



Significant Changes to Medicare Conditions of Participation for Hospitals

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Today's Presenter's



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Overview

- EMTALA Revisions (Effective 10/1/06)
 - Expanded Definition of "Labor"
 - Expanded Responsibilities for Hospitals with Specialized Capabilities
- November Revisions (Effective 1/26/07)
 - Revised History & Physical (H&P) Requirements
 - Revised Authentication Requirement
 - Revised Security Requirements for Drugs and Biologicals
 - Revised Post-Anesthesia Evaluation Requirements
- December Revisions (Effective 1/8/07)
 - Revised Restraint Requirements
 - New Training Requirements
 - Revised Reporting Requirements



EMTALA (42 C.F.R. 489.24)

- Emergency Medical Treatment and Labor Act (EMTALA)
- Quick summary: Hospitals with emergency departments must provide a medical screening examination and, if necessary, stabilizing treatment to an individual with an emergency medical condition
- “Emergency medical condition” includes, among other things, a pregnant woman who is having contractions when there is inadequate time to safely transfer before delivery, or the transfer may pose a threat to the health and safety of mother or child
- EMTALA also requires hospitals with “specialized capabilities” to accept appropriate transfers from U.S. hospitals without those capabilities



EMTALA – New Changes

- Previously:
 - Only physicians could certify that a pregnant woman was in false labor
- Now:
 - “A woman experiencing contractions is in true labor unless a physician, certified nurse-midwife, or other qualified medical person acting within his or her scope of practice as defined in hospital medical staff bylaws and state law, certifies that, after a reasonable time of observation, the woman is in false labor”



EMTALA – New Changes (cont'd)

- Previously:
 - Only hospitals with emergency departments were subject to the “specialized capabilities” requirement

- Now:
 - “A participating hospital that has specialized capabilities or facilities ... may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual. This requirement applies to any participating hospital with specialized capabilities, regardless of whether the hospital has a dedicated emergency department”



Medicare Conditions of Participation: A Little Background

- What are they?

- Why do we care?

- Officially, the changes to the Medicare Conditions of Participation are not new regulations: they finalize the Interim Rules – from 1999!





COP: Medical Staff Title 42, C.F.R. Sec. 482.22(c)(5)

■ Prior Rule:

- Medical Staff Bylaws must include provision that H&P must be completed no more than 7 days prior to admission
- Only physicians or oromaxillofacial surgeons may have H&P privileges (though CMS's Interpretive Guidelines offered flexibility)

COP: Medical Staff Title 42, C.F.R. Sec. 482.22(c)(5) (cont'd)

- New Rule:
 - Medical Staff Bylaws must include requirements that:
 - H&P completed no more than 30 days before, or 24 hours after, admission
 - The medical H&P must be placed in the patient's medical record within 24 hours after admission
 - If the H&P is done before admission, updated medical record entry documenting examination for changes in condition must be in medical record within 24 hours after admission
 - H&P to be performed by physician, oromaxillofacial surgeon, or other qualified individual in accordance with state law and hospital policy



COP: Medical Staff Title 42, C.F.R. Sec. 482.22(c)(5) (cont'd)

- Note:
 - Slight difference with Joint Commission requirements
- Standard P.C.2.120, Element of Performance 7:
 - [if an H&P is completed prior to admission]
“Updates to the patient’s condition since the assessment(s) are recorded at the time of admission”



COP: Nursing Services Title 42, C.F.R. Sec. 482.23(c)(22)

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- According to CMS, this is a clarification only
- Clarifies that orders for drugs and biologicals must be documented and signed by a practitioner:
 - Who is authorized to write orders by hospital policy and in accordance with state law, and
 - Who is responsible for the care of the patient (limited to physicians, dentists, podiatrists, optometrists, chiropractors, clinical psychologists) (physicians can delegate)
- Verbal orders are to be used infrequently



COP: Medical Record Services Title 42, C.F.R. Sec. 482.24(c)

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- Reinforces current requirement that all medical records be authenticated
- Requires all medical records to be legible, complete, dated, timed
- For five years from 1/26/07: all orders, including verbal orders, must be dated, timed, and authenticated by the ordering practitioner *or another practitioner who is responsible for the care of the patient and authorized to write orders by hospital policy in accordance with state law*
- Unless state law imposes a more stringent timeframe, all orders must be authenticated within 48 hours (as opposed to prior “as soon as possible” requirement)



