Medicare Conditions of Participation

July 27, Pasadena
July 28, Sacramento

Welcome and Introductions
CMS HOSPITAL CONDITIONS OF PARTICIPATION (CoPS) 2010

What Hospitals Need to Know

Speaker

Sue Dill Calloway RN, Esq.
CPHRM
AD, BA, BSN, MSN, JD
Medical Legal Consultant
5447 Fawnbrook Lane
Dublin, Ohio 43017
(614) 791-1468
sdill1@columbus.rr.com
The Conditions of Participation

- Regulations first published in 1966, many revisions since

- Published in the *Federal Register* first-42 CFR Part 482¹

- CMS then publishes *Interpretive Guidelines*²

- Hospitals should check this website once a month for changes

¹www.gpoaccess.gov/fr/index.html
²www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp
The Revised Final CoPs

- **Final Interpretive Guidelines** were published October 17, 2008\(^1\) (red lined)

- Updated June 5, 2009 (Tag A-450, Medical Records) and Dec. 11, 2009 (Tag A-1000, Anesthesia)

- Every hospital should have a copy of the guidelines

- Periodically check for updates

\(^1\)www.cms.hhs.gov/transmittals/downloads/R37SOMA.pdf
TJC Revised Requirements

- January 5, 2009: TJC issues 46 pages of changes to the TJC hospital manual. Reduced to 27 pages March 26, 2009¹
  - Reflects their standards as being in compliance with the CMS CoPs
  - Standards are for hospitals that use them to obtain deemed status - payment for M/M patients
- Scored after July 1, 2009 and continued in 2010

¹www.jointcommission.org/Library/WhatsNew/Hospital_deeming%20application_January_%202009_Update.htm
State Operations Manual
Appendix A - Survey Protocol,
Regulations and Interpretive Guidelines for Hospitals

Table of Contents

(Rev. 47, 06-05-09)

Transmittals for Appendix A

Survey Protocol

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Task 6 - Post-Survey Activities
Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module

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

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

Transmittal 47
Date: June 5, 2009

SUBJECT: Revised Appendix A, “Interpretive Guidelines for Hospitals”

I. SUMMARY OF CHANGES: The revised issuance of Appendix A dated October 17, 2008, inadvertently omitted language relating to 42 CFR 482.34(c)(1), concerning medical record entries. This revision corrects that omission.

NEW/REVISED MATERIAL – EFFECTIVE DATE: June 5, 2009
IMPLEMENTATION DATES: June 5, 2009

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.

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

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Mandatory Compliance

- Hospitals that participate in Medicare or Medicaid must meet the CoPs for all patients in the facility
  - Not just those patients who are Medicare or Medicaid
- Hospitals accredited by TJC, AOA, or DNV
- Healthcare have what is called “deemed status”
- This means you can get reimbursed without going through a state agency survey
- Can still be subject to a complaint or validation survey
CMS Hospital CoPs

- *Interpretative Guidelines* are a part of the State Operations Manual\(^1\)
  - Appendix A, Tag A-0001 to A-1163
  - 370 pages long
- Manuals found at\(^2\)
  - Manuals are now being updated more frequently
  - Still need to check Survey and Certification website

\(^1\)www.cms.gov


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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Conditions of Participation

- Important *Interpretive Guidelines* for hospitals (keep handy):
  - A-Hospitals and C-Critical Access Hospitals
  - AA-Psychiatric Hospitals
  - C-Labs
  - V-EMTALA (amended May 29, 2009)
  - Q-Determining Immediate Jeopardy
  - I-Life Safety Code Violations
  - All CMS forms on its website

Contact for Questions

- Resource is CDPH or regional CMS office
- CHA may be of assistance
- Note that when changes are published in the *Federal Register* there is always the name and phone number of a contact person at CMS
Survey Procedure

- Step one: Publication of regulation or revision in Federal Register
- Step two: CMS publishes Interpretive Guidelines

The Interpretive Guidelines provide instructions to the surveyors on how to survey for compliance with the CoPs

- These are called survey procedures
- Questions or directions, such as “ask patients to tell you if the hospital told them about their rights”

Interpretive Guidelines

- Surveyors use the information contained in the Interpretive Guidelines
- They do not replace or supersede the law
- Should not be used as basis for citation
- They do contain authoritative interpretations and clarifications which can assist surveyors in making determinations of compliance
### Compliance Recommendation

- Assign each section of the hospital CoPs to the manager of that department
  - Do a side-by-side gap analysis (like the TJC PPR) for each section
  - Keep a hard copy of CoP and analysis
- Designate someone in charge if a validation, complaint, or unannounced survey occurs
- Commonly referred to as the CoP king or queen

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### CMS Required Education

These will be discussed throughout presentation:

- Restraint and seclusion (annual)
- Abuse, neglect and harassment (annual)
- Infection control
- Advance directives
- Organ donation
- IVs and blood and blood products
- ED common emergencies, IVs and blood and blood products for ED
## What’s Really Important

- Life Safety Code Compliance
- Infection Control (CMS gets $50 million grant to enforce in 2010)
- Patient Rights, especially R&S, (including medication used as a restraint) and grievances
- EMTALA
- Performance improvement (they call it QAPI), medication management
- Dietary and cleanliness of dietary
- Don’t forget outpatient clinics

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## What’s Really Important

- Verbal orders
- History and physicals
- Need order for respiratory and rehab (such as physical therapy)
- Need order for diet
- Anesthesia (updated 12-11-09 and 2-5-10)
- Standing orders
- Medications within 30-minute timeframe
Survey Protocol

- First 37 pages of *Interpretive Guidelines* list the survey protocol, including sections on:
  - Off-site survey preparation by surveyors
  - Entrance activities
  - Information gathering/investigation
  - Exit conference
  - Post-survey activities

Survey Protocol (continued)

- Survey done through observation, interviews, and document review
- Monday - Friday but can come weekends or evenings
- Federal law allows CMS or CDPH surveyors access to your facility
- CAH distinct-part rehab or psych (behavioral health) surveyed under this section even though CAH has separate manual
Survey Team

Mid-size hospital with a full survey:

- Two to four surveyors for three or more days and at least one RN with hospital survey experience
- Team based on complexity of services offered
- SA (state agency) decides or RO (regional office) for federal teams

Task 1 – Off-Site Survey Prep

- Team coordinator gathers information about provider (ownership, types of services offered, locations)
- Determines if provider-based, remote locations, PPS-exempt services offered
- Information collected from CMS database such as previous surveys and findings, size of facility, and average daily census
- Team should enter together and usually goes to administration
Task 2 – Entrance Activities

- Team will explain purpose and scope of survey (in general terms)
- ENTRANCE CONFERENCE – sets tone for entire survey
- Give surveyors conference room, telephone
- Give names of department heads, their locations and phone numbers
- Provide organizational chart
- Hospital should track surveyors’ names, what they’re doing, keep copies of documents provided

Task 2 – Entrance Activities (continued)

- Provide additional information
  - Infection control plan
  - Names and addresses of all off-site locations and provider numbers
  - List of employees
  - Medical staff bylaws, rules and regulations
  - List of contracted services
  - Copy of floor plan
  - List of current patients with room numbers, doctors
  - Give preliminary date and time for exit conference
Task 3 – Information Gathering

- Purpose is to determine compliance with CoPs through observation, interviews, and document review
- Will visit patient care areas including ED and outpatient, imaging, rehab, and remote locations
- Observe actual care (IV, tube feeding, wound dressing changes)

Task 3 – Information Gathering (continued)

- Review copies of materials
- Use *Interpretive Guidelines* to guide survey
- Use Appendix Q if Immediate Jeopardy is suspected (as well as state law – change of hats)
- Surveyor has discretion whether to allow staff to accompany the surveyor
Task 3 – Information Gathering (continued)

- Surveyors will bring all significant adverse events to the team coordinator’s attention immediately
- Surveyors must respect patient privacy and confidentiality
- Work with surveyor to try to get them not to take peer-review protected documents with them

Task 4 – Analysis of Finding

- Review and analyze all information gathered
- Determine if CoPs are met and if PPS exclusionary criteria are met (42 CFR Part 412, subpart B) or swing bed (42 CFR Section 482.66)
- Prepare exit conference report
- If noncompliance with CoP then determine if at standard or condition level and how dangerous it is
Deficiency

- **Condition level** – (NOT GOOD) Noncompliance with requirements in a single standard or several standards within the condition or single tag. Represents a severe or critical health breach (need to have conversation)

- **Standard level** – Noncompliance as above, but not of such a character to limit facility’s capacity to furnish adequate care – no jeopardy or adverse effect to health or safety of patient

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Task 5 – Exit Conference

- **Objective** - inform facility of preliminary findings

- **Policy** is to do exit conference
  - Can refuse if hostile environment or
  - Counsel tries to turn into evidentiary hearing

- If recorded, must provide two tapes and tape recorders
  - Tape at same time - give surveyor one

- **Official findings** are provided in writing on Form CMS 2567
Task 5 – Exit Conference (continued)

- Surveyor can set ground rules
- Present findings of noncompliance and why these constitute a violation
- Statement of deficiencies will be mailed within 10 working days (Form 2567)
  - This form is made public no later than 90 days after survey
  - List deficiencies, plans for correction, timelines and opportunity to refute findings

Task 6 – Post-Survey Activities

- Objective is to complete the survey and certification requirements and notify staff regarding survey results
- Complete hospital restraint/seclusion death reporting worksheet as appropriate
- Enter information into hospital Medicare database
- Certification of providers with deficiencies if acceptable plan of correction
Interpretive Guidelines

- Starts with a tag number, example A-0001
  - “A” refers to the hospital CoPs
- Three sections:
  1. The regulation from the CFR
  2. The Interpretive Guideline explanatory information
  3. The survey procedure
- Survey procedure
  - Not in every tag number
  - Explains survey process, policies to be reviewed, questions to be asked and documents to be reviewed

Regulations and Interpretive Guidelines

A-0001

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

§482.2 Provision of Emergency Services by Nonparticipating Hospitals

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if:

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e)(1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by non-participating hospitals are set forth in subpart G of part 424 of this chapter.

