Monitors must be located so it is not visible to visitors or the public
Protecting Patient Personal Information 143

- Patient information can not be disclosed without informing the patient and giving the patient opportunity to agree, prohibit, or restrict the information in advance.

- This includes the patient’s presence in the hospital.

- Allowed to use information for payment or healthcare operations (case management, PI, audits, legal services, and medical reviews).

- Must have P&P that restrict access to and use of patient information.
Facility directory is permitted disclosure but must inform the patient of the information included and given the opportunity to restrict or prohibit it.

May disclose religious affiliations to the clergy.

If patient unable to consent and no representative then hospital can disclose if in patient’s best interest.

Hospital may use information to notify family member of personal representative of the patient.
Incidental Uses and Disclosures

- Certain disclosures cannot reasonably be prevented
- Someone may see a patient’s name on a sign in sheet
- Visitor could overhear a confidential conversation
- Hospitals can use patient care signs such as fall risk or diabetic diet
- Can display names on the outside of patient charts
- Use whiteboards that list patients on the unit but use caution
Incidental Uses and Disclosures

- May ask waiting patients to stand back a few feet from counter used for patient registration
- Use dividers in semi-private rooms
- Speak quietly when discussing condition in a semi-private room
- Limit access to area where white boards or x-ray light boards are in use
- Patient has a right to confidentiality of their medical records (tag 147)
- Limit disclosure to minimum necessary
Confidentiality 441

- Standard: The hospital must have a procedure for ensuring confidentiality of patient records.
  - Information may only be released to authorized individuals
  - Hospital must ensure that unauthorized individuals cannot gain access or alter patient records
  - Original medical records are released only in accordance with Federal or state laws
- Need a P&P to ensure confidentiality of MRs
Again reiterates that information can be released for payment or healthcare operations

Must have P&P that reasonably limits disclosure of information contained in the medical record to the minimum disclosure necessary

Example would be for suspected child abuse reporting
  - Would abstract out what information is basis for suspicion
  - Could not just give a complete copy of the medical record
Confidentiality 441

- Need safeguards if share MR electronically with other facilities and physicians
- Hospital must ensure that unauthorized individuals do not have access to protected health information or medical records
- Patient records must be secure at all times
- For hard copies it means locking cabinets or have pass codes or limit access to keys
- When disposing ensure safe guards taken such as shredding or erasing information from hard drives
Confidentiality 441

- Reiterated that the hospital should never release the original record unless required to do so by a court order or subpoena
  - Most will allow a certified copy to be used instead of the original so we can safeguard the original
- Make sure electronic records are not removed or deleted
- Must have P&P on how the hospital assures it retains the original medical record unless release is mandated by the law
Confidentiality 441 Survey Procedure

- Hospital has to ensure that unauthorized individuals can not gain access to or alter patient records and will look at P&P
- Will make sure patient signs HIPAA compliant authorization form to release MRs
- Surveyor is instructed to observe hospital security practices
- Are their any records that are left unsecured or unattended?
- Surveyor suppose to look at what precautions are taken to prevent electronic altering or deletion
Medical records may only be seen and viewed by those persons having a part in the patient’s care

- Recently many cases of breach especially with famous celebrities as patients
- Two fines of California hospitals for staff snooping into the medical records of the rich and famous such as Nadya Sutman
- State attorney general can enforce privacy breeches
- Federal stimulus bill (American Recovery and Reinvestment Act of 2009 or ARRA) has section called HITECH Breach Notification Law which was amended September 23, 2013
ARRA and HITECH

- President wanted to increase use of EHR with bonuses
- As the use of EMR increases, so does the number of privacy and security breeches and identity theft occurrences
- To keep pace with these risks, new legal mandates were made in the HITECH and revised September 23, 2013
- This strengthens privacy and security protections for health information
- Breech notification law requires hospitals to notify their patients if unsecured electronic health information has been breached
  - New 4 part test will result in more patients being notified of a breach
Breach Notification

- Immediate notification to victims on all breaches
- Notification to HHS on all breaches
  - Must be immediate if 500 or more victims
  - Otherwise send in an annual log
- Notification to media outlets on breaches of 500 or more patient records
- Has many rules and just need to read them
- Changes harm threshold requirement to 4 part test and new penalties
- See toolkit to comply with this law at www.hipaacow.org/Docs/BreachNotificationPolicy0909.doc
Breach Notification

- The old definition required a significant risk of financial, reputational, or other harm to the individual
- The new rule has a much lower standard of PHI disclosure or use that does not have a low probability that the PHI has been compromised
- We need to evaluate the potential breach of PHI and document our good faith evaluation and reasonable conclusion using the 4 part test
  - If you determine that the probability of compromised PHI is low you do not have a problem, if yes then patient must be notified
- Will most likely result in notifying more patients that the PHI has been breached
Low Probability Objective Risk Factors

- A breach is presumed unless the hospital or CE can show that there is a “low probability” that the PHI has been compromised based on the risk assessment considering the following four:

1. The nature and extent of the PHI involved including the types of identifiers and likelihood of reidentification

   - Was it sensitive information such as a STD such as gonorrhea or HIV status or treatment for substance abuse or mental health treatment

   - Was it just the name of the patient, or did it include their diagnosis, SSN or credit card information or just how much information was disclosed
Low Probability Objective Risk Factors

1. The nature and extent of the PHI involved including the types of identifiers and likelihood of reidentification (continued)

   - Was it a list of deidentified list of cancer diagnosis of patients seen in an outpatient department disclosed with a separate list of patient appointments for the day the patient was treated would present a higher probability of impermissible use or disclosure

   - PHI that had scanned images may include patient identifiers that would present a higher probability of disclosure
2. Whether the PHI was actually acquired or viewed

- Was there an opportunity to view or access the PHI
- PHI information sent to the wrong patient but the letter was returned unopened by the post office so good chance it was never viewed
- Patient is handed the wrong discharge instructions but nurse notices it before going over them with patient and retrieves them
- The laptop was stolen and a forensic analysis shows that none of the PHI was accessed
3. The unauthorized person who used the PHI or to whom the disclosure was made

- You have to evaluate the recipient of the impermissible disclosure
  - Was the person who received the unauthorized information a physician or another hospital who generally has a duty to protect PHI?
  - A impermissible disclosure to a party who has been trained in HIPAA and who works for the hospital or a BA may present a lower probability than disclosing it someone who has not been trained
4. The extent to which the risk to the PHI has been mitigated

- Were there any mitigating issues that lead you in good faith and reasonable conclusion that the information was not disclosed?

- Get assurance and confidential agreement from the person that the PHI has been shredded and assurances no copies have been made.

- Is the person who received the PHI a physician or healthcare professional?