COP: Pharmaceutical Services Title 42, C.F.R. Sec. 482.25(b)(2)

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■ Prior Rule:

- Drugs and biologicals must be kept in locked storage

■ New Rule:

- All drugs and biologicals must be kept in a secure area, and locked when appropriate
- Schedule II, III, IV, and V drugs to be locked within secure area
- Only authorized personnel may have access to locked areas



COP: Anesthesia Services Title 42, C.F.R. Sec. 482.52(b)(3)

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■ Prior Rule:

- The individual who administers anesthesia to an inpatient must perform and document the post-anesthesia follow-up report

■ New Rule:

- Any individual qualified to administer anesthesia may perform and document the post-anesthesia evaluation



Restraints and Seclusion: Significant Changes, Significant Challenges

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- Effective January 8, 2007
- Changes to Patients' Rights COP (Title 42 C.F.R. Sec 482.13)
- Finalized without change the standards that address Notice of Rights, Exercise of Rights, Privacy and Safety, Confidentiality of Patient Records
- Significant changes to Restraint and Seclusion standard

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"And then wham! This thing just
came right out of left field."

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Restraint and Seclusion Title 42 C.F.R. Sec 482.13(e)

■ Previously:

- Restraint/seclusion rule separated into two standards:
 - “Acute medical and surgical care”
 - “Behavior management”

■ Now:

- One standard
- Training requirements
- Broader reporting requirements



Restraint and Seclusion: “Policy Statement”

All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. *Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.*



Restraint and Seclusion: Definition (482.13(e)(1)(i))

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■ Restraint:

- 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; or
- 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 dosage for the patient's condition



Restraint and Seclusion: Definition (482.13(e)(1)(i)) (cont'd)

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■ Restraint does not include:

- Devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets;
- 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, or
 - To permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort)



Restraint and Seclusion: Definition (482.13(e)(1)(i)) (cont'd)

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■ Seclusion:

The involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. *Seclusion may only be used for the management of violent or self-destructive behavior*



Additional Considerations

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■ Note:

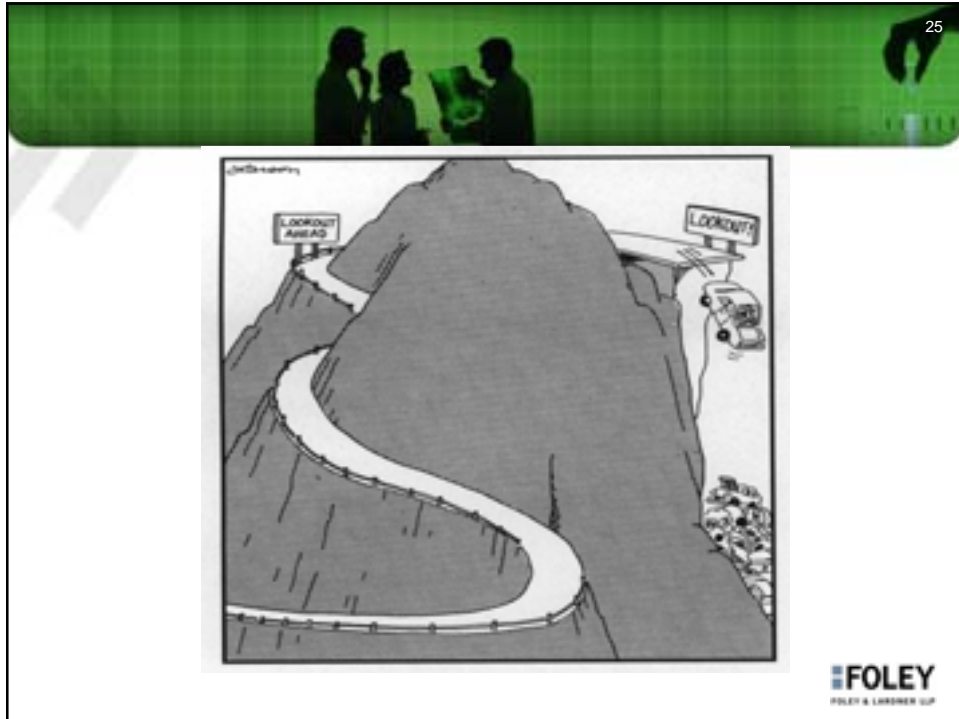
- Additional requirements apply if using restraint *and* seclusion, versus restraint *or* seclusion

■ Note:

- Additional requirements apply if ordered for “management of violent or self-destructive behavior”

- These differences/additions are significant – don’t let them trip you up!