(b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

Interpretive Guidelines §482.2

The statutory requirements that a hospital must meet are:
Compliance with Laws A-0020

- The hospital must be in compliance with all federal, state, and local laws
- Survey procedure tells surveyor to interview CEO or other person designated by hospital
- Refer non-compliance to proper agency with jurisdiction such as OSHA (TB, bloodborne pathogens, universal precautions), EPA (haz mat or waste issues), or Office of Civil Rights (privacy, discrimination, Rehabilitation Act of 1973)
- Will ask if cited for any violation since last visit

Compliance with Laws A-0023, A-0022

- Hospital must be licensed
- Personnel must be licensed or certified if required by state (doctors, nurses, PT, PA, etc.)
Compliance with Laws A-0023, A-0022 (continued)

- Verify that staff and personnel meet all standards (such as CEs) required by state law
- Review sample of personnel files to be sure credentials and licensure are up-to-date

Governing Body (Board)

- 42.CFR Section 482.12 and Tag A-0043
- Hospital must have an effective governing body responsible for the conduct of the hospital as an institution
- Written documentation identifies an individual as being responsible for conduct of hospital operations
Medical Staff and Board A-0044

- Board makes sure medical staff (MS) requirements are met
- Board must determine which categories of practitioners are eligible for appointment to MS as allowed by state law (physicians, podiatrists, dentists, and sometimes psychologists, if MS bylaws allow)
- Board grants privileges to practice in hospital
- Duplicate provisions in MS Tags A-0338 – A-0363

Medical Staff and Board (continued)

- Board appoints individuals to the MS with the advice and recommendation of the MS (A-0046)
  - Will review board minutes to make sure they are involved in appointment of MS
- Board must assure MS has bylaws and they comply with the CoPs (A-0047)
  - CHA model medical staff bylaws meet all requirements
- Board must make sure it has approved the MS bylaws and rules and regulations (A-0048)
Medical Staff and Board (continued)

- Any R&R or MS bylaws or revisions must be approved by the Board to be effective (A-0048)
- Board must ensure MS is accountable to the board for the quality of care provided to patients (A-0049)
- All care given to patients must be by or in accordance with the order of practitioner who is operating within privileges granted by the Board
  - Consider outpatient lab, radiology procedures ordered by practitioner not on MS

Medical Staff and Board (continued)

Board ensures that criteria for selection of MS members is based on (A-0050):

- MS privileges: describe privileging process and ensure there is written criteria for appt to MS
- Individual character, competence, training, experience and judgment
- Make sure under no circumstances is staff membership or privileges based solely on certification, fellowship, or membership in a specialty society (A-0051)
Medical Staff

- CMS Guidance issued to clarify it is a recommendation that MS must conduct appraisals of practitioners at least every 24 months
- MS must examine each practitioner’s qualifications and competencies to perform each task, activity, or privilege
- Include current work, specialized training, patient outcomes, education, currency of compliance with licensure requirements

Medical Staff (continued)

- Please note that there is another section later in the CoPs that also discusses medical staff
  - Tags A-0338 – A-0363
  - Many of the same sections are repeated later
CEO (A-0057)

- Board must appoint a CEO who is responsible for managing the hospital
- Verify the board has appointed a CEO
- Verify CEO is responsible for managing entire hospital

Care of Patients A-0063 – A-0068

- Board must make sure every patient is under the care of a physician (or dentist, podiatrist, or psychologist)
- Practitioners must be licensed and a member of MS
Evidence of being under care of MD/DO must be in the medical record

Board and MS must establish P&P and bylaws to ensure compliance

A-0066

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

[...the governing body must ensure that the following requirements are met:]

§482.12(c)(2) (continued)

If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

Interpretive Guidelines §482.12(c)(2)

CMS hospital regulations do permit licensed practitioners (e.g., nurse practitioners, midwives, etc), as allowed by the State, to admit patients to a hospital, and CMS does not require these practitioners be employed by a MD/DO. However, CMS regulations do require that Medicare and Medicaid patients admitted by these practitioners be under the care of an MD/DO. Evidence of being under the care of an MD/DO must be in the patient’s medical record. If a hospital allows these practitioners to admit and care for patients, as allowed by State law, the governing body and medical staff would have to establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met.
Midwife Patients

- CMS requires only Medicare patients of nurse midwife be under MD/DO care and not Medicaid patients
  - This is because there is a separate federal law on this
  - Surveyors will select Medicare patients and not Medicaid patients if under care of midwife
- CA Law: must be admitted by member of the medical staff (physician, dentist, podiatrist, psychologist if MS bylaws allow)

Care of Patients A-0067 – A-0068

- Board must make sure doctor is on duty or on-call at all times, doctor of medicine or osteopathy is responsible for monitoring care of M/M patients
- Interview nurses and make sure they are able to call the on-call MD/DO and they come to the hospital when needed
Patient admitted by non-physician needs to be monitored by a MD/DO, as required.

The board and MS must have policies to make sure Medicare/Medicaid patient is responsible for any care OUTSIDE the scope of practice of the admitting practitioner.

Know the scope of practice for NP, CRNAs, midwives, and PAs under state law:
- Look at BRN website for nurses
- PA scope currently being expanded by legislature: stay tuned

Interpretive Guidelines §482.12(c)(4)
CMS hospital regulations do permit licensed practitioners (i.e., doctors of dental surgery, dental medicine, podiatric medicine, or optometry; chiropractors; or clinical psychologists), as allowed by the State, to admit patients to a hospital. However, CMS does require that Medicare and Medicaid patients who are admitted by a doctor of dental surgery, dental medicine, podiatric medicine, or optometry, a chiropractor, or a clinical psychologist be under the care of a MD/DO with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. If a hospital allows a doctor of dental surgery, dental medicine, podiatric medicine, or optometry, a chiropractor or a clinical psychologist to admit and care for patients, as allowed by State law, the governing body and medical staff must establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met. As applicable, the patient’s medical record must demonstrate MD/DO responsibility/care.

Survey Procedures §482.12(c)(4)
- Verify that an assigned doctor of medicine or osteopathy is responsible for and is monitoring the care of each Medicare or Medicaid patient with respect to all medical or psychiatric problems during the hospitalization.
Plan and Budget A-0073 – A-0077

Need institutional plan

- Include annual operating budget with all anticipated income and expenses
- Provide for capital expenditures for 3-year period
- Identify sources of financing for acquisition of land, improvement of land, buildings and equipment
- Must be submitted for review
  - TJC has similar standards in its leadership chapter

Plan and Budget (continued)

Need institutional plan (continued)

- Must include acquisition of land and improvement to land and building
- Must be reviewed and updated annually
- Must be prepared under direction of board and a committee of representatives from the board, administrative staff, and MS (A-077)
- Verify that all 3 participated in the plan and budget
Contracted Services

- Board responsible for services provided in hospital (A-0083)
  - Whether provided by hospital employees or under contract
- Board must take action under hospital’s QAPI program to assess services provided both by employees and under direct contract
- Identify quality problems and ensure monitoring and correction of any problems
  - TJC has more detailed contract management standards in LD chapter, revised 1-1-09 and 7-1-09

Contracted Services (continued)

- Board must ensure services performed under contract are performed in a safe and efficient manner
- Review QAPI plan to ensure that every contracted service is evaluated
- Maintain a list of all contracted services (A-0085)
- Contractor services must be in compliance with CoPs
  - Consider adding section to all contracts to address CoP requirements
Emergency Services A-0091

- Remember to see the separate EMTALA CoPs and *Interpretive Guidelines*
  - Revised May 29, 2009 and now 64 pages
- If hospital has an ED, must comply with 42 CFR Section 482.55 requirements
- If no ED services, board must be sure hospital has written P&P for emergencies of patients, staff and visitors

Emergency Services A-0091 (continued)

- Qualified RN must be able to assess patients
  - Demonstrated competency
- Verify that MS has P&P on how to address emergency procedures
- Need P&P when patient’s needs exceed hospital’s capacity
- Need P&P on appropriate transport
- Train staff on what to do in case of an emergency
Emergency Services A-0091 (continued)

- Should not rely on 911 to provide transport or initial treatment of emergencies except in extraordinary circumstances for on-campus patients
- May call 911 for **off-campus** departments of the hospital
  - Should provide whatever level of care you have (A-0094)

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Emergency Services A-0091 (continued)

- If emergency services are provided at the hospital but not at the off-campus department, then you need P&P on what to do at the off-campus department when it has an emergency
  - Call 911
  - Do whatever you can to initially treat and stabilize the patient
  - Provide care consistent with your ability
  - Includes visitors, staff and patients
Patient Rights

- Changes many standards related to grievances and restraint and seclusion (R&S)
- Sets forth standards regarding R&S staff training and education
- Sets forth standards on R&S death reporting
- TJC also has chapter on 14 patient rights or RI “Rights and Responsibilities of the Individual” starting with RI.01.01.01 thru 02.02.01

Patient Rights Standards A-0115 – A-0214

- Minimum protections and rights for patients
- Right to notification of rights and exercise of rights
  - Privacy and safety
  - Confidentiality of medical records
  - Restraint issues
Who Does This Apply To?

- All hospitals that participate in the Medicare/Medicaid program
  - Most hospitals in this country
  - All parts and locations of hospitals
- Includes short term, surgical, psychiatric, rehabilitation, long term care, children’s and alcohol drug facilities, but not CAHs (unless they have DP psych or rehab unit. CAHs still need to do something, may adopt most but not all)
- Does not matter if hospital is accredited by TJC, AOA, or DNV Healthcare

Standard # 1

- Notice of patient rights, grievance process
- Hospital must ensure that the notice of patient rights is given
- Provide in a manner the patient will understand (issue of low health literacy or patient who does not speak English)
- Must have P&P to ensure patients have information necessary to exercise their rights
Notice of Patient Rights A-0116

- Rule #1 – A hospital must inform each patient of the patient’s rights in advance of furnishing or discontinuing care
- Must protect and promote each patient’s rights
- Must have P&P to ensure patients have information on their rights, including inpatients and outpatients

Notice of Patient Rights

- Confidentiality and privacy
- Pain relief
- Refuse treatment and informed consent
- Advance directives
Notify Patient of Their Rights

- When appropriate, this information is given to the patient’s representative
  - Document reason: patient unconscious, guardian, advance directive, parent if minor child, etc.
- Consider having a copy on the back of the conditions of admission form or acknowledgment of receipt of the Notice of Privacy Practices
- Have sentence that patient acknowledges receipt of their patient rights

California Law: Patients’ Rights

- Title 22 posting requirement (Ch. 1, CHA’s Consent Manual)
- Mental health patients – additional requirements (Ch. 13, CHA’s Consent Manual)
- See CHA’s Consent Manual for sample posters
Interpreters

- Rule #2 – A hospital must ensure interpreters are available
- Make sure communication needs of patients are met
- Recommend qualified interpreters
- Must comply with civil rights laws

California Law: Interpreter Services

- Written policy required (transmit to CDPH annually)
- Post signs
- Record primary language in medical record
- Maintain list of interpreters
- Train employees
- Determine which document to translate
- Details in Ch. 1 of CHA’s Consent Manual
Interpreters (continued)

- Document deaf interpreter, use of ATT language bank, etc.
- Consider posting a sign in several languages that interpreting services are available
- Include in yearly skills lab for nurses to make sure your staff knows what to do
- Review your policy and procedure and TJC requirement

Grievance Process A-0118

- Rule #3 – The hospital must have a process for prompt resolution of patient grievances
- Hospital must inform each patient with whom to file a grievance
- Provides definition which you need to include in your policy
- If TJC accredited, combine P&P with complaint standard at RI.01.07.01 in which patient and family have a right to have grievances/complaints reviewed by hospital
Grievance Process A-0118 (continued)

- **Definition:** A patient grievance is a formal or informal written or verbal complaint (when the verbal complaint about patient care is not resolved at the time of the complaint by **staff present**) by a patient, or a patient’s representative, regarding the patient’s care, abuse, neglect, issues related to the hospital’s compliance with the CMS CoP, or a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR part 489.

