EMTALA II: The Reality of Everyday Applications

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The EMTALA Investigation:
The Survey Process
Key to Survival

SCDHEC

Basis for Investigation

- Complaint driven process
- RO Direction of Investigation
- Evaluation of Allegation
- Unannounced
- In accordance with applicable survey procedures and policies
- Identity of complainant not disclosed

Conducting the Investigation

- P & P which address EMTALA
- Prompt report of an improper transfer
- Presence of signs posted in EDs
- Maintenance of medical and other records
- Maintenance of a list of on call physicians
- Maintenance of a central log

Conducting the Investigation

- Provision of an appropriate screening
- Provision of necessary stabilization
- No delay to inquire about insurance
- Provision of an appropriate transfer
- Provision of whistleblower protections
- Recipient hospital responsibilities

Survey Tasks

- Task 1: Entrance Conference
- Task 2: Case Selection
- Task 3: Record Review
- Task 4: Interviews
- Task 5: Exit Conference
- Task 6: Professional Medical Review
- Task 7: Assessment of Compliance

Entrance Conference

- CEO/president (or designee)
- Any other staff CEO considers appropriate
- Nature of the allegation
- Purpose of the investigation
- Requirements against which the complaint will be investigated

Investigation

- DED logs
- DED P & P manual:
  - triage & assessment of patients with EMCs
  - assessment of labor
  - transfers of individuals with EMCs, etc.
- DED committee meeting minutes
- DED staffing schedule (physician, nursing)

Investigation

- Consent forms for transfers
- Medical Staff Bylaws/rules and regulations
- Minutes from medical staff meetings
- Current medical staff roster
- Physician on-call lists
- Credential files – optional

Investigation

- Quality Assessment and Performance Improvement (QAPI) Plan
- QAPI minutes
- QAPI activities in ED

Investigation

- List of contracted services
- In-service training program
- Ambulance trip reports
- Memoranda of transfer
- Ambulance ownership information
- State/regional/community EMS protocols

Interviews

- Facility staff
- Admitting clerk
- Nurses on shift at time of incident
- Director of Quality Improvement
- Witnesses
- Patient
- Patient’s family
- Physician(s)

Case Selection Methodology

- Sample Size: 20-50 records
- Appears transferring hospital could have provided care
- Other cases at the time of complaint:
  - identify patterns of hospital behavior
  - protect the identity of the patient

Case Selection Methodology

- Based on nature of complaint and patients requesting emergency services:
  - Individuals transferred to other facilities
  - Gaps or non-sequential entries in the log
  - Refusals of exam, treatment, or transfer
  - Patients leaving AMA or without being seen
  - Patients returning within 48 hours

Exit Conference

- Outline basic facts uncovered during onsite investigation
- Surveyors will consider information provided by the hospital:
  - Should provide additional documentation
  - Clarify any particular findings, as necessary
- Description of process if a violation is determined

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The EMTALA Enforcement Process:

Termination or No Termination

OCR Referral

Assessment of Compliance

- Relative to each regulatory provision
- Frequency of occurrence
- Dates of occurrence
- Patterns in terms of race, color, diagnosis, nationality, handicap, and financial status
- Single occurrence constitutes a violation
- Sufficient for an adverse recommendation

Completion of Deficiency Report

- In Compliance. Complaint not substantiated
- In Compliance, but Previously Out of Compliance
- Out of Compliance and the violation presents an immediate jeopardy to patient health and safety
- Out of compliance and the violation does not present an immediate jeopardy to patient health and safety

CMS Review of Investigation

- CMS reviews the investigation findings
- 5-day advisory medical review
- May confer with hospital representatives
- Shares as much data as possible
- Determines whether:
  - Hospital complied
  - Violation constitutes an immediate jeopardy

Procedures for Termination Immediate Jeopardy

- Time starts when CMS determines noncompliance
- Date of the preliminary determination letter
- Fax, email or telephone followed by written letter
- CMS findings based on:
  - investigation
  - results of medical review
- Projected termination date (23rd calendar day)
- Date CMS issues "Notice of Termination Letter" and notifies the public
  - at least 2 calendar days prior to termination date
  - but no more than 4 calendar days

Immediate Jeopardy Examples

- Situation that prevents individuals from getting MSEs and/or a lack of treatment reflecting both the capacity and capability of the hospital
- Examples:
  - stabilizing treatment not provided when required;
  - failure of an on-call physician to respond appropriately,
  - improper transfer; or
  - evidence there was denial of treatment as a direct result of requesting payment information before assessment

Procedures for Termination Not Immediate Jeopardy

- Time starts when CMS determines noncompliance
- Date of the preliminary determination letter
- Fax, email or telephone followed by written letter
- CMS findings based on:
  - investigation
  - results of medical review
- Projected termination date (90th calendar day)
- Date CMS issues "Notice of Termination Letter" and notifies the public

