# CMS HOSPITAL CONDITIONS OF PARTICIPATION (CoPS) 2009

Medical Records Section

TELNET 2508 July 16, 2009 10-11:30 am EDT

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## Speaker


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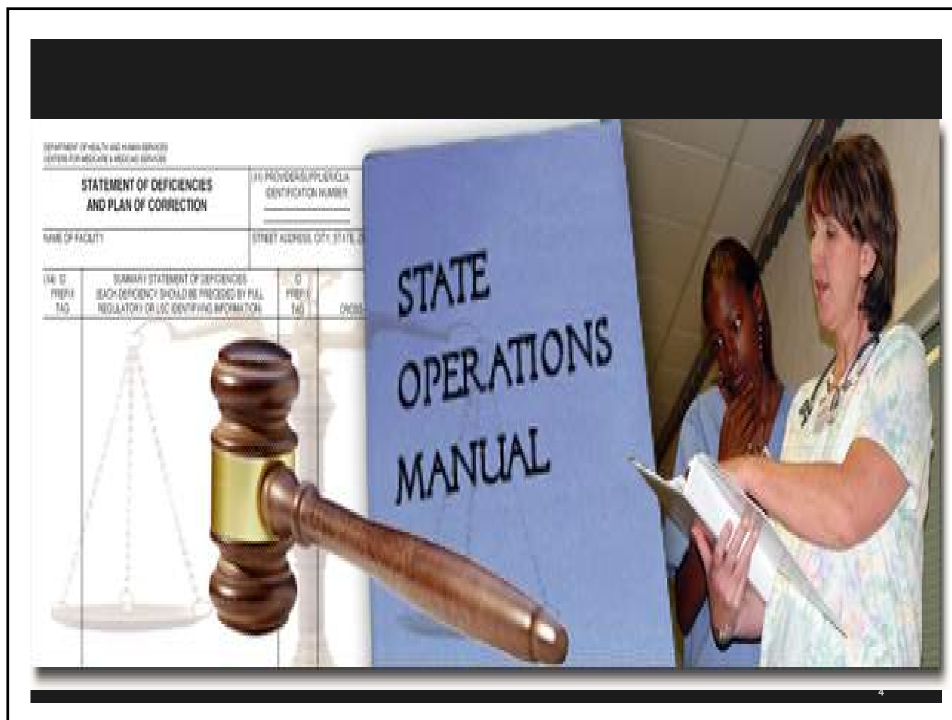
# Objectives

- Recall that CMS has a section on medical records services that was revised on October 17, 2008
- Describe when a history and physical must be done and what is required by CMS and the Joint Commission
- Discuss the CMS and TJS standard on verbal orders





# The Conditions of Participation CoPs

- Regulations first published in 1966
  - Many revisions since with final interpretive guidelines were issued **10-17-08**
- Published in the Federal Register first-42 CFR Part 482[1]
- CMS then publishes **Interpretive Guidelines**[2]
- Hospitals should check this website once a month for changes

[1]www.gpoaccess.gov/fr/index.html

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



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## TJC 2009 Revised Requirements

- March 26, 2009 TJC issues 27 pages of changes to the TJC hospital manual[1]
  - Reflects their standards as being in compliance with the CMS CoP
  - Standards are for hospitals that use them to get deemed status and payment for M/M patients
- Scored after July 1, 2009

[1]www.jointcommission.org/Library/WhatsNew/Hospital_deeming%20application_January_%20 2009_Update.htm

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

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

**Transmittal 37** | **Date: October 17, 2008**

**SUBJECT: Revise Appendix A, "Interpretive Guidelines for Hospitals"**

**I. SUMMARY OF CHANGES:** Appendix A is being revised to reflect amended regulations and survey and certification policy issuances concerning the Conditions of Participation for Hospitals, 42 CFR Part 482. It also contains new guidance related to the Patients' Rights Final Rule, 42 CFR 482.13(e), (f), and (g), published in the Federal Register December 8, 2006 (71 FR 71378). In addition, Regulatory text that appears in brackets was included in a previous tag, but is repeated for clarity and accuracy in representing the regulatory citation.

**NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance**
**IMPLEMENTATION DATE: Upon Issuance**

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

*A-0431*

**§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 out patient records. The hospital must create and maintain a medical record for every individual, both inpatient and out patient 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 structured appropriately to meet the needs of the hospital and the patients

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## Medical Record Services 0431

- Provide MR services
  - One unified MR service responsible for all MR, both inpatient and outpatient
  - An administrator responsible for MR
  - Surveyors will sample 10% of daily census and at least 30 records
- Keep MR on every patient
- MR includes radiology films and scans, pathology slides, computerized information, etc.