“Staff Present” Grievances

- Remember – not a grievance if resolved by “staff present”
  - Document this in medical record
- Expanded definition of what is meant by “staff present”
  - Now includes any hospital staff present at the time of the complaint or who can quickly be at the patient’s location (nursing administration, nursing supervisors, patient advocates) to resolve the patient’s complaint
Grievances A-0118

- Hospitals should have process in place to deal with minor request in more timely manner than a written request
  - Examples: change in bedding, housekeeping of room, and serving preferred foods
  - Does not require written response
- If complaint cannot be resolved at the time of the complaint or requires further action for resolution, then it is a grievance
- All the CMS requirements for grievances must be met

Patient or Their Representative

- If someone other than the patient complains about care or treatment
  - Contact the patient and ask if this person is their authorized representative
  - If not, then it may be a grievance/complaint under TJC standards
- July 1, 2009 changes bring TJC and CMS standards closer
Patient or Their Representative (continued)

- Not a grievance if patient is satisfied with care, but family member is not
- If person is not authorized representative, then must obtain patient’s permission to discuss medical record information with that person because of state and federal privacy laws
- Document both of these elements in the risk management file or other file

Grievances A-0118

- Billing issues are not generally grievances unless a quality of care issue
- A written complaint is always a grievance whether inpatient or outpatient (email and fax is considered written)
- Information on patient satisfaction surveys generally not a grievance unless patient asks for resolution or unless the hospital usually treats that type of complaint as a grievance
Grievances A-0118 (continued)

- If complaint is telephoned in after patient is released then this is also considered a grievance
- Complaints on abuse, neglect, or patient harm will always be considered a grievance
  - Exception is if post-hospital verbal communication would have been routinely handled by staff present
- If patient asks you to treat as grievance it will always be a grievance

Grievance Process

- Conduct in-services on importance of “PR” and good customer service
  - Require staff to deal with patient’s request timely
- Monitor patient satisfaction surveys
- Disgruntled patients will contact CMS, TJC, CDPH, QIO, OIG, OCR, OSHA, DNV, AOA, and others
### Grievance Process - Survey Procedure

- Review the hospital policy to assure its grievance process encourages all personnel to alert appropriate staff concerning grievances.
- Hospital must assure that grievances involving situations that place patients in immediate danger are resolved in a timely manner.
- Conduct audits and performance improvement (PI) to make sure your facility is following its grievance P&P.

### Grievance Process - Survey Procedure (continued)

- Surveyor will interview patients to make sure they know how to file a complaint or grievance.
  - Including right to notify state agency (CDPH) and QIO. Include phone numbers.
  - Remember TJC/accreditation participation requirements (APR) requirements.
  - Should be in writing in patient right’s handout.
Grievance Process A-0119

- Rule #4 – The hospital must establish a process for prompt resolution
- Inform each patient whom to contact to file a grievance by name or title
- Operator must know where to route calls
- Make form accessible to all

Grievance Process A-0119 (continued)

- Rule #5 – The hospital’s governing board must approve and is responsible for the effective operation of the grievance process
  - Elevates issue to higher administrative level
- Have a process to address complaints timely
- Coordinate data for PI and look for opportunities for improvement
- Read this section with the next rule
- Most boards will delegate this to hospital staff
Grievance Process A-0119 (continued)

- Rule #6 – A-0119 – A-0120
- The hospital’s board must review and resolve grievances unless it delegates the responsibility in writing to the grievance committee
- Board is responsible for effective operation of grievance process
  - Grievance process reviewed and analyzed through hospital’s PI program
  - Grievance committee must be more than one person and committee needs adequate number of qualified members to review and resolve

Grievance Survey Procedure

- Go back and make sure your governing board has approved the grievance process
- Look for this in the board minutes or a resolution that the grievance process has been delegated to a grievance committee
- Does hospital apply what it learns?
Rule #7 – The grievance process must include a mechanism for timely referral of patient concerns regarding the quality of care or premature discharge to the appropriate QIO.

Each state has a state QIO under contract from CMS and list of QIOs¹ (In California, the QIO is HSAG (Health Services Advisory Group)).

QIO are CMS contractors who are charged with reviewing the appropriateness and quality of care rendered to Medicare beneficiaries in the hospital setting.

¹http://www.qualitynet.org/dcs/ContentServer?pagename=Medqic/MQGeneralPage/GeneralPageTemplate&name=QIO%20Listings

QIO (continued)

QIOs must make hospitals aware that a beneficiary has a complaint regarding the quality of care, disagrees with coverage decision or wishes to appeal a premature discharge.

Patients can ask that complaint be forwarded to the QIO by the hospital or can complain directly to the QIO.
IM and Detailed Notice Forms

- Hospital to provide a Medicare patient with an Important Message from Medicare (IM Notice) within 48 hours of admission.
- The hospital must deliver to the patient a copy of this signed form again if more than two days stay. Must be done within 48 hours of discharge.
- About 1% of Medicare patients voice concern about being discharged prematurely.
  - These patients must be given a more detailed notice and request the QIO to review their case.
- New forms IM “You Have the Right” and “Detailed Notice”
- Website for beneficiary notices¹

¹www.cms.hhs.gov/bni
Grievance Procedure A-0121

- Hospital must have a clear procedure for the submission of a patient’s written or verbal grievances
- Surveyor will review your information to make sure it clearly tells patients how to submit a verbal or written grievance
- Surveyor will interview patients to make sure information provided tells them how to submit a grievance
- Must establish process for prompt resolution of grievances

Hospital Grievance Procedure A-0122

- Rule #8 – Hospital must have a P&P on grievance
- Specific timeframe for reviewing and responding to the grievance
- Grievance resolution process must include giving the patient a written notice of its decision, IN MOST CASES
- The written notice to the patient must include the steps taken to investigate the grievance, the results and date of completion
Facility must respond to the substance of each and every grievance

Need to dig deeper into system problems indicated by the grievance using the system analysis approach

Note the relationship to TJC sentinel event policy and LD medical error standards, CMS guidelines for determining immediate jeopardy, HIPAA privacy and security complaints, and risk management/patient safety investigations

Grievances

Timeframe of 7 days would be considered appropriate and if not resolved or investigation not completed within 7 days, must notify patient still working on it and hospital will follow up

Most complaints are not complicated and do not require extensive investigation

Will look at timeframes established

Must document if grievance is so complicated it requires an extensive investigation
Grievances A-0123

- Explanation to the patient must be in a manner the patient or legal representative understand
- The written response must contain the elements required in this section - not statements that could be used in legal action against the hospital
- Written response must include the steps taken to investigate the complaint
- Surveyors will review the written notices to make sure they comply with this section

Grievances A-0123 (continued)

- CMS says if patient emailed the complaint, hospital may email back response
- Must maintain evidence of compliance with the grievance requirements
- Grievance is considered resolved when patient is satisfied with action or if hospital has taken appropriate and reasonable action
**TJC Complaint Standard**

- TJC has complaint standard RI.01.07.01 with changes July 1, 2009 and in 2010
- Patient and family have a right to submit complaints and grievances (C&G)
  - 20 EPs
  - Make sure patient is aware of the process, which must include time frames (EP 19)
- Resolve C&G that hospital recognizes as significant
  - Acknowledge receipt of the complaint

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**TJC Complaint Standard (continued)**

- Notify the patient of follow up
- Provide patient with phone number and address to file a C&G with the SA (CDPH) and QIO (for quality of care issues or premature discharge)
- Allow to voice C&G freely without being subject to coercion, discrimination or unreasonable interruption in care
- Must give written response with steps taken, results, date of completion, etc.
California Law: Patient Complaints

- Written P&P required
- Post notice giving CDPH district office phone number for patients to call with complaints
- If hospital receives a written complaint about MD or podiatrist, must inform patient that MBC/Board of Podiatric Medicine is only agency that may take action against license

Accreditation Program: Hospital Chapter: Rights and Responsibilities of the Individual

Standard RI.01.07.01
The patient and his or her family have the right to have complaints reviewed by the hospital.

Rationale for RI.01.07.01
A business is often judged by how it handles dissatisfied customers; the same is true for health care organizations. Addressing complaints promptly helps to satisfy the needs of patients and their families during a vulnerable time in their lives, and may also prevent adverse events from occurring in the organization. Complaints can range from the straightforward, such as the temperature of a patient’s room, to the complex, such as the patient’s care being adversely impacted by an insufficient supply of medications. Failure to effectively communicate regardless of the complexity of the complaint, patients and their families expect the organization to work toward a resolution as quickly as possible.

Elements of Performance for RI.01.07.01

1. The hospital establishes a complaint resolution process. (See also LD.04.02.07, EP 1; MS.03.21.01, EP 1)

2. The hospital informs the patient and/or his or her family about the complaint resolution process. (See also MS.03.01.01, EP 1)

3. The hospital reviews and, when possible, resolves complaints from the patient and his or her family. (See also MS.09.01.01, EP 1)

4. The hospital acknowledges receipt of a complaint that the hospital cannot resolve immediately and notifies the patient of follow-up to the complaint.

5. The hospital provides the patient with the phone number and address needed to file a complaint with the relevant state authority. (See also MS.09.01.01, EP 1)

6. The hospital allows the patient to voice complaints and recommends changes freely without being subject to coercion, discrimination, reprisal, or unreasonable interruption of care. (See also MS.09.01.01, EP 1)

7. For hospitals that use Joint Commission accreditation for desired status purposes: In its resolution of complaints, the hospital provides the individual with a written notice of its decision, which contains the following:
   - The name of the hospital complaint person
   - The steps taken on behalf of the individual to investigate the complaint
   - The results of the process
   - The date of completion of the complaint process

8. For hospitals that use Joint Commission accreditation for desired status purposes: The hospital determines time frames for complaint review and response.

9. For hospitals that use Joint Commission accreditation for desired status purposes: The process for resolving complaints includes a mechanism for timely referral of patient concerns regarding quality of care or patient discharge to the quality improvement organization (QIO).
Standard #2: Exercise of Rights

- Right to participate in the development and implementation of their plan of care
- Right to refuse care and formulate advance directives
- Right to have a family member or representative of his or her choice

Rule #1 – Patients have the right to participate in the development and implementation of their plan of care (making informed decisions regarding their care)

- Includes inpatients and outpatients
- Includes discharge planning and pain management
- Requires hospital to actively include the patient in developing the plan of care including changes
Patient Participation in Plan of Care (continued)

- If patient refuses to participate, document this
- Include patient’s legal representative if patient is a minor or lacks capacity
- Plan of care is frequently cited
- Includes choices related to pain management, patient care issues, and discharge planning
- Patients needing post-hospital care are given choice of home health or nursing homes
- Section 1802 of SSA guarantees free choice by Medicare patients for LTC or home health

Rule #2 - Patients Have a Right:

- To make informed decisions regarding their care
- To be informed of their diagnosis and prognosis
- To request or refuse treatment (sign out AMA, remember EMTALA requirements)
- To have a family member and their own MD notified promptly of their admission to the hospital even if not the admitting physician (A-0133)
Informed Consent A-0131

- Amended 3 sections of the hospital *Interpretive Guidelines*
- Requirements on informed consent in patient rights, sections of *Interpretive Guidelines*, medical records and surgical services
- Right to make informed decisions

Informed Consent A-0131 (continued)

- Right to delegate the right to make informed decisions to another (agent named in advance directive, guardian, etc.)
- Patient has a right to give an informed consent for surgery or a treatment
- Right to be informed of health status and to be involved in care planning and treatment
- Informed decision on discharge planning to post-acute care
- Right to request or refuse treatment and P&P to assure patient’s right to request or refuse treatment
Informed Consent (continued)

- Right to informed decisions about planning for care after discharge
- Right to receive information in a manner that is understandable (issue of health care literacy)
- Right to get information about health status, diagnosis and prognosis
  - Hospital has to have process to ensure these rights
- Required to have policies and procedures on all of these

Disclosures to Patients A-0131

- There are two disclosures that must be in writing
  - If physician-owned hospital
  - If a doctor or an ED physician is not available 24 hours-a-day to assist in emergencies
- Must provide information at beginning of inpatient stay or visit
- May be included in conditions of admission form/notice of privacy practice that all inpatients and outpatients sign
Patient Rights A-0132

- Right to make and have the advance directive followed when unconscious or incapacitated
  - Staff must provide care that is consistent with these directives
  - P&P must include delegation of patient rights to representative if patient incapacitated
- Note rights as inpatient vs. outpatient (AD requirements of TJC)

Advance Directives

- Hospital policy should have clear statement of any limitations such as conscience
- At a minimum, clarify any difference between facility-wide conscience objections and those raised by individual doctors
- Hospital must provide written information to the patient on their rights under state law, at time of admission
  - “Your Right to Make Decisions About Medical Treatment” developed by CDPH
- Both inpatients and outpatients have rights but don’t have to give list in writing to outpatients
- Document whether or not patient has an AD
Advance Directives A-0132 (continued)

- Cannot condition treatment on whether or not patient has an AD
- Not construed as a mechanism to demand inappropriate or medically unnecessary care
- Ensure compliance with state laws on AD
- Inform patients they may file complaints with CDPH
- See Ch. 3 of CHA’s Consent Manual regarding state AD laws
- Provide and document advance directives education
  - Staff on P&P
  - Community

Patient Rights (continued)

- Includes the right for medical decisions such as pain management
- Disseminate policy on advance directive, identify state authority permitting an objection (Probate Code Sections 4734-4736; see CHA’s Consent Manual)
- Includes psychiatric or behavioral health AD (some states have a psychiatric AD; California does not. However, California recognizes out-of-state ADs)
3rd Standard: Privacy and Safety A-0143

- The right to personal privacy
- To receive care in a safe setting
- To be free from all forms of abuse or harassment
- Rule #1 – The right to personal privacy
  - Right to respect, dignity, and comfort
  - Privacy during personal hygiene activities (toileting, bathing, dressing) pelvic exam, etc.