- Can we rely on the promise of the party to whom the information was improperly disclosed?
Standard: MR must contain information to justify the following:

- Admission
- Continued hospitalization
- Support the diagnosis
- Describe the patient’s program
- Describe the patient’s response to medication
Content of Records 449

- MR must describe the patient’s response to intervention, care, and treatment
  - Nurse and physician should document response after invasive procedures
- Records must be promptly filed in chart
- MR must contain evaluations, care plans (often cited for lack of care plan), radiology reports, and consults
This section amended June 5, 2009

All entries must be legible, complete, dated and **timed** and authenticated by the person responsible for ordering, providing, or evaluating the service provided.

One of the top problematic standards is due to the TJC and CMS that every entry needs to be TIMED

- All orders need to be dated and timed
- All consult and progress notes need to have a time on them

**RC.01.01.01** The hospital maintains complete and accurate medical records and top problematic standard for TJC hospitals
Every Entry Must Be Timed

All entries in the medical record must be dated, timed, and authenticated, in written or electronic form, by the person responsible for providing or evaluating the service provided.

- The time and date of each entry (orders, reports, notes, etc.) must be accurately documented. Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries is necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or timelines of various signs, symptoms, or events. (71 FR 68687)

- The hospital must have a method to establish the identity of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.
Specify in MR or hospital policy who can make entries in medical record

Need method to identify author (written signatures, initials, computer key, or other code) and a list of written signatures must be available

See previously discussed AHIMA brief
Legible and Authenticated

- Must have P&P if electronic medical record is used as to how alterations are prevented after its been authenticated
- MS R&R address countersignature when required by policy or state law and this is defined in MS R&R
Standing Orders  450

- Another problematic standard for hospitals

- If Doctor Jones goes the cabinet and pulls out her 3 page standing orders for total knee surgery
  - Must sign, date, and time the last page
  - Must identify the total number of pages such as page 3 of 3
  - Must initial any deletions, additions, or strike outs

- Standing orders used by an individual physician do not have to be approved by MEC but protocols should (see tag 405 also)
CMS Requirements on Order Sets, Protocols, Preprinted Orders, and Standing Orders

Sue Dill Calloway RN MSN JD

There are three separate tag numbers that hospitals must review in order to understand the Center for Medicare and Medicaid Services (CMS) requirements for standing orders, protocols, and order sets. Additionally, CMS included information on this topic in the changes to the hospital CoPs which was published in the Federal Register and which became effective July 16, 2012. Any hospital that accepts Medicare or Medicaid reimbursement must follow the conditions of participation (CoPs) and they must be followed for all patients seen in the hospital.

The development of protocols and standings orders is better described as a journey. Initially CMS said that a physician order was needed first and that standing orders had to be signed before one could implement them. Then on October 17, 2008, CMS updated the hospital condition of participation (CoP) manual. Seven days later, on October 24, 2008, CMS issued a survey and certification memo to explain the section.
Rubber Stamps 450

- Just don’t allow the use rubber stamps
  - Just have physician or LIP sign their name, date, and time or fix an electronic signature
  - Unless for legibility only such as in block letter stamp
- CMS says if rubber stamp used, must have signed statement only that individual will use it
- However, the problem is that the hospital may not be paid for care if stamp used
  - Medicare payment policy does not allow it to be used
  - Many fiscal intermediaries and insurance companies do not allow either
CMS Signature Guidelines

- April 16, 2010 CMS issues new signature guidelines and says no rubber stamps

- CMS issued a change request updating the Program Integrity Manual on signature guidelines for medical review purposes

- Requires legible identifier in form of handwritten or electronic signature

- Third exception is cases where national coverage determination (NCD), local coverage determination (LCD) or if CMS manual has specific guidelines takes precedence over above
CMS Manual System

Pub 100-08 Medicare Program Integrity

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

Transmittal 327
Date: March 16, 2010
Change Request 6698

SUBJECT: Signature Guidelines for Medical Review Purposes

I. SUMMARY OF CHANGES: Medicare claim review contractors (carriers, fiscal intermediaries (called affiliated contractors, or ACs), Medicare administrative contractors, the comprehensive error rate testing contractor, and recovery audit contractors) are tasked with measuring, detecting and correcting improper payments in the fee for service Medicare program. These contractors review claims and medical documentation submitted by providers.

The previous language of the Program Integrity Manual required a legible identifier in the form of a handwritten or electronic signature for every service provided or ordered. This CR updates these requirements and adds e-prescribing language.

EFFECTIVE DATE: MARCH 1, 2010
IMPLEMENTATION DATE: April 16, 2010

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

<table>
<thead>
<tr>
<th>R/N/D</th>
<th>CHAPTER / SECTION / SUBSECTION / TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>3/3.4.1.1/Documentation Specifications for Areas Selected for Prepayment or</td>
</tr>
</tbody>
</table>
Contractors, or ACs), Medicare administrative contractors (MACs), the comprehensive error rate testing (CERT) contractor, and recovery audit contractors) are tasked with measuring, detecting and correcting improper payments in the fee for service (FFS) Medicare program. These contractors review claims and medical documentation submitted by providers.

The previous language in the PIM required a “legible identifier” in the form of a handwritten or electronic signature for every service provided or ordered. This CR updates these requirements and adds e-prescribing language.