Not Immediate Jeopardy Examples

- Examples:
- Transfer was appropriate, but physician certification was not signed or dated
- An appropriate, functioning central log that on one particular day is not fully completed
- A written hospital policy that is missing, but nonetheless being implemented

Procedures for Termination

- The hospital has the opportunity:
  - to present evidence to CMS that it believes demonstrates its compliance
  - to comment on evidence CMS believes demonstrates the hospital's noncompliance
- CMS' regional offices retain delegated enforcement authority
- Final enforcement decisions are CMS RO

Referral to Office for Civil Rights

- Office for Civil Rights (OCR)
- May take action under the Hill-Burton Subpart G Community Services regulations
- 42 CFR 124.603(b)(1)

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Office of Inspector General Enforcement:

Referral Criteria

Civil Monetary Penalties (CMPs) and Exclusion

Authority

- Title XI of the Social Security Act
- CMPs and assessments
- Against entities found to have acted improperly
- 42 U.S.C. § 1395 sets maximum fine of:
  - $25,000 for hospitals with less than 100 beds
  - $50,000 for larger hospitals

Authority

- Exclusion from the Medicare Program:
  - Hospital that has negligently violated its EMTALA obligations

Authority

- Responsible physician:
  - 42 U.S.C. § 1395dd(d)(1)(B)
    - CMP up to $50,000 per incident
    - Exclusion for gross and flagrant or repetitive violations

Authority

- Who negligently violates this statute:
  - Signs a certification when he/she knows the risks outweigh the benefits
  - Misrepresents:
    - the patient's condition or
    - the hospital's obligation

Regulatory References

- Title 42 Public Health
- Chapter V: OIG - HEALTH CARE, DHHS
- PART 1003--CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS
  - 1003.102-Basis for civil money penalties and assessments
  - 1003.103-Amount of penalty
  - 1003.105-Exclusion from participation in Medicare, Medicaid and all Federal health care programs

Settlement Agreements

- No decision made:
  - on the merits of the OIG's allegations
  - or the respondent's defenses
- Compromise by OIG and settling party
- Settling party has contested the OIG's allegations and denied any liability
- No CMP judgment or finding of liability made against the settling party

Potential Referral

- Hospital is in Compliance
  - Past Violation, No Termination
- Hospital is not in Compliance
  - Immediate Jeopardy to Patient Health and Safety
  - Rarely: Situation Does Not Pose an Immediate Jeopardy

Procedures for QIO Review

- Confirmed Violations
- Before imposing sanctions under §1867 of the Act
- For violations of 42 CFR 489.24,
- 42 CFR 489.24(h) requires that CMS obtain consultation from the QIO

EMTALA Case Referral to OIG

- Financial Screening
- Trauma or Acute Emergency Condition
- High Risk Event (such as Birth) Occurs Prior to Arrival at Another Hospital
- Death or Serious Harm Results from Dump
- Egregious Violation Prioritized by CMS

Type of Patients

- Psychiatric/detoxification/developmentally delayed
- Pregnant or post-partum
- Pediatric or infant
- Senior or elderly

Fines Assessed

- Hospitals:
  - Average of $26,800
  - Range of $5,000 to 120,000
- Physicians:
  - Average of $14,000
  - Range of $10,000 to 20,000
  - On- call, medical screening examination, stabilization and transfer issues

Not outcome based?

- 9 cases indicated a fatal outcome
- Average fine for these cases was $45,500
- Well above the average when the outcome was not necessarily fatal
- Note the criteria for OIG referral

Most Common Tags

- 85% Medical Screening (406)
- 43% Stabilizing Treatment (407)
- 20% Appropriate Transfer (409)
- <20% Duty to Accept (411)
- Delay in Screening (408)
- On-Call Responsibility (404)

Overcrowding or Diversion Issues

- 7 cases due to overcrowding or diversion issues
- Average is well below overall average
- 5 of the 7 cases settled for $15,000 or less
- Emergency rooms often:
  - Experience overcrowding
  - Struggle with diversionary issues

EMTALA II: Questions or Concerns

The Reality of Everyday Applications

Morning Topics

- The EMTALA Investigation:

  The Survey Process, Key to Survival

- The EMTALA Enforcement Process:

  Termination, OCR Referral

- Office of Inspector General Enforcement:

  Referral Criteria, CMPs and Exclusion

Questions?

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EMTALA TAG Recommendations

- Delete: "A woman experiencing contractions is in true labor unless a physician certifies that, after a reasonable time of observation, the woman is in false labor."
- 2007 IPPS Final Rule, revised the second sentence of that definition of labor to state:

  "… physician, CNM, or other qualified medical person acting within scope of practice as defined in hospital medical staff bylaws and State law, certifies ..."