Personal Privacy

- Person not involved with care may not be present while exam is being done unless consent obtained (medical students who are observing, not those caring for patient)
- Need consent for video/electronic monitoring (cameras in patient rooms, not in hallways or lobbies)
- May include in your Conditions of Admission form that all patients sign on admission or make sure patients are aware such as in ICU
Personal Privacy (continued)

- Surveyor will conduct observations to determine if privacy provided during exams, treatments, surgery, personal hygiene activities, etc.
- Surveyor will look to see if names or patient information is posted in plain view
- Survey procedure will ask if patient names are posted in public view

Care in a Safe Setting A-0144

- Rule #2 – The right to receive care in a safe setting
  - Includes following standards of care and practice for environmental safety, infection control, and security such as preventing infant abductions, preventing patient falls and medication errors
  - Right to respect for dignity and comfort
Care in a Safe Setting (continued)

- Includes washing hands between patients - see CDC or WHO hand hygiene and TJC 2009 Measuring Hand Hygiene Adherence
- Review and analyze incident or accident reports to identify problems with a safe environment
- Review policies and procedures
- Does facility have P&P to curtail unwanted visitors or contraband materials?

Privacy and Safety A-0145

- Rule #3 – The patient has the right to be free from all forms of abuse, harassment and neglect
  - Must have process in place to prevent this
  - Criminal background checks as required by state law
- Must provide ongoing (yearly) training on abuse, harassment, and neglect

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Privacy and Safety A-0145 (continued)

- Consider annual training in yearly skills lab
- Must have P&P on this
- Adequate staffing section
- Have proactive approach to identify events that could be abuse

Freedom From Abuse and Neglect

- Abuse is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish
  - Includes staff neglect or indifference to infliction of injury or intimidation of one patient by another
- Remember TJC has standard and definitions, RI.01.06.03
Freedom From Abuse and Neglect (continued)

- Neglect is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness
- Investigate all allegations of abuse or neglect
- Do not hire persons with record of abuse or neglect
- Report all incidents to proper authority, board of nursing, etc.
- Remember state, child, elder, dependent adult abuse and neglect reporting requirements (law enforcement)

Freedom From Abuse and Neglect (continued)

- Includes freedom from abuse by staff as well as by other patients and visitors
- Hospital must have a mechanism in place to prevent this
- Effective abuse program includes prevention
  - Adequate number of staff who have been screened
  - Identify events that could lead to or contribute to abuse
  - Protect during investigation
  - Investigate and report and respond
Freedom From Abuse and Neglect (continued)

- Make sure hospital has a policy in place for investigating allegations of abuse
- Make sure staffing sufficient across all shifts
- Make sure appropriate action taken if substantiated
- Make sure staff know what to do if they witness abuse or neglect

TJC Abuse and Neglect

- Remember to include TJC’s standard, RI.01.06.03, and definitions of abuse and neglect into your policy also, if accredited
- Patients have the right to be free from abuse, neglect, and exploitation
  - This includes physical, sexual, mental, or verbal abuse and TJC has definitions for all of these terms
### TJC Abuse and Neglect (continued)

- Determine how hospital will protect patients from abuse and neglect while receiving care
- Evaluate all allegations that occur within the hospital
- Report to proper authorities as required by law

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### Standard #4: Confidentiality

- Rule #1 – Patients have a right to confidentiality of their medical records and to access their medical records (A-0146)
  - Sufficient safeguards to ensure access to all information
  - HIPAA compliant authorization for release
  - Comply with stricter state confidentiality laws
- See CHA’s *California Health Information Privacy Manual*
Standard #4: Confidentiality (continued)

- MRs are kept secure and viewed only when necessary by staff involved in care
- Do not post patient information where it can be viewed by visitors
- TJC IM.02.01.01 standard requires that hospitals protect the privacy of health information, maintain security of same (white boards)

Access to Medical Records

- Rule #2 – Patients have the right to access the information contained within their medical records
- Right to inspect their record or to get a copy (30 day rule under HIPAA, but only 5 days to inspect/10 days to copy under California law)
- Limited exceptions such as psychotherapy notes, information could cause harm to patient or another, under promise of confidentiality, etc.
- See CHA’s California Health Information Privacy Manual, Ch. 3, for details
Access to Medical Records (continued)

- Rule #3 – Access to the medical record must be within a reasonable time frame and hospitals cannot frustrate efforts of patients to get records
- If patient is incompetent, then personal representative (such as guardian, parent, or agent under AD) has right to access
- Reasonable cost for copying, postage or summary (no retrieval fee)

Standard #5: Restraints (A-0154 – A-0214)

- Many changes were made
- Combined the two sections on medical/surgical and behavioral restraints into one section
- Need to rewrite policies and procedures and train all staff (don’t forget ED staff, outpatient clinics as necessary)
Restraint Worksheet

- CMS has developed restraint worksheet\(^1\) which is not an official OMB form
  - CMS cannot mandate hospital to fill out, but will save time on phone
- Must still notify regional office by phone the next business day
  - Document this in medical record
  - CMS has manual to address complaint surveys
  - Put regional office contact information in your P&P\(^2\)

\(^2\)www.cms.hhs.gov/RegionalOffices/01_overview.asp

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CMS Manual System

Pub. 100-07 State Operations
Provider Certification

Transmittal 50

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

Date: JULY 10, 2009

SUBJECT: Revisions to Chapter 5, “Complaint Procedures”

I. SUMMARY OF CHANGES: Chapter 5, Section 5140. “Hospital Restraints/Seclusion Death Reporting and Investigation,” is updated to reflect changes in policies and procedures related to new and amended regulations at 42 CFR 482.13(c), (d), and (g). We have deleted just the information contained in §5140.2, “Hospital Reporting Methods,” because the information is no longer valid. However, we will reserve that section for a future revision. In addition, we have added new Exhibits 292 through 295 to facilitate implementation of the Data Use Agreement Process described in §5140.4.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: July 10, 2009
IMPLEMENTATION DATE: July 10, 2009

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.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)
Standard #5: Restraints

- Changes affect only regular hospitals. Critical Access Hospitals (CAHs) have own manual
- CAHs do not have a patient rights section and are not required to follow new restraint and seclusion (R&S) section unless they have a DP psych or rehab unit
- CAHs must have P&P so they can either use TJC standards or select some or all of hospital ones
  - Some CAHs have adopted all if in system with regular hospitals

Standard #5: Restraints

- Rule #1 – Patients have a right to be free from physical or mental abuse and corporal punishment
- This includes that restraint and seclusion (R&S):
  - Will be used only when necessary
  - Not as coercion, discipline, convenience or retaliation
  - Used only for patient safety and discontinued at earliest possible time
- R&S guidelines from CMS apply to all hospital patients even those in behavioral health
Right to be Free From Restraint

- Hospitals should consider adding this right to their patient rights statement if not already there (already included in CHA sample form)

- Patients must be provided information about their rights (staff must document or have patient sign that they received their rights)
  - Could include information in admission packet

- Do not consider using R&S as a routine part of fall prevention (A-0154)

Rule #2: Hospital Leadership’s Role

- Like TJC, leadership is responsible for creating a culture that supports right to be free from R&S

- Leadership must make sure systems and processes in place to eliminate inappropriate R&S and monitors use thru PI process

- Leadership makes sure used only for physical safety of patient or staff

- Leadership ensures hospital complies with all R&S requirements (A-0154)
Restraints Protocols

- CMS previously did not recognize or allow the use of protocols like TJC does
- Protocols are now not banned by the new regulations (A-0168) but still need separate order for R&S
- Must contain information for staff on how to monitor and apply, like intubation protocol

Protocols

- Requiring an order even with a protocol is basically the same process hospitals were doing previously
- Medical record must include documentation of individualized assessment, symptoms and diagnosis that triggered protocol
- Need MS involvement in developing and monitoring their use
If a patient becomes violent or has self-destructive behavior (V/SD) in the ICU or ED, CMS has one set of standards that apply.

Decision to use R&S is not driven by diagnosis but by assessment of the patient.

TJC standards changed July 1, 2009.

- 10 new standards
- All the 2009 R&S standards were eliminated except two (forensic and one on behavioral management) for hospitals that use TJC for deemed status.

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TJC uses terms “behavioral health” and “non-behavioral health.”

CMS uses terms “violent and/or self-destructive” (V/SD) and “non-violent and non-self destructive.”

CMS says it is not the department in which the patient is located but the behavior of the patient.
Rule #3: Know Definition 159

- Definition: Physical restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely
  - Mechanical restraints include belts, restraint jackets, cuffs, or ties
  - Manual method of holding the patient is a restraint

DEFINITIONS OF RESTRAINT and SECLUSION

A restraint is:
- Any manual method, physical or mechanical device, material, or equipment that restricts, immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely that cannot be removed easily by the patient;
- A drug or medication used as a restraint is a medication used to control behavior or restrict a patient’s movement and is not a standard treatment or dosage for the patient’s condition.
- If all four side rails are up, or if belts are being used to keep a patient in bed or from getting up, they are considered to be a restraint and all the policy/procedure and documentation guidelines apply.