**B. Policy:** Clarifies and updates various sections of the Program Integrity Manual.

### II. BUSINESS REQUIREMENTS TABLE

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility (place an “X” in each applicable column)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>A/B DM MAC I M A C M A C F I CARRIER RHI Shared System Maintainers FISS MCS VMS CWF OTHER</td>
</tr>
<tr>
<td>6698.1</td>
<td>All signature requirements in this CR are effective retroactively for CERT for the November 2010 report period.</td>
<td></td>
</tr>
<tr>
<td>6698.2</td>
<td>All signature requirements for ACs, MACs, PSCs and ZPICs are applicable for reviews conducted on or after 30 days after the issuance of this CR.</td>
<td>x x x x x</td>
</tr>
<tr>
<td>6698.3</td>
<td>For medical review purposes, Medicare requires that services provided/ordered be authenticated by the author. The method used shall be a handwritten or an electronic signature. Stamp signatures are not acceptable.</td>
<td>x x x x x</td>
</tr>
<tr>
<td>6698.4</td>
<td>Other regulations and CMS instructions regarding signatures (such as timeliness standards for particular benefits) take precedence. In cases where the relevant regulation, NCD, LCD and CMS manuals have specific signature requirements, (e.g. signatures on plans of care must be signed prior to services being rendered), those signature requirements take precedence.</td>
<td>x x x x x</td>
</tr>
<tr>
<td>6698.5</td>
<td>For medical review purposes, if the relevant regulation, NCD, LCD and CMS manuals are silent on whether the</td>
<td>x x x x x</td>
</tr>
<tr>
<td>6698.6</td>
<td>signature be legible or present and the signature is illegible/missing, the reviewer shall follow the guidelines listed in the PIM to discern the identity and credentials (e.g. MD, RN) of the signator.</td>
<td>CERT, PSC, ZPIC</td>
</tr>
<tr>
<td>6698.7</td>
<td>If there are reasons for denial unrelated to signature requirements the reviewer shall not proceed to signature authentication. If the criteria in the relevant Medicare policy cannot be met but for a key piece of medical documentation which contains a missing or illegible signature, the reviewer shall proceed to the signature assessment.</td>
<td>CERT, PSC, ZPIC</td>
</tr>
<tr>
<td>6698.8</td>
<td>If the signature is illegible, ACs, MACs, PSCs, ZPICs and CERT shall consider evidence in a signature log or attestation statement to determine the identity of the author of a medical record entry.</td>
<td>CERT, PSC, ZPIC</td>
</tr>
<tr>
<td>6698.9</td>
<td>If the signature is missing from an order, ACs, MACs, PSCs, ZPICs and CERT shall disregard the order during the review of the claim.</td>
<td>CERT, PSC, ZPIC</td>
</tr>
<tr>
<td>6698.10</td>
<td>If the signature is missing from any other medical documentation, ACs, MACs, PSCs, ZPICs and CERT shall accept a signature attestation from the author of the medical record entry.</td>
<td>CERT, PSC, ZPIC</td>
</tr>
<tr>
<td>6698.11</td>
<td>Reviewers may encourage providers to list their credentials in the log. However, reviewers shall not deny a claim for a signature log that is missing credentials.</td>
<td>CERT, PSC, ZPIC</td>
</tr>
<tr>
<td>6698.12</td>
<td>Reviewers shall consider all submitted signature logs regardless of the date they were created.</td>
<td>CERT, PSC, ZPIC</td>
</tr>
<tr>
<td>6698.13</td>
<td>Reviewers shall NOT consider attestation statements where there is NO associated medical record entry.</td>
<td>CERT, PSC, ZPIC</td>
</tr>
<tr>
<td>6698.14</td>
<td>Reviewers shall NOT consider attestation statements from someone other than the author of the medical record entry in question (even in cases where two individuals are in the same group, one may not sign for the other in medical record entries or attestation.</td>
<td>CERT, PSC, ZPIC</td>
</tr>
</tbody>
</table>
Signing Off Documents

- Can’t use system of auto authentication that says can not review because not transcribed yet

- There must be a system where the practitioner did indeed review the document and sign it

- If time of transcription appears on the H&P it still has to be dated, timed, and signed

- Exception would be a system that stamps the date and time on the document when the physician is reviewing it
Verbal Orders 454 and 457 2013

- Recall verbal order (VO) section starting in NS section at tag number 407
- Repeats some section of verbal orders
- Standard: All orders, including verbal orders, must be dated, timed and authenticated promptly by the ordering practitioner or by another practitioner responsible for care of the patient
  - If allowed by state law
  - If within their scope of practice
  - If allowed by P&P and MS bylaws or R/R
Changes Effective June 7, 2013

A-0454
(Rev. )

§482.24(c)(2) - All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Interpretive Guidelines §482.24(c)(2)

The hospital must ensure that all orders, including verbal orders, are dated, timed, and authenticated promptly. The Merriam-Webster online dictionary defines “promptly” as performed readily or immediately.

Verbal orders are orders for medications, treatments, interventions or other patient care that are transmitted as oral, spoken communications between senders and receivers, delivered either face-to-face or via telephone.

The receiver of a verbal order must date, time, and sign the verbal order in accordance with hospital policy. CMS expects hospital policies and procedures for verbal orders to include a read-back and verification process.

The prescribing practitioner must verify, sign, date and time the order as soon as possible after issuing the order, in accordance with hospital policy, and State and Federal requirements.

Authentication of a verbal order may be written, electronic, or faxed. The hospital must have a method for establishing the identity of the practitioner who has given a verbal order, including verification of the author of faxed verbal orders or computer entries.

In some instances, the ordering practitioner may not be able to authenticate his or her order, including a verbal order (e.g., the ordering practitioner gives a verbal order which is written and transcribed, and then is “off duty” for the weekend or an extended period of time). In such cases it is acceptable for another practitioner who is responsible for the patient’s care to authenticate the order, including a verbal order, of the ordering practitioner as long as it is permitted under State law, hospital policies and medical staff bylaws, rules, and regulations. Hospitals may choose in their policies to restrict which practitioners it would authorize to authenticate another practitioner’s orders. For example, a hospital could choose to restrict authentication of orders for pediatric patients to practitioners who are privileged to provide pediatric care. (77 FR 29053, May 16, 2012)

- All practitioners responsible for the patient’s care are expected to have knowledge of the
Verbal Orders 454

- 2 verbal order changes July 16, 2012 and IG issued March 15, 2013 & effective June 7, 2013
- Added that another practitioner could sign off the verbal order if allow
- VO is another problematic standard with CMS and TJC
- Hospital may choose to restrict practitioners who can authenticate others orders if they want such as restrictions for pediatric patients
Verbal Orders 454 and 457

- All doctor can sign VO for any other doctor on the case
  - Unless your state law prohibits this
- Person who takes VO must write it down with date and time and then read it back
- Don’t take a verbal order unless necessary such as physician is at home and patient needs urgent orders
Verbal Orders 454 and 457

- When doctor or LIP authenticates and signs off order must date and time it also
- Must have physician or LIP sign off order within time frame set by your state law
- If no state law then your P&P and many hospitals picked 30 days
  - CMS did away with the 48 hour requirement if no state law but should still signed them off as soon as possible
Verbal Orders 457

- Verbal orders are a patient safety issue and have lead to many errors in healthcare

- Rewrite your P&P and Medical staff by-laws to be consistent with these standards

- Need hospital P&P to reflect these guidelines including who can sign off the verbal order
CMS Verbal Orders

- To be used infrequently and never for convenience of the physicians
  - 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 or at home or in office
- New regulation broadens category of practitioners who can sign orders off
Verbal Orders P&P Should Include

- Limitations on VO such as not for chemotherapy
- List the elements for a complete VO (patient name, drug, dose, frequency, name of person giving and taking order, etc.)
- Define who can receive VO and the method to ensure authentication
  - Many do not take medication orders from a medical assistant in the doctor’s office
  - Many other licensed individuals to accept VO within the scope of their practice such as pharmacist takes medication orders
Signing Off Verbal Orders

- 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.
- TJC standard now similar to CMS.
- Still top problematic standard with the Joint Commission.

**RC.02.03.07** Qualified staff receive and record verbal orders

- Common problematic standard for both CMS and TJC.
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 but moved to PC.02.01.03 in 2010)
§482.24(c) (3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

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

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

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

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

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

**What is covered by this regulation?**

There is no standard definition of a “standing order” in the hospital community at large (77 FR 20055, May 16, 2012), but the terms “pre-printed standing orders,” “electronic standing orders,” “order sets,” and “protocols for patient orders” are various ways in which the term “standing orders” has been applied. For purposes of brevity, in our guidance we generally use the term “standing order(s)” to refer interchangeably to pre-printed and electronic standing orders, order sets, and protocols. However, we note that the lack of a standard definition for these terms and their interchangeable and indistinct use by hospitals and health care professionals may result in confusion regarding what is or is not subject to the requirements of §482.24(c)(3), particularly with respect to “order sets.”