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## Staffing of Medical Records 432

- Organization must be appropriate for size 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
- Ensure proper coding and indexing of records
- Surveyor will look at job descriptions and staffing schedules



## Retention of Record A-438

- MR on each patient
- Both inpatients and outpatients
- MR must be accurate (contains all orders, test results, care plans, treatment and response to treatment), complete, retained and accessible (accessible 24 hours a day)

## Medical Records

- Use a system of author identification and protect security of all records
- Protected from fire, water damage and other threats
- Must be promptly completed  and within 30 days
- Kept at least 5 years (439) in original, microfilm, computer memory or other electronic storage



## Medical Records (continued)

- Certain medical records may be retained longer if required by state or federal law (OSHA, EPA, FDA)
- See retention law memo from AHIMA at www.ahima.org
- Will request records from 48-60 months ago

Table 3: Federal Record Retention Requirements

| Type of Documentation | Retention Period | Citation/Reference |
|---|---|---|
| Abortions and related medical services documentation | Maintained for three years. | 42 CFR 36.56<br>42 CFR 50.309 |
| Ambulatory surgical services | Retention periods are not specified. | 42 CFR 416.47 |
| Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services | 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 state law or five years after the date of discharge, whichever is longer. | 42 CFR 485.721(d)<br>42 CFR 486.161(d) |
| Clinics, rural health | Six years from date of last entry and longer if required by state statute. | 42 CFR 491.10(c) |
| Competitive medical plans (see HMOs, competitive medical plans, healthcare prepayment plans) | | |
| Comprehensive outpatient rehabilitation facilities (CORFs) | Five years after patient discharge. | 42 CFR 485.60(c) |
| Critical access hospitals (CAHs) | 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. | 42 CFR 485.638(c) |
| Department of Veterans Affairs—Diagnostic and operation index file | Destroy monthly listing after receipt of consolidated biannual listing.<br>Destroy consolidated biannual listing or prior equivalent 20 years after date of report. | Records Control Schedule (RCS)10-1, Section XXII—Medical Administration Service (136) (1985) |
| Department of Veterans Affairs—Disposition data files (PTF) | Destroy after one year and after a PTF master record has been created at the data processing center. | Records Control Schedule (RCS)10-1, Section XXII—Medical Administration Service (136) (1985) |
| Department of Veterans Affairs—Gains and losses file | Destroy master set after one year. | Records Control Schedule (RCS)10-1, Section XXII—Medical Administration |

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# Retrieval A-0440

- 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
- MR have to be accessible for departments that need them like the emergency department

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## Confidentiality 441 and 442

- 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.
- Surveyor will ask for policy
- Release only for court orders, subpoenas, in house education purposes, etc.

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## Content of Records A-449

- Contain records, notes, reports assessment to justify
- Admission
- Continued hospitalization
- Support the diagnosis

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## Content of Records A-449 (continued)

- Describe the patient's progress
- Describe response to medications and to interventions, care, and treatment
- Records must be promptly filed in chart



## Legible and Authenticated 450

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

## 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.*



## Legible and Authenticated (continued)

- Must have P&P if electronic medical record
- If non MD does H&P or document exams, must be authenticated
- MS R&R address countersignature when required by policy or state law and this is defined in MS R&R

## Medical Records 450

- If rubber stamp used-must have signed statement only that individual will use it, but do not allow for signature or you may not be paid for care
- If electronic MR must demonstrate how alterations are prevented
- Can’t use system of auto authentication that says can not review because not transcribed yet

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## Verbal Orders 454 and 457

- Recall verbal order section starting in MS section at tag number 407
- Repeats same section
- All doctor can sign VO for any other doctor on case for five years
- Person who takes VO must read it back and write it down with date and time

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## Verbal Orders 454 and 457 (continued)

- When doctor or LIP authenticates and signs off order must date and time it also
- Sign off 48 hours unless state law specifies specific time frame, even all lab orders
- Can't sign off within 30 days unless state law is that specific and not just records be completed within this time frame



## Verbal Orders 454 and 457

- Recall verbal order section starting in MS section at tag number 407
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## Verbal Orders 407

- Verbal orders are a patient safety issue
  - Have lead to many errors
  - Joint Commission has standard and NPSG, CMS has standard in CMS hospital CoPs, QIO 7th scope of work, National Coordinating Council recommendations



## Verbal Orders 407 (continued)

- Rewrite your P&P and Medical staff by-laws to be consistent with these standards
- Repeated VO section in MR starting with tag 454 and reiterated area of verbal orders offer too much room for error
- Changed language from prescribing to ordering practitioner

## 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
- New regulation broadens category of practitioners who can sign orders off

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## 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
- Provide guidelines for clear and effective communications

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## Signing Off Verbal Orders

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



## Verbal Orders

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

## Joint Commission Verbal Orders

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

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## 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, not older than 30 days old and updated within 24 hours and updated 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

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## H&P 358

- 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



## H&P Admission

- There needs to be an updated entry in the medical record to reflect any changes
- Person who does the H&P must be licensed and qualified
  - Example, family physician does H&P 2 weeks ago for patient having CABG today
  - Surgeon would review, update, and determine if any changes since it was done and authenticate document