A restraint does not include:
- Devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed (including stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, crib covers, if age specific), or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).
Restraint Definition

- A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or standard dosage for the patient's condition (A-0160) (chemical restraint)
- Use of PRN drug is prohibited only if medication meets definition of drug used as a restraint
- Ativan for ETOH withdrawal symptoms is okay

When Drug is not a Restraint

- Medication is within pharmacy parameters set by FDA and manufacturer for use
- Use follows national practice standards
- Used to treat a specific condition based on patient’s symptoms
- Standard treatment would enable patient to be effective or function appropriately
Definition of Seclusion

- Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving (A-0162)
- Seclusion may be used only for the management of V/SD behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others
- Does not include being on a locked unit with others, or time out if patient can leave area (A-0162)

Seclusion (continued)

- It is when the patient is alone in a room and physically prevented from leaving
- May use seclusion only for management of V/SD behavior that is a danger to patient or others
Learning From Each Other

- Learning from Each Other – Success stories and Ideas for Reducing Restraint/Seclusion in Behavioral Health, tools and forms in appendix
- Published in 2003 by many organizations such as American Psychiatric Nurses Assn, National Association of Psychiatric Health Systems (NAPHS) with support of AHA
- See NAPHS and AHA guiding principles


Restraint and Seclusion

- Time limits on length of order apply such as four hours for an adult
- One hour face-to-face evaluation must be done (A-0183)
- Therapeutic holds to manage V/SD patients are a form of restraint
Restraints Do Not Include

- Forensic restraints such as handcuffs, shackles, or other restrictive devices applied by law enforcement or police are not R&S (A-0154)
  - Closely monitor and observe for safety reasons
- Orthopedically prescribed devices, surgical dressings or bandages, protective helmets (A-0161)
- Methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests (A-0161)

Restraints Do Not Include (continued)

- Protecting the patient from falling out of bed
  - Cannot use side rails to prevent patient from getting out of bed if patient can not lower
- Striker beds or the narrow carts (guernies) with use of side rails are not a restraint
- IV board unless tied down or attached to bed
- Postural support devices for positioning or securing (A-0161)
- Device used to position a patient during surgery or while taking an x-ray
Restraints Do Not Include  (continued)

- Recovery from anesthesia is part of surgical procedure and medically necessary (A-0161)
- Mitts unless tied down or pinned down or unless so bulky or applied so tightly patient can not use or bend their hand (A-0161)
  - Mitts that look like boxing gloves are a restraint
- Padded side rails put up when on seizure precaution
- Giving child a shot to protect from injury (A-0161)
  - Physically holding a patient for forced medications is a physical restraint

Restraints Do Include

- Tucking in a sheet so tightly that patient cannot move (A-0159)
- Use of enclosed bed or net bed unless the patient can freely exit the bed such as zipper inside the bed
- Freedom splint that immobilizes limb
Restraints

- Devices with multiple purposes – such as side rails or Geri chairs, when they cannot be easily removed by the patient
  - Restricting the patient’s movement constitutes a restraint
- If belt across patient in wheelchair and he can unsnap belt or Velcro then it is not a restraint (A-159)
- If patient can lower side rails when she wants then it is not a restraint, but document this
- If a patient can remove a device it is not a restraint

Restraints (continued)

- Stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers (A-0161) are okay (not a restraint) as long as age or developmentally appropriate
- Use of these safety interventions must be addressed in your policy
- Holding an infant or toddler is not a restraint
Weapons A-0154

- CMS does not consider the use of weapons by hospital staff on patients as safe in the application of restraint (A-0154)
- Could use on criminal breaking into building
- Weapons include pepper spray, mace, nightsticks, tazers, stun guns, pistols, etc.
- Okay if patient is arrested and use by law enforcement (non-employed staff such as police)

Assessment

- Should do comprehensive assessment to reduce risk of slipping, tripping or falling
  - Identify medical problems that could be causing behavioral changes (A-0154) such as increased temp, hypoxia, low blood sugar, electrolyte imbalance, drug interactions, etc.
  - Use of restraint is not considered routine part of a falls prevention program (A-0154)
Determine Reason for R&S

- Surveyor will look to see if there is evidence that staff determined the reason for the R&S (A-0154)
- This should be documented and be specific
- Consider a field on the order sheet to include this
- Usually to prevent danger to the patient or others
- Danger to self, maintain therapeutic environment (such as to prevent patient from removing vital equipment), physically attempting to harm others or property, patient demonstrated lack of understanding to comply with safety directions

Reasons to Restrain

(Check all that apply)
- Unable to follow directions
- High risk of falls
- Aggressive
- Disruptive/combative
- History of hip fracture/falls
- Self injury
- Interference with treatments
- Removal of medical devices
- Other: ________________________________
Restraints can be used only when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm (A-0154, A-0164, A-0165)

Type or technique used must also be least restrictive

Is what the patient doing a hazard?

- Allowing sundowners to walk or wander at night (A-0154)

Request from patient or family member is not sufficient basis for using if not indicated by condition of patient
Less Restrictive

- Must do an assessment of patient
- Must document that restraint is least restrictive intervention to protect patient safety based on assessment
- What was the effect of least restrictive intervention
- Must train on what is least restrictive interventions

Least Restrictive Restraint to More

- Side rails
- Hand mittens
- Lap board
- Roll belt/lap belt
- 2 point soft restraint
- Wrap IV site
- Hand mitten
- Freedom splint is a restraint!
- Net bed
- Soft extremity restraint
- Geri chair
- Vest restraint
- 3 or 4 point soft
- Arm board
- Soft wrist restraint
Rule # 5: Alternatives

- Alternatives should be considered along with less restrictive interventions (A-0186)
- What other things could prevent using R&S (such as sitter or family member staying with patient)
- Distractions such as watching video games or working on a laptop computer
- Try nonphysical intervention skills (A-0200)
- Considering having a list of alternatives in the toolkit

Consider Alternatives

- Bed sensor
- Close to nurses station
- Activity apron
- E-Z release hugger (if patient can release)
- Reality orientation/familiarize patients to room
- Verbal instructions/support
- Frequent visits with patient (hourly except night shift)
### Consider Alternatives (continued)

- Skin sleeves
- Sensor alarm
- Posey lateral wedges
- Access to call cord
- Lower chairs
- Allow wandering, if possible
- Food/hydration
- Low beds or mattress on floor
- Encourage family visits
- Pain/discomfort relief
- Diversion activities such as TV, CDs, DVDs, music therapy, picture books, games
- Provide structured, quiet environment
- Exercise/ambulate
- Toileting routine

### Alternatives to Restraints (continued)

- Be calm and reassuring
- Approach in non-threatening manner
- Wrap around Velcro band while in wheelchair (if patient can release)
- Relaxation tapes
- Make photo album
- Back rubs or massage therapist
- Wanderguard system
- Limit caffeine
Alternatives to Restraints (continued)

- Watching TV
- Massage or family can hire massage therapist
- Punching bag
- Avoid sensory overload
- Fish tanks
- Tapes of families or friends
### Restraint Alternatives

<table>
<thead>
<tr>
<th>Behavior/Medical Condition</th>
<th>Restraint Alternatives</th>
<th>Environmental &amp; Equipment Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verbally Abusive</td>
<td>Begin with medical evaluation to rule out physical or medication problems.</td>
<td>Relaxation techniques (music, guided imagery, etc.)</td>
</tr>
<tr>
<td>(Physically Reactive)</td>
<td>Educate for acute medical conditions such as MI, URI, ear infections or other infections processes.</td>
<td>Theme/Relaxation Reminders (books, music, etc.)</td>
</tr>
<tr>
<td></td>
<td>Educate for pain, comfort and/or other physical needs such as hunger, thirst, position changes, bowel and bladder urges.</td>
<td>Magnification box to create awareness of the patient/resident’s voice level and provide feedback.</td>
</tr>
<tr>
<td></td>
<td>Attempt to identify triggering events or issues that stimulate the behavior.</td>
<td>Lavatory, bedside call, active mobile.</td>
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<td></td>
<td>Consider using behavior tracking form to assist in identification of triggers toward patient.</td>
<td>Tapes of familiar or familiar relatives or friends.</td>
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<td></td>
<td>Consult with family regarding post coping mechanisms that proved effective during times of increased stress levels.</td>
<td>Move to a quiet area, possibly a more familiar area. Decrease external stimuli.</td>
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<td></td>
<td>Provide calm/peaceful environment.</td>
<td>Such books.</td>
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<td>Validate feelings such as saying “You sound like you are angry.”</td>
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<td>Relax.</td>
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<td>Active listening. Assess potential issues identified.</td>
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<td>Set limits.</td>
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<td>Develop trust by assigning consistent caregivers whenever possible.</td>
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<td></td>
<td>Avoid confrontations. Staff to decrease voice levels.</td>
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<td></td>
<td>Approach in calm/peaceful manner.</td>
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<td></td>
<td>Provide rest periods.</td>
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<td></td>
<td>Social Services referral.</td>
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<td></td>
<td>Psychologist/Psychiatric referral.</td>
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<td>Touch therapy and/or massage (hand or back).</td>
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<td></td>
<td>Reduce external stimuli (overhead paging, TV, radio, noise, etc.).</td>
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<td>Evaluate staffing patterns.</td>
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<tr>
<td></td>
<td>Evaluate sleep/wake patterns.</td>
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<td></td>
<td>Maintain regular schedule.</td>
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<td>Limit caffeine.</td>
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<td></td>
<td>Fuddling bag.</td>
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<td></td>
<td>Avoid sensory overload.</td>
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</tr>
</tbody>
</table>

#### For the WANDERER:
1. Wandering stimulates circulation and promotes beneficial muscle activity and oxygenation of the cells. It also channels excess energy and anxiety. When possible allow the patient to wander on the unit observed by nursing personnel.
2. Engaging the patient in a structured, repetitive activity will keep him busy and burn up restless energy.
3. For confused patient who wander because they become disoriented, hang a plastic picture frame containing familiar items outside room to provide orientation cues.
4. Since wanders perceive breaks in carpet patterns or tiles as dangerous holes or puddles, place a mat in front of exit doorways or use a different pattern of carpet in front of exits or doorways that are “off limits.”
5. Usually a patient wanders into another room in search of a bathroom. Frequent toileting, especially before bedtime and throughout the night. Many patients crawl out of bed because they is wet or his bladder is full.
6. At night, place call bell through the sleeve of the nightgown or pajama top. Place the bedside table, with water and reach. Providing a steady background noise such as a ticking clock, or special music can also help keep patient calm and in their rooms.
7. Make sure the patient’s room temperature is comfortable and adjusted to suit the patient’s comfort level.

#### For the UNSTEADY PATIENT:
1. Keep the room free from obstacles and make sure the bed is in low position.
2. Provide adequate lighting and night-light to increase the patient’s visual perception and for prevent hallucinations.
3. Check that the patient’s walker, cane, or other assistive devices are within reach and are always in the same location. If the patient wears glasses, make sure they are on, and if he wears a hearing aid,
Rule #6: Restraints: LIP Can Write Orders

- LIPs can write orders for restraints
- Any individual permitted by both state law and hospital policy for patients independently, within the scope of their licensure, and consistent with granted privileges, to order restraint, seclusion
  - NP, licensed resident, PA, but not a medical student
- Remember must specify who in your P&P (A-0168)

Rule #7: Restraints: Notify Doctor ASAP A-0170

- Any established time frames must be consistent with ASAP (not in 1 or 3 hours)
- Hospital MS policy determines who is the attending physician
- Hospital P&P should address the definition of ASAP (A-0182, A-0170)
- RN or PA who does 1 hour face-to-face must notify attending physician and discuss findings (A-0182)
- Be sure to document if LIP or nurse notifies physician
Rule # 8: Restraints: Order Needed

- An order for the restraint is needed from the physician or other LIP who is responsible for the care of the patient (A-0168)
- Include in P&P: use in an emergency
- P&P to include category of who can order (PA, NP, resident, can not be med student)
- PRN order prohibited if for medication used as a restraint, okay if not a restraint
- No PRN order for restraints either (A-0167, A-0169), with 3 exceptions (A-0169)

PRN Order 3 Exceptions

- Repetitive self-mutilating behavior (A-0169), such as Lesch-Nyham Syndrome
- Geri chair if patient requires tray to be locked in place when out of bed
- Raised side rails if require all 4 side rails to be up when the patient is in bed
- Do not need new order every time but still a restraint
Rule #9: Restraints – Plan of Care