- Not all pre-printed and electronic order sets are considered a type of “standing order” covered by this regulation. Where the order sets consist solely of menus of treatment or care options designed to facilitate the creation of a patient-specific set of orders by a physician or
Standard: hospitals can use preprinted and electronic standing orders, order sets, and protocols for patient orders only if the hospital has the following 4 things:

- Make sure the orders and protocols have been reviewed and approved by the MS (such as the MEC) and the hospital’s nursing and pharmacy leadership

- Demonstrate that the orders and protocols are consistent with nationally recognized and evidenced based guidelines
Tag 457  Standing Orders

- No standard definition of standing orders
- For brevity CMS uses standing orders to include pre-printed orders, electronic standing orders, order sets and protocols
  - Said these are forms of standing orders
- States lack of standard definition may result in confusion
- Not all preprinted and electronic order sets are considered a standing order covered by this regulation
Tag 457 Standing Orders

- Example: doctor or qualified practitioner picks from an order set menu and treatment choices can not be initiated by nurses or other non-practitioner staff then menus are not standing orders covered by this regulation.

- Menu options does not create an order set subject to these regulations.

- The physician has the choice not to use this menu and could create orders from scratch or modify it.
In cases, where a nurse can initiate without a prior specific order,
  - Then policy and practice must meet these regulations
  - Doesn’t matter what it is called
  - Must meet certain pre-defined clinical situations
  - Emergency response or part of an evidenced-based treatment where it is NOT practical for a nurse to obtain a written order or verbal order

Hybrids still require compliance with this section
  - Order set has a protocol for nurse initiated such as KCL
Standing Order Requirements  457

- Must be well-defined clinical situations with evidence to support standardized treatments
- Appropriate use can contribute to patient safety and quality care
- Can be initiated as emergency response
- Can be initiated as part of an evidenced based treatment regime where not practicable to get a written or verbal order
- Must be medically appropriate such as RRT
Standing Order Requirements 457

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

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

- Hospital must document standing order is consistent with nationally recognized and evidenced based guidelines
- Burden is on the hospital to show there is sound basis for the standing order
- Must have regular review to ensure it's still useful and a safe order
- P&P address how to correct it, revise or modify
- Must be placed in the order section of the chart
- Must be dated, timed, and signed
Make sure there is periodic and regular review of the orders and protocols conducted by the MS, nursing and pharmacy leadership to determine the continued usefulness and safety.

Make sure they are dated, timed, and authenticated promptly in the medical record.

- Signed off by the ordering practitioner of another practitioner on the case.
- Could be signed off by non-physician if allowed by hospital policy, state law, the person state law scope of practice, and MS bylaws or R/R.
Subcutaneous Insulin Order Set

Guidelines for Insulin Use and Care of the Hospitalized Patient with Hyperglycemia

Purpose of the Tool: Encourage proper use of inpatient insulin by encouraging the use of long acting scheduled (basal) insulin, pre-meal scheduled insulin with adjustment doses, and reduced adjustment doses for MS. Use of traditional sliding scale insulin as sole insulin regimen is strongly discouraged. Improve glycemic control AND reduce hypoglycemic events.

Submitter: Greg Maynard MD, MS
Tool Author: (if not the same as the submitter): Same
E-mail contact information: gmaynard@ucsd.edu

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

THE NEW* YALE INSULIN DRIP PROTOCOL

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

Initiating An Insulin Drip

1. INSULIN INFUSION: Mix 1 unit Regular Human Insulin per 1 cc 0.9% NaCl. Administer via infusion pump (in increments of 0.5 U/hr).
2. PRIMING: Flush 50 cc of Insulin/NS drip through all IV tubing. Before infusion begins (to saturate the insulin binding sites in the tubing).
3. THRESHOLD: IV insulin is indicated in any critically ill patient with persistent BG ≥ 140 mg/dL. Consider use if BG ≥ 110 mg/dL.
4. TARGET BLOOD GLUCOSE (BG) LEVELS: 90-110 mg/dL.
5. BOLUS & INITIAL INSULIN DRIP RATE: If initial BG ≥ 150, divide initial BG level (mg/dL) by 70, then round to nearest 0.5 units for bolus and initial drip rate. If initial BG < 150 mg/dL, divide by 70 for initial drip rate only (i.e., NO bolus).
   Examples: 1) Initial BG 335 mg/dL: 335 ÷ 70 = 4.78, rounded up to 5 units IV bolus + start drip @ 5 units/hr.
   2) Initial BG 148 mg/dL: 148 ÷ 70 = 2.11, rounded down to 2 units/hr (NO bolus)

Fingerstick (FS) Blood Glucose Monitoring

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

Changing the Insulin Drip Rate

If BG < 50 mg/dL:
D/C insulin drip

If BG 50-69 mg/dL:
D/C INSULIN DRIP

Give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes
=> When BG ≥ 90 mg/dL, wait 1 hour, recheck BG, then restart drip at 50% of most recent rate (if BG still ≥ 90 mg/dL)

If BG ≥ 90 mg/dL:
D/C INSULIN DRIP

If symptomatic (or difficult to assess), give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes
Chronic Obstructive Pulmonary Disease (COPD): Diagnosis and Management of Acute Exacerbations

Guidelines Being Compared:

1. **Global Initiative for Chronic Obstructive Lung Disease (GOLD)**. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Vancouver (WA): Global Initiative for Chronic Obstructive Lung Disease (GOLD); 2011. 76 p. [503 references]


A direct comparison of recommendations presented in the above guidelines for the diagnosis and management of acute exacerbation of COPD is provided below. The UMHS guideline provides recommendations for the outpatient setting; GOLD addresses both hospital and home settings.