## History and Physicals

- 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
- There needs to be a complete H&P in the chart for every patient
  - Except in emergencies
  - Can make entry in progress notes



## History and Physicals (continued)

- New 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 (2.120) 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

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## TJC MS.03.01.01 H&P

- EP6 Specifies minimal content (can vary by setting, level of service, tx & 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

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## TJC MS.03.01.01 H&P

- 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 (continued)

- Must document complications and hospital acquired infections (HAI) and unfavorable reactions to drugs and anesthesia (465)
- It is important for all practitioners to be aware of the need to document complications and how to do this correctly

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## Informed Consent A-466

- Interpretive guidelines issued on April 13, 2007, and minor changes October 17, 2008
- Now three separate sections related to informed consent in patient rights, medical record and surgical services
- 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

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## 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

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## Medical Records 466

- 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

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## Consider List of Procedures

| Procedure Name | Requires Informed Consent |
|---|---|
| ▪Ablations | Yes |
| ▪Amniocentesis | Yes |
| ▪Angiogram | Yes |
| ▪Angiography | Yes |

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## Consider List of Procedures (continued)

| Procedure Name | Requires Informed Consent |
|---|---|
| ▪Angioplasties | Yes |
| ▪Arthrogram | Yes |
| ▪Arterial Line insertion (performed alone) | Yes |
| ▪Aspiration Cyst (simple/minor) | No |

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## Consider List of Procedures (continued)

| Procedure Name | Requires Informed Consent |
|---|---|
| Aspiration Cyst (complex) | Yes |
| Blood Administration | Yes |
| Blood Patch | Yes |
| Bone Marrow Aspiration | Yes |

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## Consider List of Procedures (continued)

| Procedure Name | Requires Informed Consent |
|---|---|
| Bone Marrow Biopsy | Yes |
| Bronchoscopy | Yes |
| Capsule Endoscopy | Yes |
| Catherizations, Cardiac & vascular | Yes |
| Cardioversion | Yes |

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## Informed Consent Manual

- One hospital (Providence Everett Medical Center) has their informed consent manual on the Internet
- It has an excellent list of which procedures need informed consent
- List can be used by others to determine which procedures they want to have informed consent
- Remember one with reasonable known risks should be considered
- Sample manual[1]

[1]http://www.providence.org/resources/everett/ ConsentTrainingBooklet.doc



## Informed Consent Forms

- Need for all surgeries
- Exception is emergencies
- All inpatients and outpatients
- For all procedures specified

## Informed Consent Forms (continued)

- Needs to reflect a process
- Form must follow policies
- Must include state or federal requirements
- Must contain minimum requirements (mandatory)

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## 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

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## Well designed (optional) may also include:

- 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

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## Well designed (optional) may also include: (continued)

- 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

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## Well designed (optional) may also include: (continued)

- Statement, if applicable, that QMP who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital

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## 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

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## Chart Must Contain 467

- Medical record must contain all orders, nursing notes, reports, medication records, radiology, lab reports, and vital signs
- Orders must be authenticates or signed off
- All reports of treatment which includes complications
- Any other information used to monitor the patient's condition



## Discharge Summary 468

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

## Discharge Summary 468 (continued)

- 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

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## Final Diagnosis 469

- Every medical record has to have a final diagnosis
- Medical records must be completed within 30 days
- Includes inpatient and outpatient charts

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## Other Important Sections

- There are other important sections that pertain to health information management that are found in other sections of the 370 pages 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

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## Documentation in the MR

- Notification of the OPO in all deaths
- Organ donation documentation
- Grievances (118)
- Interpreters
- Patient rights (129)

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## Documentation in the MR (Continued)

- Plan of care (129)
- Advance directives (132)
- Abuse and neglect assessment (145)
- Disclosure of financial interest (131)
- Disclosure if no physician on duty 24 hours a day (131)

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## 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

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## Physician Order 406

- 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 Order 406 (continued)

- Orders for drugs must be documented and signed by practitioners allowed to write them
  - Doctors and if allowed, NP and PAs
- Rubber stamps - will not be paid for order for M/M patients and some insurance companies so many hospitals do not allow rubber stamps

## Physician Order 406 (continued)

- Order must have name of patient, age and weight (if applicable), date and time of order, drug name, strength, frequency, dose, route, quality and duration, and special instructions for use, and name of pre scriber
  - 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

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## Physician Order 406 (continued)

- Chest pain protocol or asthma protocol with Albuterol and Atrovent are an example of initiation of orders
- 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

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## Preprinted Order Sets

- Must date and time when the order set is signed
- Must indicate on last page the total number of pages in the order set
- If want to strike out something in the order sheet or delete it or add order on blank line then physician needs to initial each place
- Should add this to the MR audit sheet to make sure there is compliance with this guideline

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## 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

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## 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



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## Speaker

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