- Restraints must be used in accordance with a written modification to the patient's plan of care (A-0166)
  - What was the goal of the plan of care
  - Use of restraint should be in modified plan of care
- Care plan should be reviewed and updated in writing
  - Within time frame specified in P&P (A-0166)
  - Plan reflects a loop of assessment, intervention, evaluation and reevaluation

Physical Restraints: Development of Plan of Care

**Key Steps**

1. Establish Medical Necessity
2. Develop Plan of Care
3. Implement Care Plan Interventions

**Key Elements**

- Identify medical symptoms, fall risk, behavior problems, and inability to treat a medical condition.
- Match goals and interventions with specific conditions.
- Coordinate plan and care with health care team, resident, family, caregivers.
- **Alternatives to Physical Restraints**
  - Supervision, monitoring, increased interaction
  - Proper positioning and body alignment
  - Changes in treatment
  - Psychosocial intervention
  - Environmental manipulation
- **Use of Physical Restraints**
  - Least restrictive device
Restraints: Plan of Care (continued)

- Orders are time limited and this is included in the plan of care
- For patient who is V/SD may want to debrief as part of plan of care but not mandated by CMS
- Debriefing no longer mandated by TJC for behavioral patients (deemed status)
- Can add information on debrief to R&S toolkit
- California Law requires two reviews after R&S: clinical/quality review and debriefing (acute psychiatric hospital or psych unit of GACH only)

Rule #10: End at Earliest Time

- Restraints must be discontinued at the earliest possible time (A-0154, A-0174)
- Regardless of the time identified in the order
- If you discontinue and still time left on clock and behavior reoccurs, you need to get a new order
- Temporary release for caring for patient is okay (feeding, ROM, toileting) but a trial release is seen as a PRN order and not permitted (A-0169)
Restraints: End at Earliest Time

- Restraints used only while unsafe condition exists
- The hospital policy should include who has authority to discontinue restraints (A-0154, A-0174)
- Under what circumstances restraints are to be discontinued and who is allowed to take them off
- Based on determination that patient’s behavior is no longer a threat to self, staff, or others (put this in your P&P)
- Surveyors will look at hospital policy
- Policy should also include procedures to follow when staff need to apply in an emergency

Rule #11: Assessment of Patient

- Staff must assess and monitor patient’s condition on ongoing basis (A-0154, A-0174, A-0175)
- Physician or LIP must provide ongoing monitoring and assessment also (A-0175)
- One reason is to determine if R&S can be removed
- Took out word “continually” monitored except for V/SD patients and now says at “an interval determined by hospital policy”
Rule #11: Assessment of Patient (continued)

- Intervals are based on patient’s need, condition and type of restraint used (V/SD or not)
- CMS doesn’t specify time frame for assessment like TJC used to (TJC used to say every 2 hours for medical patients and every 15 minutes for behavioral health patients)
- CMS says this may be sufficient, or waking patient up every 2 hours in night might be excessive
- This must be in your hospital P&P frequency of evaluations and assessments (A-0175) and document to show compliance
- California law requires documentation of observation at least every 15 minutes (acute psychiatric hospital or psych unit of GACH only)

Rule #12: Documentation

- Most hospitals use special documentation sheet for assessment parameters, including frequency of assessment, and hospital policy should address each of these (A-0175, A-0184)
- If doctor writes a new order or renews order, need documentation that describes patient’s clinical needs and supports continued use (A-0174)
- Document:
  1. Fluids offered (hydration needs), vital signs
  2. Toileting offered (elimination needs)
  3. Removal of restraint and ROM and repositioning
  4. Mental status, circulation
Rule #12: Documentation (continued)

- Attempts to reduce restraints, skin integrity, and level of distress or agitation, etc.
- Document the patient’s behavior and interventions used
- Behavior should be documented in descriptive terms to evaluate the appropriateness of the intervention (A-0185)
- Example: patient states that Martians have landed and attempts to strike the nurses with his fists, bite the nurse on her arm. Patient picked up chair and threw it against the window

Rule #12: Documentation (continued)

- Document clinical response to the intervention (A-0188)
- Symptoms and condition that warranted the restraint must be documented (A-0187)
**Document Type of Restraint**

- 4 Side Rails
- Elbow Immobilizers
- Soft Wrist Restraint(s)
- Hand Mitt(s)
- Soft Wrist Restraint(s)
- Vest
- Soft Ankle Restraint(s)
- Papoose Board

**Category of Order**

- Initial order
- Continuation order
- Verbal order

I have assessed the patient, attempted or considered alternative(s), determined the need for restraints, and have notified ______________________ and have obtained an order for the application of restraints.

Print Name of L.I.P.

RN Signature ___________________________ Date: ___________ Time: ___________

Print Name ________________

**Licensed Independent Practitioner (L.I.P.) to Complete**

(Please, Resident, Advanced Practice Nurse, or Physician Assistant)

In accordance with Centers for Medicare and Medicaid (CMS) Conditions of Participation, Standard 432.13(c)(3) (ii), I have personally evaluated this patient (within one hour of application if this is an initial order) and have determined the need to use/continue the use of restraints/seclusion as specified by this order.

I have notified ______________________ on Date ___________ Time ___________

Print Name of Attending Staff Physician

L.I.P. Signature ___________________________ Date: ___________ Time: ___________

Print Name ________________

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**Restraint Flow Sheet**

*Key: (*) = Observation/intervention
(*) = See nurse’s note/comments

<table>
<thead>
<tr>
<th>DATE:</th>
<th>0000</th>
<th>0200</th>
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<th>2200</th>
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<tbody>
<tr>
<td>1.</td>
<td>Circulation Check</td>
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<td>2.</td>
<td>Elimination-IR</td>
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<td>3.</td>
<td>Skin Condition Check</td>
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<td>4.</td>
<td>Food/Fluids Offered</td>
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<td>5.</td>
<td>Hygiene</td>
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<td>6.</td>
<td>Passive ROM Exercise</td>
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<td>7.</td>
<td>Restraint Check</td>
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<td>8.</td>
<td>LOC/Orientation*</td>
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<td>9.</td>
<td>Assess Early Release</td>
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<td>10.</td>
<td>Trial Release</td>
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<td>11.</td>
<td>Restraint Reapplied</td>
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<td>12.</td>
<td>Restraint Discontinued</td>
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<td>13.</td>
<td>Observe q 15 Minutes</td>
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<td>(For Behavioral Health)</td>
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</tbody>
</table>

Initials of nurse

COMMENTS:

11-17 Initials and Signature __________ 7-3 Initials and Signature __________ 3-11 Initials and Signature __________

* LOC/Orientation
  1. Awake/Alert
  2. Confused
  3. Drowsy
  4. Sleepy
  5. Similar
  6. Coma
  7. Sedated for Mechanical Ventilation

**Key: (*) = Observation/intervention
(*) = See nurse’s note/comments

<table>
<thead>
<tr>
<th>DATE:</th>
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<tbody>
<tr>
<td>1.</td>
<td>Circulation Check</td>
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</table>
Log and QAPI

- Hospital takes actions thru QAPI activities
- Hospital leadership should assess and monitor use to make sure medically necessary
- Consider log to record use: shift, date, time, staff who initiated, date and time each episode was initiated, type of restraint used, whether any injuries to patient or staff, age and gender of patient
### Restraint Review Form

<table>
<thead>
<tr>
<th>Criteria #</th>
<th>Criteria</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>117</td>
<td>All episodes of restraints are ordered/ countersigned by the physician</td>
<td>Yes / No / NA</td>
</tr>
<tr>
<td></td>
<td>Responsible Person:</td>
<td></td>
</tr>
<tr>
<td>118</td>
<td>When emergency use of restraint is ordered, the physician visits within</td>
<td>Yes / No / NA</td>
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<tr>
<td></td>
<td>one (1) hour to authorize continued use.</td>
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<td></td>
<td>Responsible Person:</td>
<td></td>
</tr>
<tr>
<td>119</td>
<td>Each episode of restraint has a specific time limit documented in the</td>
<td>Yes / No / NA</td>
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<tr>
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<td>order by the physician.</td>
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<td>Responsible Person:</td>
<td></td>
</tr>
<tr>
<td>120</td>
<td>Each episode of restraint has a written order limited to one (1) hour by</td>
<td>Yes / No / NA</td>
</tr>
<tr>
<td></td>
<td>the physician.</td>
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<td></td>
<td>Responsible Person:</td>
<td></td>
</tr>
<tr>
<td>121 (A)</td>
<td>Each episode and re-evaluation of restraint is documented in the patient's</td>
<td>Yes / No / NA</td>
</tr>
<tr>
<td></td>
<td>medical record by the physician.</td>
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<td></td>
<td>Responsible Person:</td>
<td></td>
</tr>
<tr>
<td>121 (B)</td>
<td>Each episode and re-evaluation of restraint is documented in the patient's</td>
<td>Yes / No / NA</td>
</tr>
<tr>
<td></td>
<td>medical record by the nurse.</td>
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<td>Responsible Person:</td>
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</tr>
<tr>
<td>122</td>
<td>Documented evidence that non-physical interventions were initiated and</td>
<td>Yes / No / NA</td>
</tr>
<tr>
<td></td>
<td>ineffective prior to placing patient in restraint. (medication, quiet</td>
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<td>time, counseling and etc.)</td>
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<td>Responsible Person:</td>
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</tr>
<tr>
<td>123</td>
<td>A Treatment Team Meeting was held to reassess the patient's condition</td>
<td>Yes / No / NA</td>
</tr>
<tr>
<td></td>
<td>after each restraint episode.</td>
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<td></td>
<td>Responsible Person:</td>
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<tr>
<td>124</td>
<td>Documented evidence that the patient was asked for family to be notified,</td>
<td>Yes / No / NA</td>
</tr>
<tr>
<td></td>
<td>and with consent, staff attempts to contact the family to inform them of</td>
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<td></td>
<td>the restraint episode.</td>
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<td>Responsible Person:</td>
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<tr>
<td>125</td>
<td>Documented evidence that the patient is continuously monitored by an</td>
<td>Yes / No / NA</td>
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<td></td>
<td>assigned staff while in restraint (Restraint Monitoring Form).</td>
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<td>Responsible Person:</td>
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</tr>
<tr>
<td>126</td>
<td>Any pre-existing medical conditions, physical disabilities and limitations</td>
<td>Yes / No / NA</td>
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<tr>
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<td>that would place the patient in greater risk during restraint is identified.</td>
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<td></td>
<td>Responsible Person:</td>
<td></td>
</tr>
<tr>
<td>127</td>
<td>Documented evidence that every hour the limbs of the patient were</td>
<td>Yes / No / NA</td>
</tr>
<tr>
<td></td>
<td>exercised and are exercised, if necessary while in restraints.</td>
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<tr>
<td></td>
<td>Responsible Person:</td>
<td></td>
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</tbody>
</table>
**Rule #13: Use as Directed**

- Restraints and seclusion must be implemented in accordance with safe, appropriate restraining techniques (A-0167)
- As determined by hospital policy in accordance with state law. See Ch. 5 of CHA’s *Mental Health Law* manual regarding state law
- Use according to manufacturer’s instructions and include in your policy as attachment
- Follow any state law provision or standards of care and practice
- Was there any injury to patient and if so fill out incident report, make any necessary reports (adverse event, unusual occurrence, etc.)