**Areas of Agreement**

*Diagnosis and Initial Assessment*
History and Physical 458 and 461

- Repeats same provisions on H&P as in medical staff section under tag number 358 and 359

- H&P done within 24 hours and on chart for patient admitted

- H&P for surgery patient not older than 30 days old and updated within 24 hours and on chart before patient goes to surgery

- PA and NP can do if allowed by hospital and all state laws allow and physician reviews and authenticates with date, time, and signature
H&P 358   2013

- Repeated in tag number 461 and 463
- CMS changed standard to be consistent with TJC standard
- MS must adopt bylaws to carry out their responsibilities on H&Ps
- The bylaws must include a requirement that a H&P be completed no more than 30 days before or 24 hours after admission on each patient
  - Must be on chart before surgery
  - TJC MS.01.01.01 tell you whether in bylaw, R/R, or a policy but when CMS states where it will be you must follow that
Can include in progress notes or has stamp sticker, check box, or entry on H&P form

- Should say that H&P was reviewed, the patient examined, and that “no change” has occurred in the patient’s condition since the H&P was completed

- CMS says this will meet update requirement

- There needs to be a complete H&P in the chart for every patient before they go to surgery
  - Except in emergencies where an entry can be made in the progress notes
History and Physicals

- Regulation expands the number of categories of people who can do a H&P
  - If state law and the hospital allows (which most do) a PA or NP may perform
- Physician is still responsible for the contents and must sign off the H&P when done by one of these allied health professionals
- Need to do PI to make sure all H&P are on the chart especially when the patient goes to surgery
TJC PC.01.02.03  H&P

- EP4 requires H&P be no more than 30 days old and done within 24 hours of admission.
- EP5 if H&P done within 24 hours update then update prior to surgery (also RC.01.03.01).
- EP7 requires an update to a history and physical (H&P) at the time of the admission.
- RC.02.01.03 EP3 document H&P in MR for operative or high risk procedure and for moderate and deep sedation.
EP6 Specifies minimal content
- Can vary by setting, level of service, treatment and services

EP7 MS must monitor the quality of the H&Ps

EP8 Medical staff requires person be privileged to do H&P and requires updates
EP9 As permitted by state law, allow individuals who are not LIPs to perform part or all of the H&P

EP10 MS defines when it must be validated and countersigned by LIP with privileges

MS defines scope of H&P for non-inpatient services
MR Must Contain 464 and 465

- Must have admitting diagnosis in chart (463)
- All consults and findings by clinical staff and others must be documented (464)
- Information must be promptly filed in the MR so staff has access to it (464)
MR Must Contain 464 and 465

- Must document complications and hospital acquired infections
  - HAI and now called healthcare associated infections
- Must document unfavorable reactions to drugs and anesthesia (465)
  - See changes to tag 508 in the Pharmacy section
- It is important for all practitioners to be aware of the need to document complications and how to do this correctly
Informed Consent 466

- Now three separate sections related to informed consent in patient rights, medical record and surgical services
- Remember consent is a process and not a form
- Be sure consent on chart before patient goes to surgery
- Properly executed informed consent for procedures and treatments specified by MS
- Need list of all surgeries (as defined now by ACS and AMA) and procedures with yes or no
Informed Consent MR Mandatory Minimum Elements

- Name of hospital
- Name of procedure or treatment
- Name of responsible practitioner who is performing
- Statement that benefits, material risks and alternatives were explained
- Signature of patient with date and time
CMS has list of optional elements which they call a well designed consent form

Medical record must contain an informed consent for procedures and treatments specified as requiring on and MS by-laws should address this

Consider state laws requiring informed consent such as for invasive procedures and any federal laws such as informed consent for research
# List of Procedures

<table>
<thead>
<tr>
<th>Procedure Name</th>
<th>Requires Informed Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ablations</td>
<td>Yes</td>
</tr>
<tr>
<td>Amniocentesis</td>
<td>Yes</td>
</tr>
<tr>
<td>Angiogram</td>
<td>Yes</td>
</tr>
<tr>
<td>Angiography</td>
<td>Yes</td>
</tr>
<tr>
<td>Angioplasties</td>
<td>Yes</td>
</tr>
<tr>
<td>Arthrogram</td>
<td>Yes</td>
</tr>
<tr>
<td>Arterial Line insertion (performed alone)</td>
<td>Yes</td>
</tr>
<tr>
<td>Aspiration Cyst (simple/minor)</td>
<td>No</td>
</tr>
</tbody>
</table>
### Table of Contents

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- REFUSAL TO TREATMENT OR SIGN
- DURATION OF CONSENT
- Obtaining consent on unidentifiable individual
- Competency.
- Incompetency.
- Person Authorized

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Consent</th>
</tr>
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<tr>
<td>Bone Marrow Aspiration</td>
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<td>Bone Marrow Biopsy</td>
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<td>Bronchoscopy</td>
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<tr>
<td>Capsule Endoscopy</td>
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<td>Catherizations, Cardiac &amp; vascular</td>
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<td>Cardioversion</td>
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<td>Central Line</td>
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<td>Chemotherapy</td>
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<tr>
<td>Chest Tube Insertion</td>
<td>Yes</td>
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<tr>
<td>Circumcision</td>
<td>Yes</td>
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<tr>
<td>Core Biopsy - (stereotactic or ultrasound guided)</td>
<td>Yes</td>
</tr>
<tr>
<td>Dialysis Catheter Insertion</td>
<td>Yes</td>
</tr>
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</table>
Informed Consent Forms

- Need for all surgeries
- Exception is emergencies
- All inpatients and outpatients
- For all procedures specified as per the hospital policy
  - Generally a consent is required for an invasion procedure
  - Especially one with reasonable known risks
Informed Consent Forms

- Needs to reflect a process
  - This is important to both CMS and TJC

- Form must follow policies

- Must include state or federal requirements
  - Emphasis on must include and follow state law consent laws

- Must contain the six minimum requirements which are mandatory by CMS
  - CAH CMS requirements see Tag 304 and 320
Medical Records

- Medical record must contain an informed consent for procedures and treatments specified as requiring one

- Medical staff by-laws should address this

- Consider state laws requiring informed consent such as for invasive procedures

- Consider any federal laws such as informed consent for research, and state laws on informed consent
Well Designed or Optional

- Name of the practitioner who conducted the informed consent discussion with the patient or the patient’s representative
- Date, time, and signature of witness
- Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient’s representative
Well Designed or Optional

- Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital’s policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.

- Still have to inform patient if someone is doing important parts of the surgery but having it in writing is optional.

- Except mandatory for CAH hospitals.
Survey Procedure

- Verify hospital has assured MS has list of procedures and treatments that require consent
- Verify informed consent forms six mandatory elements
- Compare the hospital standard informed consent form to the P&Ps to make sure consistent
- Make sure any state law requirements are included
Resources

- A site for consent forms that list the risks, and complications, and alternatives of many procedures (provided by the Queensland Government.)¹

- They have forms for pediatrics, orthopedics, vascular, urology, surgical, renal, plastic surgery, psychiatry, ophthalmology, maxillofacial, medical imaging, neurosurgery, ear, nose and throat and many more.²

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<thead>
<tr>
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<td>V</td>
<td>Vermilionectomy</td>
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**HERNIA - LAPAROSCOPIC INGUINAL HERNIA REPAIR**

A. INTERPRETER/ CULTURAL NEEDS

An Interpreter Service is required  yes☐ no☐
If yes, is a qualified Interpreter present  yes☐ no☐
A Cultural Support Person is required  yes☐ no☐
If yes, is a Cultural Support Person present  yes☐ no☐

B. CONDITION AND PROCEDURE

The doctor has explained that I have the following condition: (Doctor to document in patient’s own words)

-----------------------------------------------------------------------------------------------

-----------------------------------------------------------------------------------------------

The following procedure will be performed to the ................................................................. side(s):

(Doctor to document which side)

Repair of the hernia (rupture) laparoscopically i.e.