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Restraints *or* Seclusion

- May only be used when less restrictive interventions are determined to be ineffective to protect the patient, a staff member or others from harm
- Must use the least restrictive type or technique that will be effective to protect the patient, a staff member, or others from harm

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Restraints *or* Seclusion (cont'd)

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- Must be used:
 - In accordance with written modification to the patient's plan of care; and
 - Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy and in accordance with state law



Restraints *or* Seclusion (cont'd)

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- The use must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient (physician, dentist, podiatrist, optometrist, chiropractor, and clinical psychologist) and authorized to order restraint or seclusion by hospital policy in accordance with state law
- Note:
 - Don't have to give dentist, chiropractor, podiatrist, etc., authority to order restraint
- Note:
 - Commentary allows physicians to delegate to other qualified healthcare personnel (PAs and APRNs), to extent recognized under state law and hospital policy



Restraints *or* Seclusion (cont'd)

- Orders may NEVER be written as a standing order or PRN
- Attending physician must be consulted as soon as possible (undefined) if the attending physician did not order the restraint or seclusion

Restraints *or* Seclusion (cont'd)

- Unless state law is more restrictive, each order *used for the management of violent or self-destructive behavior* that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following for a total of 24 hours:
 - 4 hours for adults 18 or older;
 - 2 hours for children 9-17;
 - 1 hour for children under 9

Restraints *or* Seclusion (cont'd)

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- Unless state law is more restrictive:
 - After 24 hours, before writing new order for restraint or seclusion *for the management of violent or self-destructive behavior*, physician or other LIP responsible for care of the patient must see and assess the patient



Restraints *or* Seclusion (cont'd)

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- Unless state law is more restrictive:
 - Each order for restraint used to ensure the physical safety of *the non-violent or non-self-destructive patient* may be renewed according to hospital policy



Restraints *or* Seclusion (cont'd)

- Must be discontinued at earliest possible time, regardless of the order
- Patient's condition must be monitored by a physician or LIP, or by staff who have completed training as specified in 482.13(f)
- Hospital policy must specify training requirements for physicians and other LIPs. At a minimum – must have working knowledge of hospital policy



Restraints *or* Seclusion (cont'd)

- When used *for management of violent or self-destructive behavior* that jeopardizes the immediate physical safety of the patient, a staff member, or others, patient must be seen face-to-face within one hour after initiation by:
 - Physician or LIP, or
 - RN or PA trained in accordance with 482.13(f)





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Restraints *or* Seclusion (cont'd)

- That face-to-face evaluation is necessary to evaluate:
 - The patient's immediate situation;
 - The patient's reaction to the intervention;
 - The patient's medical and behavioral condition; and
 - The need to continue or terminate the restraint or seclusion



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Restraints *or* Seclusion (cont'd)

- If the face-to-face is conducted by RN or PA, the RN or PA must consult the attending physician or LIP who is responsible for the patient's care as soon as possible (undefined) after the completion of the one-hour face-to-face



Restraint *or* Seclusion (cont'd)

- Medical record documentation must include:
 - The one-hour face-to-face medical and behavioral evaluation if used to manage violent or self-destructive behavior
 - A description of the patient's behavior and the intervention used
 - Alternatives or other less restrictive interventions attempted (if applicable)
 - The patient's condition or symptom(s) that warranted the restraint or seclusion
 - The patient's response to the intervention, including the rationale for the continued use of the intervention
 - Although not stated in the law – also document staff consults with physician