**Rule #14: One Hour Rule**

- The lightning rod for public comment. AHA sued CMS over this provision
- Standard for behavioral health patients or V/SD
- Time limits for R&S used to manage V/SD behavior and drugs used as restraint to manage them (A-0178)
- Must see (face-to-face visit) and evaluate the need for R&S within one hour after the initiation of this intervention
One Hour Rule A-0178 (continued)

- Big change is face-to-face evaluation can be done by physician, LIP or an RN or PA trained under 42 CFR Section 482.13(f)
- TJC changed standard to allow RN to do 1 hour face-to-face assessment
- Physician does not have to come to the hospital to see patient now, telephone conference may be appropriate

One Hour Rule A-0178 (continued)

- Training requirements are detailed and discussed later
- TJC used to have 4 hour period of time for order on adult patient (now follows CMS)
- To rule out possible underlying causes of contributing factors to the patient’s behavior
One Hour Rule Assessment 482.13(f)

Must see the patient face-to-face within one hour after the initiation of the intervention, unless state law more restrictive (A-0179) (no stricter California law)

- Practitioner must evaluate:
  1. The patient's immediate situation
  2. The patient's reaction to the intervention
  3. The patient's medical and behavioral condition
  4. And the need to continue or terminate the restraint or seclusion

- Must document this (A-0184) and change documentation form to capture this information

One Hour Rule Assessment 482.13(f) (continued)

- Include in form that the evaluation includes a physical and behavioral assessment (A-0179)
- This would include a review of systems, behavioral assessment, as well as patient’s history, drugs and medications and most recent lab tests
- Look for other causes such as drug interactions, electrolyte imbalance, hypoxia, sepsis, etc. that may be contributing to the V/SD behavior
- Document change in the plan of care
- Must be trained in all the above (A-0196)
Rule #15: Time Limited Orders

- Time limits apply. Written order is limited to (A-0171):
  - 4 hours for adults
  - 2 hours for children (9-17)
  - 1 hour for under age 9
- Related to R&S for violent or self destructive behavior and for safety of patient or staff
- Same as TJC time frame for how long the order is valid
PHYSICIAN ORDERS

RESTRAINTS FOR VIOLENT/SELF-DESTRUCTIVE PATIENT

Date of Restraint Order – Single Episode:

An evaluation of patient's condition and necessity for restraints must be completed within 1 hour of application of any type of restraint.

Alternatives to restraints attempted:

☐ Family involvement
☐ Relaxation techniques
☐ Verbal de-escalation
☐ Redirection/Reorientation
☐ Decreased stimulation

NO ALTERNATIVES / IMMINENT RISK
☐ Anticipation of dehydration
☐ Discomfort assessed/reassessed
☐ Sit/1:1 Observation
☐ Other

Date/Time of Face-to-Face (must be within 1 hour of restraints initiation)

Pre-existing Conditions that would present greater risk:

☐ Pre-existing medical conditions
☐ History of sexual abuse
☐ Physical disability
☐ History of physical abuse
☐ Other

1. The patient's immediate situation:

2. The patient's reaction to intervention:

3. The patient's medical and behavioral condition:

4. Do restraints need to be continued? Yes – order will be obtained

☐ No – RN will remove restraint & document discontinuance on flowsheet

Authorized RIN/IND/PH:

(Signature) (Date/Time)

☐ Restraint Plan discussed with multidisciplinary team and care plan is modified.
☐ Family notified of restraint policy and intent to apply restraints.

(Due to change from this restraint policy would be indicated.)
Rule #16: Renew Order

- The original order for both violent or destructive behavior may be renewed up to 24 hours then physician reevaluates in person (exceptions)
- Nurse evaluates patient and shares assessment with practitioner when need order to renew (A-0171, A-0172)
- Unless state law if more restrictive (no stricter California law)
- After the original order expires, the MD or LIP must see the patient and assess before issuing a new order

Rule #16: Renew Order (continued)

- Each order for non-violent or non-destructive patients may be renewed as authorized by hospital policy (A-0173)
- Remember TJC requires an order to renew restraints on medical patients (which they now call non-behavioral health patients) every 24 hours
Rule #17: Need Policy on R&S

- Will interview staff to make sure they know the policy (A-0154)
- Surveyor to look at use of R&S and make sure it is consistent with the policy
Rule #18: Staff Education

- Staff training requirements
- All staff having direct patient contact must have ongoing education and training in the proper and safe use of restraints and be able to demonstrate competency (A-0175)
- Yearly education of staff as when skills lab is done
- Document competency and training
- Hospital P&P should identify what categories of staff are responsible for assessing and monitoring the patient (RN, LVN, nursing assistant, A-0175)

Rule #18: Staff Education (continued)

- Patients have a right to safe implementation of R&S by trained staff (A-0194)
- Training plays critical role in reducing use (A-0194)
- Staff, including agency nurses, must not only be trained but must be able to demonstrate competency in the following:
  - The application of restraints (how to put them on), monitoring, and how to provide care to patients in restraints
Rule #18: Staff Education (continued)

- This must be done before performing any of these functions (A-0196)
- Training must occur in orientation
- Training must occur on periodic basis consistent with hospital policy

Rule #18: Staff Education (continued)

- Again consider yearly during skills lab
- Remember that the TJC PC.03.03.03 and 03.02.03 requires staff training and competency now
- The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:
  - Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require R&S
Rule #18: Staff Education (continued)

- Consider document in your tool kit although not required by CMS or TJC now (deemed status)
- Teach staff what is de-escalation and not just staff on the behavioral health unit
- Avoid confrontation and approach in a calm manner
- Active listening
- Validate feelings such as “you sound like you are angry”
- Some have personal de-escalation plan that lists triggers such as not being listening to, feeling pressured, being touched, loud noises, being stared at, arguments, people yelling, darkness, being teased, etc.

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Personal De-escalation Plan

Patient Name:__________________________  Date:__________________________

PROBLEM BEHAVIORS: What type of behaviors are problems for you?
- Losing control
- Feeling unsafe
- Injuring yourself
- Other__________________________

TRIGGERS: What type of things (triggers) make you feel unsafe or upset?
- Not being listened to
- Feeling lonely
- Darkness
- Being teased or picked on
- Other__________________________

PARTICULAR TIME OF DAY/ NIGHT:

PARTICULAR TIME OF YEAR:

WARNING SIGNS: Please describe your warning signs, for example what other people may notice when you begin to lose control?
- Sweating
- Crying
- Wringing hands
- Disturbing sounds
- Racing heart
- Clenching fists
- Crying
- Hyper
- Not taking care of self
- Crying
- Other__________________________

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Rule #18: Staff Education (continued)

- The use of non-physical intervention skills (A-0200)
- Choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition (A-0201)
- The safe application and use of all types of R&S used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia, A-0202)

Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary (A-0204)

Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the one hour face-to-face evaluation (A-0205)
Rule #18: Staff Education (continued)

- Including respiratory and circulatory status, skin integrity, vital signs, and special requirements of 1 hour face-to-face

- The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification (A-0206). Patients in R or S are at higher risk for death or injury

- All staff who apply, monitor, access, or provide care to patient in R must have education and training in first aid technique and certified in CPR
  - To render first aid if patient in distress or injured
  - Develop scenarios and develop first aid class to address these

Rule #18: Staff Education (continued)

- Staff must be qualified as evidenced by education, training, and experience

- Hospital must document in personnel records that the training and competency were successfully completed (A-0208)

- If security guards respond to V/SD patients would need to train them (many give a 8 hour Crisis Prevention Institute course)
Rule #18: Staff Education (continued)

- Individuals doing training program must be qualified (A-0207)
- Trainers must have high level of knowledge – need to document their qualifications
- Train-the-trainer programs are done by many facilities
- CMS said need to revise training program every year which should take person 4 hours to do

Training: Time and Time Spent

- National Association of Psychiatric Health Systems (NAPHS), initial training in de-escalation techniques, restraint and seclusion policies and procedures
- Recommended 7-16 hours of training but number of hours not mandated by CMS
- In fact, in Federal Register CMS recommended sending one person to CPI training class as a train-the-trainer

*http://www.crisisprevention.com
Education: Physicians and LIPs

- Physician and other LIP training requirements must be specified in hospital policy (A-0176)
- At a minimum, physicians and other LIPs authorized to order R or S by hospital policy in accordance with state law must have a working knowledge of hospital policy regarding the use of restraint or seclusion
- Hospitals have flexibility to determine what other training physicians and LIPs need

Rule #19: Stricter State Laws

- The following requirements will be superseded by existing state laws that are more restrictive (A-0180)
- State laws can be stricter but not weaker or they are preempted
- States are always free to be more restrictive
- California law: Stricter requirements apply to acute psychiatric hospitals and psych unit of GACHs only. See Ch. 5 of CHA’s *Mental Health Law Manual*
Rule #20: 1:1 Monitoring R&S A-0183

- For behavioral health patients – which CMS now calls violent or self destructive behavior that is a danger to patient or others
- Can't use R&S together unless the patient is visually monitored in person face-to-face or by audio and video equipment
  - Person to monitor patient face-to-face or via audio & visual must be assigned and a trained staff member
  - Must be in close proximity to the patient (A-0183)
  - There must be documentation of this in the medical record
- California law: No video/audio monitoring in acute psychiatric hospital or psych unit of GACH

Rule #20: 1:1 Monitoring R&S A-0183 (continued)

- Documentation will include least restrictive interventions, conditions or symptoms that warranted R&S, patient’s response to intervention, and rationale for continued use
- This needs to be in hospital’s P&P
- Modify assessment sheets to include this information
Rule #21: Deaths A-0214

- Report any death associated with the use of restraint or seclusion
- Remember, the SMDA also requires reporting
- May need to report to CDPH as adverse event or unusual occurrence
- Sentinel event reporting to Joint Commission is voluntary but need to do RCA within 45 days
- See Hospital Reporting of Deaths Related to R&S, OIG Report, Sept. 2006, OEI-09-04-00350¹

¹www.oig.hhs.gov

Rule #21: Deaths A-0214 (continued)

- The hospital must report to CMS:
  - Each death that occurs while a patient is in restraint or in seclusion at the hospital
  - Each death that occurs within 24 hours after the patient has been removed from R&S
  - Each death known to the hospital that occurs within 1 week after R&S where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death
Rule #21: Deaths A-0214 (continued)

▪ “Reasonable to assume” includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation

▪ Must be reported to CMS regional office by telephone no later than the close of business the next business day following knowledge of the patient's death

▪ Staff must document in the patient's medical record the date and time the death was reported to CMS

▪ This includes patients in soft wrist restraints

▪ Hospitals should revise post-mortem records to list this requirement

▪ Hospitals need to ensure that their policies and procedures include these requirements
Conclusions

- Every nurse, hospital or other healthcare provider should be familiar with these standards
- Governing board should be educated
- Policies and procedures should be revised as necessary

Hospital CoPs for QI

- CMS issued new hospital CoPs for QA and Performance Improvement
- Starts with Tag A-0263
Hospital CoPs for QI (continued)

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

Report adverse events pursuant to California law (see Ch. 20 of CHA’s Consent Manual)

CMS Hospital CoPs (continued)

- Triggers can help hospitals find errors (look at adverse events and sentinel events)
- Trigger tools available on IHI website¹
- Program must incorporate quality indicator data including patient data (A-0274)
- Look at information submitted to or from QIO

¹www.ihi.org
CMS Hospital CoPs (continued)

- QIO to advance quality of care for Medicare patients
- Sign up with your state QIO to get newsletters and other information
- Participate in CHPSO
- Use data to monitor safety of services and quality of care (A-0275)
- Identify opportunities for improvement (A-0276)
- Board determines frequency and detail of data collection (A-0277)
- Focus on high risk, high volume, or problem prone (A-0285)