-----------------------------------------------------------------------------------------------

E. RISKS OF THIS PROCEDURE

There are some risks/ complications. See patient information sheet- "Laparoscopic Inguinal Hernia Repair" for detailed information about the risks involved. If you have not been given an information sheet, please ask for one.

(a) The television method may fail and the surgeon may need to do open surgery.

(b) Damage to large blood vessels, gut or bladder when the sharp trocar and cannula are inserted.

(c) Rarely gas, which is fed into the abdominal cavity, can cause heart and lung complications.

(d) Trouble passing urine after the operation due to spasm of the bladder sphincter.

(e) Swelling of the testicle and scrotum in male patients. Also the penis may show bruising. The testicle may stop making sperm and it may
F. SIGNIFICANT RISKS AND RELEVANT TREATMENT OPTIONS

The doctor has explained any significant risks and problems specific to me, and the likely outcomes if complications occur. The doctor has also explained relevant treatment options as well as the risks of not having the procedure.

(Doctor to document in Medical Record if necessary. Cross out if not applicable.)

G. PATIENT CONSENT

I acknowledge that:

The doctor has explained my medical condition and the proposed procedure. I understand the risks of the procedure, including the risks that are specific to me, and the likely outcomes.

The doctor has explained other relevant treatment options and their associated risks. The doctor has explained my prognosis and the risks of not having the procedure.

I have been given a Patient Information Sheet on Anaesthesia (Version 2: 11/2002).

I have been given a Patient Information Sheet (Version 4: 06/2004) about the procedure and its risks.

I was able to ask questions and raise concerns with the doctor about my condition, the procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.

I understand that the procedure may include a blood transfusion.

I understand that a doctor other than the Consultant

Name of Patient/ Substitute decision maker and relationship ...........................................

Signature  ...........................................

Date ...........................................

Substitute Decision Maker Under the Powers of Attorney Act 1988 and/or the Guardianship and Administration Act 2000. If the patient is an adult and unable to give consent, an authorised decision-maker must give consent on the patient’s behalf.

H. INTERPRETER’S STATEMENT

I have given a translation in ................................. (state the patient’s language here) of the consent form and any verbal and written information given to the patient/ parent or guardian/ substitute decision maker by the doctor.

Name of Interpreter ...........................................

Signature  ...........................................

Date ...........................................

I. DOCTOR’S STATEMENT

I have explained
- the patient’s condition
- need for treatment
- the procedure and the risks
- relevant treatment options and their risks
- likely consequences if those risks occur
- the significant risks and problems specific to this patient.

I have given the patient/ substitute decision-maker
Minnesota Informed Consent

Consent form for surgery or invasive procedure

1. I, [print patient's name]:
   a. Agree that I will have [include both the medical term and patient words]: ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________

   b. At [name of facility]:
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________

   c. The reason for this procedure is [medical condition]: ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________

   d. This will be done or supervised by:
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________

   e. My doctor may have help from others. Help could include opening and closing the wound. Help might also include taking grafts, cutting out tissue, implanting devices. I have been told who will help, if known. The key team members that will assist are:
   Name/title: ____________________________ Critical task: ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________
   ____________________________

2. I have talked to my doctor or health care team about:
   a. What the procedure is and what will happen.
   b. How it may help me (the benefits).
   c. How it might harm me (the most likely and most serious risks).
   d. The long-term effects the procedure might have.
   e. My other choices for treatment. The risks and benefits of those choices.
Federal and Minnesota state regulations require additional documentation and consent for hysterectomy and sterilization.  

Hysterectomy - Department of Health and Human Services (DHHS) requires a hysterectomy acknowledgement statement (HAS). Below is a sample HAS. It is not mandatory for the provider to use this sample acknowledgment statement. Any document that the recipient, or her representative, has signed that shows the provider informed the recipient that she would be incapable of reproducing due to the hysterectomy is permissible.

**Sample Hysterectomy Acknowledgment Statement**

My doctor informed me, both orally and with written materials, that the performance of a hysterectomy would make me sterile (not able to have children).

Signed __________________________ Date __________________________

Note: If the recipient signs the acknowledgment after the hysterectomy, the acknowledgment must show that the recipient was informed of the consequences of the hysterectomy before the procedure was performed.

Sterilizations - This requires exact language, and a DHHS approved form. This form is required by DHHS/CMS for Medicaid paid sterilizations and must be submitted with the bill. Any alternate form would have to be approved the Secretary of DHHS. The brochures with the specific federal consent form are available at:

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2 Requirements related to hysterectomy and sterilizations are under Title 42: Public Health Subpart F—Sterilizations § 441.258 Consent form requirements and § 441.256 Additional condition for Federal financial participation (FFP)
• Medical record must contain all orders, nursing notes, reports, medication records, radiology, lab reports, and vital signs

• Orders must be authenticated or signed off

• All reports of treatment which includes complications

• Any other information used to monitor the patient’s condition
Hospitals may consider redesigning the discharge process in light of federal law if higher than average rate of readmission will be financially penalized.

Remember the CMS discharge worksheet.

All medical records must have a discharge summary:
- With outcome of hospitalization
- Disposition of the patient
- Provisions for follow up care
Discharge Summary 468

- NQF has 34 Safe Practices for Better Healthcare that has a section on discharge summaries
- Many hospitals may consider dictating the discharge summary immediately when the patient is discharged
- Hospital then needs to document that it got the discharge summary to the primary care physician timely
- 78% of the time the PCP did not have a copy of the discharge summary when the patient came for the first visit after hospitalization
Follow-up care includes post hospital appointments, how care needs will be met, and any plans for home health care, LTC, hospice or assisted living.

Can delegate to NP or PA if allowed by state law but physician must authenticate and date it and time it.

Document that list of LTC or home health agencies is given to the patient.
The revised 3rd draft worksheet went from 137 pages to 88 based on the pilot studies.

Published November 9, 2012 and some changes will be published in 2014 and DP one final (2014).

There is a section on discharge planning.

States medical records (like a discharge summary) must be dictated and in hands of PCP by first post hospital visit.

Pilot phase of the program will continue into the fall with all states testing the worksheets.
§482.43 Condition of Participation: Discharge Planning

The hospital must have in effect a discharge planning process that applies to all patients. The hospital’s policies and procedures must be specified in writing.