Simultaneous Restraints *AND* Seclusion

- Look out!
- All the requirements listed above apply, **AND**:
- Permitted **ONLY** if the patient is continually monitored:
 - Face-to-face by an assigned, trained staff member, or
 - By trained staff in close proximity to the patient using *both* video and audio equipment



Staff Training Requirements 42 C.F.R. Sec. 482.13(f)

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- Policy Statement:
 - The patient has the right to safe implementation of restraint or seclusion by trained staff

- Staff must be trained and able to demonstrate competency in:
 - The application of restraints
 - The implementation of seclusion
 - Monitoring, assessment, and providing care for a patient in restraint or seclusion



Staff Training Requirements

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- Such training must occur:
 - Before performing any of the actions specified in the standard

 - As part of orientation

 - Subsequently on a periodic basis consistent with hospital policy



Staff Training Requirements (cont'd)

- Appropriate staff must have education, training, and demonstrated knowledge based on the specific needs of the patient population on:
 - Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion
 - The use of nonphysical intervention skills
 - Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition



Staff Training Requirements (cont'd)

- The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia)
- Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary
- 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 1-hour face-to-face evaluation
- The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification



Staff Training Requirements (cont'd)

- Trainer requirements:
 - Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors
- Training documentation:
 - The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed
- Although not required by law – keep documentation of the trainer's qualifications
- Keep in mind:
 - These training requirements apply to contract/temporary staff as well



Death Reporting Requirements 42 C.F.R. Sec. 482.13(g)

- Prior Rule:
 - Report death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion
- New Rule:
 - Much broader



Death Reporting Requirements

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- Hospital must report to CMS:
 - Each death that occurs while patient is in restraint or seclusion
 - Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion
 - Each death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death
 - “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



Death Reporting Requirements (cont'd)

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- Each death must be reported to CMS 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



CMS Commentary

- Commentary accompanies regulation
- CMS describes “expectations”
- Not law, but ...
- These expectations often become basis for Interpretive Guidelines



CMS Commentary (cont'd)

- For example, the commentary notes the following regarding policies and procedures:
 - Policy should specify interval at which restrained or secluded patient is assessed
 - “Policies should address the frequency of assessment and the assessment parameters (for example, vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity)”
 - Policies “should guide staff in how to determine an appropriate interval for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used”



CMS Commentary (cont'd)

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- Policies should address the use of safety restraints for children
- Policies should address “emergency situations” when restraint and/or seclusion must be instituted before an order can be obtained
- Policies should address the definition of “as soon as possible” in terms of when to contact the attending physician
- Policies should address updating the treatment plan/plan of care
- Policies should specify “additional elements of documentation, such as name, title, and credentials of staff members involved in the procedure ...”



What About the Joint Commission?

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- The Joint Commission Standards – some significant differences from the COP
- Which do you have to follow?
 - If the hospital is both Medicare certified and JC accredited, it must comply with both the COP and the JC Standards
 - If the COP and the JC Standards *conflict*, then follow COP
 - If one is more stringent than the other, but they do not conflict, follow the more stringent provision



COP v. The JC

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- The JC still separates medical v. behavioral restraints
- Requires policies and procedures
- Example of a more stringent COP:
 - If the restraint or seclusion is initiated by an RN, the JC requires notification of an LIP within 12 hours. The COP requires notification of the attending physician *as soon as possible if the order is by anyone other than the attending*
- Example of a more stringent JC standard:
 - For behavioral restraint, the JC requires monitoring every 15 minutes. For all restrained/secluded patients, the COP requires monitoring at an interval determined by hospital policy



COP v. The JC (cont'd)

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- For behavioral health, the JC requires (among other things):
 - Additional staff training
 - Initial intakes and assessments to be designed to obtain information that could minimize the use of restraint or seclusion
 - Family notification (when patient has consented to keeping family informed)
 - An evaluation every 15 minutes
 - A “debriefing” post episode





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Recommendations

- Review and revise your current processes to ensure compliance with the revised COPs
- Consider a form for the documentation
- Consider adding the training to an annual competency
- Review “sitter” guidelines
- Be on the lookout for CMS Interpretive Guidelines
- If you are JC accredited, make sure that you keep those provisions in mind when making any changes
- Whatever changes you make, make sure they are workable in your environment



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Questions & Answers

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