QAPI

- Must not only track medical errors and adverse events but also analyze their causes (A-0287, A-0310)
- RCA is one tool to identify causes
- Review and update MERP (medication error reduction plan), as indicated
- Hospital must take action based on data (A-0289) and measure its success (A-0290)
- Example: process hospitals took to get MI patient timely thrombolytics and timely antibiotics and blood culture for pneumonia patients
QAPI (continued)

- Hospital must document and track performance to make sure improvements are sustained (A-0291)
- Continue to track antibiotics given timely in the OR before surgical procedure and prophylactic treatment to prevent DVT/PE in major surgery patients
- Number of PI projects depends on scope and complexity of hospital services so large hospital doing CABG would measure indicators on this
- Hospital may want to develop and implement IT system to improve patient safety and the quality of care (A-0299)

QAPI (continued)

- Hospital must document what PI projects are being done and the reason for doing them (A-0301) and progress on them (A-0302)
- Board, MS, and administration are responsible for and accountable for ongoing program (A-0309)
- Decide which are priorities (A-0312) and address issues to improve patient safety (A-0313)
- Clear expectations for patient safety are established (A-0314)
- California law requires a patient safety plan that includes specific elements (see handout regarding SB 158 and SB 1058)
QAPI Patient Safety (continued)

- Need adequate resources for PI and patient safety (A-0315, A-0316)
- This means people who can attend meetings, data so analysis can be made and other resources
- Safer IV pumps, new anticoagulant program, implement central line bundle, sepsis, and VAP bundle, preventing inpatient suicides, wrong site surgery, retained FB, new processes for neuromuscular blocker agents, implement policy on Phenergan administration and Fentanyl patches
- So what’s in your PI and Safety Plans?

Next Sections

- Medical staff
- Dietary
- Nursing services
- Laboratory services
- Radiology
- Medical records services
- Autopsies
- Pharmacy services
Medical Staff 482.22(A) A-0338

- Hospital must have an organized MS that operates under bylaws approved by Board
- May have only one MS for entire hospital campus (all campuses, provider-based locations, satellites and remote locations)
- Integrated into one governing body with the MS bylaws that apply equally to all
- See previous MS Tags A-0044 – A-0094

Medical Staff A-0340

- MS must periodically conduct appraisals of its members, MS bylaws determine frequency of appraisals
- Recommends at least every 24 months (TJC is 24 months)
- To be sure they are suitable for continued membership
Medical Staff A-0340 (continued)

- Must evaluate MS qualifications and competencies, within scope of practice or privileges requested
- Look at special training, current work practice, patient outcomes, education, maintenance of CME, adherence to MS rules, certification, licensure and compliance with licensure requirements

Medical Staff Appraisals

- Appraisal procedures must evaluate each member
- To determine if should be continued, revised, terminated or changed
- If request for privileges goes beyond the specified list for that category of practitioner, need appraisal by MS and approval by the board
- Must keep separate credentials file for each MS member
- If limit privileges must follow laws such as reporting to NPDB
- MS bylaws need to identify process for periodic appraisals
Medical Staff A-0341

- MS must examine credentials and make recommendations to the board on appointment of the candidates and must look at the following:
  - Request for privileges, evidence of current licensure, training and professional education, documented experience, and supporting references of competence
  - Can’t make a recommendation based solely on presence or absence of board certification although can require board certification

Medical Staff Organization A-0347

- MS is accountable to Board for quality of medical care provided
- If MS has executive committee, majority of members must be MD/DO
- MS must be well organized; formalized organizational structure and lines are delineated between the MS and the Board
Medical Staff

- MS must adopt and enforce bylaws (A-0353)
- Board must approve bylaws and any changes also (A-0354)
- MS bylaws must include statement of duties and privileges in each category, (e.g., participate in PI, evaluate practitioner on objective criteria, promote appropriate use of health care resources, A-0355)

Medical Staff (continued)

- Privileges for each category (e.g., active, courtesy, consulting, referring, emergency case)
- Cannot assume every practitioner can perform every task/activity/privilege that is specified for that category of practitioner
- Individual ability to perform each must be individually assessed (core privileging, A-0355)
Medical Staff (continued)

- MS bylaws must describe organizational structure of the MS (A-0356)
- Adopt R&Rs which make it clear what are acceptable standards of patient care for diagnosis, medical care, surgical care, and rehab
- Survey procedure: describe formation of MS leadership
- Survey procedure: verify that bylaws describe who is responsible for review and evaluation of the clinical work of MS

Medical Staff (continued)

- MS bylaws must describe the qualifications to be met by a candidate for membership on the MS (e.g., provide level of acceptable care, complete medical records timely, participate in QI, be licensed, A-0357)
- Survey procedure: MS bylaws describe qualifications such as character, training, experience, current competence, and judgment
H&P A-0358

- Repeated in Tags A-0461 and A-0463
- 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 for each patient
- California law requires H&P be performed “within 24 hours after admission, or immediately before”
- Must be on chart before surgery

H&P Admission

- There must 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 use 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 must 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 H&P
- If state law and the hospital allows (which most do), a PA or NP may perform (California allows)
- 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 no more than 30 days old and done within 24 hours
- EP5 if done within 24 hours update, update prior to surgery (also RC.01.03.01)
- EP7 requires an update to 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
- MS.01.01.01 requires H&P process be in MS bylaws (2010)

TJC MS.03.01.01 H&P

- EP6 Specifies minimum 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
- 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
Autopsies A-0364

- MS should attempt to secure autopsies in all cases of unusual deaths
- Must define mechanism for documenting permission to perform an autopsy

California law
- Written authorization from patient or legal representative or
- Verbal authorization if recorded on tape or other recording device
- CHA Form 11-1, “Authorization for Autopsy”
- Must be system for notifying MS and attending doctor when autopsy is performed

Nursing Services A-0385

- Must have an organized nursing service that provides 24 hour nursing services
- Must have at least one RN furnishing or supervising 24 hours
- SSA at 1861(b) states you must have an RN on duty at all times (except small rural hospitals under a waiver)
- Survey procedures: determine nursing services is integrated into hospital PI
- Make sure there is adequate staffing (ratios and patient acuity system)
- Survey procedure – look for job descriptions including director of nursing/chief nursing officer
Chief Nursing Officer

- CNO must be RN, A-0386
- CNO responsible for determining types and numbers of nursing personnel
- California law: nurse-to-patient ratios and patient acuity system
- CNO responsible for operation of nursing service
- Survey procedure: look at organizational chart
- May read job description of CNO to make sure it provides for this responsibility
- May verify CNO approves patient care P&Ps

Nurse Staffing A-0392

- Nursing service must have adequate number of nurses and personnel to care for patients (ratios and patient acuity system)
- Must have nursing supervisor
- Every department or unit must have an RN present (not available if working on two units at same time)
- Survey procedure: look at staffing schedules that correlate number and acuity of patients
Verify Licensure A-0394

- Must have procedure to ensure nursing personnel have valid and current license
- Survey procedure: review licensure verification P&P
- Can verify licensure on line by most state boards of nursing
  - www.rn.ca.gov/online_services/perm-verif.shtml

RN for Every Patient A-0395

- An RN must supervise and evaluate the nursing care for every patient
- RN must do admission assessment
- Must use acceptable standard of care
- Evaluation includes assessing each patient’s needs, health status and response to interventions
Nursing Care Plan A-0396

- Hospital must ensure that nursing staff develop and keep current a nursing care plan for each patient
- Starts upon admission, includes discharge planning, physiological and psychosocial factors
- Based on assessing the patient’s needs
- Care plan is part of the patient’s medical record and must be initiated soon after admission, revised and implemented

Agency Nurses A-0398

- Agency nurses (CMS calls them non-employee nurses) must adhere to P&Ps
- CNO must provide adequate supervision and evaluate (once a year) activities of agency nurses
- Orientation must include to hospital and to specific unit, emergency procedures, nursing P&P, and safety P&Ps
Preparation/Admin of Drugs A-0404

- Drugs must be prepared and administered according to state and federal law (A-0404)
- Need a practitioner’s order
- Surveyor will observe nurse prepare and pass medications
- Medications must be prepared and administered within acceptable national standards of practice (TJC MM chapter), manufacturer’s directions and hospital policy

Administration of Meds A-0405

- Medication management is a hot topic with CMS and TJC
- All drugs administered under the supervision of nursing or other personnel if permitted by law
- In accordance with approved medical staff P&Ps
- Surveyor will review sample of medication records to ensure they conform to physicians’ orders
Administration of Meds A-0405 (continued)

- Surveyor will make sure medication is given within 30 minutes of scheduled time
- Check QAPI activities to see if administration of drugs is monitored
- Many hospitals have changed to this 30 minute time frame but some still have one hour on either side and feel this is appropriate since only a survey procedure

Physician Order A-0406

- CMS issued standing order memo Oct. 24, 2008
- Also discusses preprinted orders and use of stamps
- Flu and pneumovax can be given by protocol approved by the MS after assessment of contraindications
- Orders for drugs must be documented and signed by practitioners allowed to write them
- Doctors and if allowed NPs 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
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

Have a culture so can ask questions

Now allowed to have standard procedures with drugs and biologicals that have been approved by MS

Can implement them but be sure physician signs, dates, and times an order

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

Code teams gives ACLS drugs in an arrest

Timing of orders should not be a barrier to effective emergency response

Preprinted order – should send memo so doctors and providers are aware of new guidelines

Caution when using preprinted orders (fentanyl patches)
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 add order on blank line, then physician must initial each place
- Should add this to the MR audit sheet to make sure there is compliance with this guideline

Verbal Orders A-0407

- Verbal orders are a patient safety issue
- Have led to many errors
- TJC has standard and NPSG, CMS has standard in CMS hospital CoPs, QIO 7th scope of work, National Coordinating Council recommendations
- Rewrite your P&P and medical staff bylaws to be consistent with these standards
- Repeated VO section in MR starting with Tag A-0454 and reiterated area of verbal orders offer too much room for error
- Changed language from prescribing to ordering practitioner
CMS Verbal Orders

- Emphasizes that VOs are to be used infrequently and never for convenience of the physicians
- This means that physician should not give verbal orders in nursing station if he or she can write them
- Can be used in emergency or if surgeon is scrubbed in during surgery
- 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 (such as 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
### Signing Off Verbal Orders

- Physician must sign off a verbal order, **date**, and **time** 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
- California law requires prescriber, attending, or covering physician to sign off

### Verbal Orders

- New 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 hours and if no state law then within 48 hours (California law: 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 required by law
- Write it down and read back the completed order or test result (NPSG 2009)

Blood Transfusions and IVs A-0409

- Blood transfusions and IV medications must be administered according to state law and MS bylaws
- Must have special training for this and within scope of practice
- Survey procedure: determine if personnel have special training which should include fluid and electrolyte imbalance and blood and blood components, and venipuncture technique

- Paul Gann handout: “A Patient’s Guide to Blood Transfusion” (see Ch. 4 of CHA’s Consent Manual)
Incident Reports

- There must be procedure for reporting transfusion reactions, adverse drug reactions and errors in administration of drugs (A-0410)
- Survey procedure - request procedure for reporting - they may review the incident reports or other documentation through QAPI program
- California law
  - Adverse event reporting
  - Pharmacy reporting requirement
  - See Ch. 20 of CHA’s Consent Manual for reporting requirement details

Hosted Luncheon