Interpretive Guidelines §482.43

Hospital discharge planning is a process that involves determining the appropriate post-hospital discharge destination for a patient; identifying what the patient requires for a smooth and safe transition from the hospital to his/her discharge destination; and beginning the process of meeting the patient’s identified post-discharge needs. Newer terminology, such as “transition planning” or “community care transitions” is preferred by some, since it moves away from a focus primarily on a patient’s hospital stay to consideration of transitions among the multiple types of patient care settings that may be involved at various points in the treatment of a given patient. This approach recognizes the shared responsibility of health care professionals and facilities as well as patients and their support persons throughout the continuum of care, and the need to foster better communication among the various groups. Much of the interpretive guidance for this CoP has been informed by newer research on care transitions, understood broadly. At the same time, the term “discharge planning” is used both in Section 1861(ee) of the Social Security Act as well as in §482.43. In this guidance, therefore, we continue to use the term “discharge planning.”

When the discharge planning process is well executed, and absent unavoidable complications or unrelated illness or injury, the patient continues to progress towards the goals of his/her plan of care after discharge. However, it is not uncommon in the current health care environment for patients to be discharged from inpatient hospital settings only to be readmitted within a short timeframe for a related condition. Some readmissions may not be avoidable. Some may be avoidable, but are due to factors beyond the control of the hospital that discharged the patient. On the other hand, a poor discharge planning process may slow or complicate the patient’s recovery, may lead to readmission to a hospital, or may even result in the patient’s death.
Transfer Form Documentation Requirements

The “medical information” that is necessary for the transfer or referral includes, but is not limited to:

- Brief reason for hospitalization (or, if hospital policy requires a discharge summary for certain types of outpatient services, the reason for the encounter) and principal diagnosis;
- Brief description of hospital course of treatment;
- Patient’s condition at discharge, including cognitive and functional status and social supports needed;
- Medication list (reconciled to identify changes made during the patient’s hospitalization) including prescription and over-the-counter medications and herbal. (Note, an actual list of medications needs to be included in the discharge information, not just a referral to an electronic list available somewhere else in the medical record.);
- List of allergies (including food as well as drug allergies) and drug interactions;
- Pending laboratory work and test results, if applicable, including information on how the results will be furnished;
- For transfer to other facilities, a copy of the patient’s advance directive, if the patient has one; and
- For patients discharged home:
Third Revised Worksheets

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

DATE: November 9, 2012
TO: State Survey Agency Directors
FROM: Director
Survey & Certification Group


Memorandum Summary

- Patient Safety Initiative: The Centers for Medicare & Medicaid Services (CMS) is continuing to test revised surveyor worksheets for assessing compliance with three hospital Conditions of Participation (CoPs): Quality Assessment and Performance Improvement (QAPI), Infection Control, and Discharge Planning. We are focusing on compliance with these CoPs as a means to reduce hospital-acquired conditions (HACs), including healthcare associated infections (HAIs), and preventable readmissions.

- Draft Worksheets Made Public: Via this memorandum we are making the revised draft worksheets publicly available. As was the case previously, there may be additional revisions to the worksheets at the end of FY 2013.

Patient Safety Initiative Pilot Phase

The Survey & Certification Group (SCG) Patient Safety Initiative is continuing to pilot test three revised surveyor worksheets designed to help surveyors assess compliance with the hospital CoPs for QAPI, infection control, and discharge planning. In S&C-12-01 released October 14, 2011 and in S&C-12-32 released May 18, 2012, we made available to the public copies of the initial and revised draft surveyor worksheets. These worksheets were used during the pre-test and pilot phases of the SCG initiative, from September 2011 through September 2012.
CMS Hospital Worksheets

- Goal is to reduce hospital acquired conditions (HACs) including healthcare associated infections

- Goal to prevent unnecessary readmission and currently 1 out of every 5 Medicare patients is readmitted within 30 days

- Hospitals can be financially penalized after October 1, 2012 if they have a higher than average rate of readmissions

- The underlying CoPs on which the worksheet is based did not change
Discharge Planning Worksheet

- Does hospital track readmission rates as part of discharge planning?
  - Does assessment include if readmission was potentially preventable?
  - If preventable then did the hospital make changes to the planning process?

- Does hospital collect feedback from post-acute providers for effectiveness of the hospital’s discharge planning process?
  - This would include places like LTC, assisted living or home health agencies
Discharge Planning Tracers

- If patient discharged home is their initial implementation of the discharge plan?
- Did staff provide training to patient including recognized methods such as teach back?
- Were the written discharge instructions legible and use non-technical language (low health literacy)
- Was a list of all medication patient will take after discharge given with a clear indication of any changes?
  - TJC revised their 5 EPs on medication reconciliation July 1, 2011
If transferred to another inpatient facility was the discharge summary ready and sent with patient?

Was discharge summary sent before first post-discharge appointment or within 7 days of discharge?

Was follow up appointment scheduled?

Was there documentation in the medical record of results of tests pending at the time of discharge both to the patient and the post hospital provider?

Was patient readmitted within 30 days?
Every medical record has to have a final diagnosis

Medical records must be completed within 30 days

- Taking 30 days to dictate the discharge summary is not going to work as hospitals reengineer the discharge process
- Want to document medical necessity to avoid RAC denial of claims

Includes inpatient and outpatient charts
Other Important Sections

- There are other important sections that pertain to health information management that are found in other sections of the CoP hospital manual,

- There should be documentation in the medical record for the following;
  - Restraint and seclusion (50 pages of standards)
  - Medications
  - Pre and post-anesthesia evaluations
Documentation in the MR

- Notification of the OPO in all deaths
  - Make sure the one call rule on all deaths or imminent deaths is documented in the medical record
- Organ donation documentation
- Grievances (118)
- Interpreters
  - Be sure to document use of interpreters during critical parts of the care
- Patient rights (129)
Documentation in the MR

- Plan of care (129)
  - Often cited for not having a current plan of care
- Advance directives (132)
- Abuse and neglect assessment (145)
- Disclosure of financial interest (131)
- Disclosure if no physician on duty 24 hours a day (131)
Autopsies 0364

- MS should attempt to secure autopsies in all cases of unusual deaths
- Must define mechanism for documenting permission to perform an autopsy
- Must be system for notifying MS and attending doctor when autopsy is performed
Physician Order 406  2013

- CMS issues standing order memo 10-24-08
- Also includes preprinted orders and use of stamps
- Flu and pneumovax can be given by protocol approved by the MS after assessment of contraindications
  - Physician does not need to sign off order
- Need physician orders for rehab (PT), medications and biologicals, and diet orders and problematic standard for hospitals
A-0406

(Rev.)

§482.23(c)(1) (ii) — Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).

§482.23(c)(3) - With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under §482.12(c)...

§482.23(c)(3)(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.
Physician Order 406

- Orders for drugs must be documented and signed by practitioners allowed to write them or standing orders as set forth in Tag 457
  - Doctors and if allowed, NP, PAs, PharmD
- Rubber stamps - will not be paid for order for M/M patients and some insurance companies so many hospitals do not allow rubber stamps
  - Also covered in tag 450
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 prescriber

- Encourage a culture where staff 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
  - Make sure protocols approved by the Medical Staff
  - Document order in order sheet
- Code teams give ACLS drugs in an arrest
- Timing of orders should not be a barrier to effective emergency response
- Preprinted orders - should send memo so doctors and providers are aware of new guidelines
Restraint and Seclusion

- There are 50 pages of R&S standards
- Discuss how to document the use of R&S, orders, reason for R&S, alternatives etc.
- Section on what is needed in your P&P
- Discusses what is required for physician and staff education
- No need to fill out restraint worksheet if patient dies from 2 soft wrist restraints which did not cause death
  - But must have internal log and document in medical record
Incident Reports

- There must be procedure for reporting transfusion reactions, adverse drug reactions and errors in administration of drugs (410)

- Survey procedure – look at their procedure for reporting

- Surveyors may review the incident reports or other documentation through QAPI program
Update: Maintaining a Legally Sound Health Record—Paper and Electronic

The health record is the legal business record for a healthcare organization. As such, it must be maintained in a manner that follows applicable regulations, accreditation standards, professional practice standards, and legal standards. The standards may vary based on practice setting, state statutes, and applicable case law. An attorney should review policies related to legal documentation issues to ensure adherence to the most current standards and case law.

HIM professionals should fully understand the principles of maintaining a legally sound health record and the potential ramifications when the record’s legal integrity is questioned. This practice brief will review the legal documentation guidelines for entries in and maintenance of the health record—both paper and electronic. Many of the guidelines that originally applied to paper-based health records translate to documentation in electronic health records (EHRs). In addition, new guidelines and functionalities have emerged specific to maintaining legally sound EHRs. It is of the utmost importance to maintain EHRs in a manner that will support a facility’s business and legal processes, otherwise duplicate paper processes will need to be maintained.

AHIMA convened an e-HIM® work group to re-evaluate and update the 2002 practice brief
Amendments, Corrections, and Deletions in the Electronic Health Record Toolkit

www.ahima.org/infocenter/documents/AmendmentsCorrectionToolkit.pdf

American Health Information Management Association
2009
Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology
Policies and Procedures

- Hospitals need a policy and procedure (P&P) to ensure compliance with standards such as those required by CMS and TJC
- Staff should be aware that surveyors may often pull and P&P
- P&P need to be consistent with regulations and the standards of care
- Surveyors will also hold the hospital to the standards contained in your P&P
- So make sure they are current and up to date
II. Confidentiality

The Medical Record is confidential and is protected from unauthorized disclosure by law. The circumstances under which UC__ may use and disclose confidential medical record information is set forth in the Notice of Privacy Practices (see: Privacy Policy and Procedure No. _____, “Notice of Privacy Practices”) and in other UC__ Privacy Policies and Procedures.

III. Content

A. Medical Record content shall meet all State and federal legal, regulatory and accreditation requirements including but not limited to Title 22 California Code of Regulations, sections 70749, 70527 and 71549, and the Medicare Conditions of Participation 42 CFR Section 482.24. Appendix A contains a listing of required Medical Record documentation content, and current electronic or paper format status.

B. Additionally, all hospital records and hospital-based clinic records must comply with the applicable hospital’s Medical Staff Rules and Regulations requirements for content and timely completion.

C. All documentation and entries in the Medical Record, both paper and electronic, must be identified with the patient’s full name and a unique UC__ Medical Record number. Each page of a double-sided or multi-page forms must be marked with both the patient’s full name and the unique Medical Record number, since single pages may be photocopied, faxed or imaged and separated from the whole.

D. All Medical Record entries should be made as soon as possible after the care is provided, or an event or observation is made. An entry should never be made in the Medical Record in advance of the service provided to the patient. Pre-dating or backdating an entry is prohibited.
The End! Questions?

- Sue Dill Calloway RN, Esq. CPHRM, CCMSCP
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Education
- Board Member Emergency Medicine Patient Safety Foundation
- 614 791-1468
- sdill1@columbus.rr.com
- HIPAA changes follow
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 164

RIN: 0945-AA03

Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules

AGENCY: Office for Civil Rights, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) or “the
Final HIPAA


Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules

A Rule by the Health and Human Services Department on 01/25/2013

ACTION Final Rule.
HIPAA Revised Law

- Covers changes to HIPAA privacy, security, Enforcement, and Breach Notification Rules
- Modified the HIPAA Privacy Rule as required by the Genetic Information Nondiscrimination Act (GINA) to prohibit most health plans from using or disclosing genetic information for underwriting purposes
- Increased and tiered civil money penalties
- Replaces the breach notification rule’s “harm” threshold with a more objective standard under HITECH
The U.S. Department of Health and Human Services (HHS) announced the new rule to strengthen the privacy and security protections for health information established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

- Is a 563 page document and published January 25, 2013
- Final rule effective March 26, 2013 but the compliance date is September 23, 2013 for most of the sections
HIPAA Revised Law

- Changes in the final rule expand many of the privacy and security requirements to Business Associates (BAs)
- Business associates may also be liable for the increased penalties for noncompliance based on the level of negligence up to a maximum penalty of $1.5 million
- Clarified when breaches of unsecured health information must be reported to HHS under HITECH (Health Information Technology for Economic and Clinical Health)
HIPAA Revised Law

- Make business associates (BAs) of hospitals directly liable for compliance with certain HIPAA Privacy and Security Rules’ requirements

- Patients can ask for a copy of their medical records in an electronic form

- If a patient pays by cash they can instruct the hospital not to share information about their treatment with their health plan

- Establish new standards for the use of patient-identifiable information for fundraising and marketing
HIPAA Revised Law

- Raise the maximum penalty for noncompliance to $1.5 million per violation
- Expand liability to "business associates" of hospitals and other "HIPAA-covered entities," such as data miners and health IT service providers
- Business associates have to give specific notifications to individuals whose PHI (protected health information) is breached, HHS and in some cases, the media when a breach of unsecured information happens under HITECH
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<th>HIPAA Revised Law</th>
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<td>Prohibits hospitals from selling an individual’s health information without getting the individual’s authorization in the manner required by the Regulations</td>
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<td>Hospital must review and update policies and procedures and practices</td>
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<td>Must update BA agreements</td>
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<td>Must train staff and document compliance with these new regulations</td>
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<td>Removed the harm provision in breach notification rule</td>
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HIPAA Revised Law

- Require modifications to, and redistribution of, a covered entity’s notice of privacy practices (NPP)
- Modify the patient’s authorization and other requirements to facilitate research
- Disclosure of child immunization proof to schools
- Enable access to decedent information by family members or others
- New tiered penalty structure for covered entities that violate the law
  - It increases fines to as much as $50,000 for "willful neglect" of information without correction, and $1.5 million for multiple violations of identical provisions
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Thank you for attending!!

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