EMTALA TAG Recommendations

- The TAG recommends that hospitals with specialized capabilities not be required to maintain emergency departments.
- CMS: The recommendation is consistent with current CMS policy.
  - Survey and Certification Letter 07-19, released April 26, 2007

EMTALA TAG Recommendations

- Hospitals with specialized capabilities that do not have a DED be bound as hospitals that have a DED
- CMS: The recommendation is consistent with current policy
  - 2007 IPPS Final Rule indicates that any participating hospital with specialized capabilities, even if it does not have a DED, may not refuse to accept appropriate transfer if the hospital has the capacity to treat the individual

Meeting #6

- Telemedicine
- On Call
- Community Wide or state Plans
- Psychiatric Issues
- IPPS 2008 Public Comment Period

EMTALA Alert May 2007

- FR release
- www.NelsonMullins.com
- www.nmrs.com/news/nelson-mullins-newsletter.cfm
  - A detailed summary of the meeting
  - TAG's recommendations
  - Potential practical implications for hospitals, physicians and the public

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EMTALA and Behavioral Health:

Why does this population gets so much EMTALA attention?

Ramifications of the Paucity of Community Resources

Emergency Medical Condition (EMC)

- A medical condition manifesting itself by:
  - Acute symptoms of sufficient severity
  - including severe pain
  - psychiatric disturbances
  - and/or symptoms of substance abuse

EMC definition continued:

- Absence of immediate medical attention could reasonably be expected to result in:
  - Placing the health of the individual in:
    - serious jeopardy
    - serious impairment to any bodily functions
    - serious dysfunction of any bodily organ or part

42 CFR 489.24 (b)

Psychiatric EMC

- Patient is considered to be a harm to self or others
- Suicidal or homicidal ideations
- Extreme inability for self-care

CMS Interpretive Guidelines A407

Appropriate Medical Screening Exam (MSE)

- Process required to reach:
  - within reasonable clinical confidence
  - emergency medical condition (EMC) exists or not
- Non-discriminatory manner
- Spectrum from simple to complex process depending on symptoms

42 CFR 489.24 (a)(1)(i)

Issues Related to MSE

- Qualified Medical Professional (QMP)
- Ongoing process until the individual is stabilized, admitted or transferred
- Must be the same for all patients
- Within the facility's capability

Challenges Associated with Behavioral Health MSE Issues

- Psychiatric illness can coexist with or be caused by medical disease
- Medical issues may be overlooked in a patient with a long psychiatric history
- ED MDs are often first to assess patients with behavioral health complaints

"Medical Clearance"

- Is "medical clearance" the same for an ED physician as it is for a psychiatrist in a private setting or free-standing psychiatric facility?
- ACEP proposes the language "focused medical assessment"
- Initial ED assessment is often the only medical evaluation the patient will receive

MSE in Patients with Behavioral Health Complaints

- Appropriate MSE must be two pronged
  - medical and psychiatric
- Underlying medical condition
- Injuries from suicide attempts
- Injuries from accidents
- Alcohol or drug use
- Danger to self or others

Standard of Care Issues

- Routine labs are not necessarily required
- How elevated must the blood alcohol level be before delaying psychiatric evaluation?
- Psychiatric facilities may not accept transfer of inebriated individuals
- Pharmacological treatment for acute agitation or psychosis

CMS Interpretive Guidelines A407

- Chemical or physical restraints may:
  - allow stabilization for a period of time
  - remove the EMC
- Underlying medical condition may persist
- If not treated for the long term, may experience an exacerbation of the EMC

Stabilization

- The provision of such medical treatment of the condition necessary to assure ***that no material deterioration of the condition is likely to result from or occur during the transfer***

42 CFR 489.24 (b)

CMS Interpretive Guidelines A407

- A psychiatric patient is considered stable when that person is protected and prevented from harming:
  - him or herself
  - or others

Request for pharmaceutical services

- Is this considered use of the ED for non-emergency care?
- Requests for medication as a result of a medical or psychiatric condition
- Generally would have an EMTALA obligation
- Investigate further, "why is the request being made?"

Fulfilling EMTALA Obligation

- If no EMC, EMTALA obligation is fulfilled
- If EMC, must provide necessary stabilizing treatment ***within the capability and capacity of the hospital***

Capability

- Physical space
- Equipment
- Supplies
- Specialized services
- Level of care that the personnel can provide

Capacity

- Census: occupancy of a specialized unit
- The number of staff on duty
- The equipment on the hospital's premises
- Whatever hospital customarily does to accommodate patients in excess

42 CFR 489.24 (b)

Appropriate Transfer Requirements

- Provide medical treatment within capability
- Receiving facility has agreed to accept
- Send all medical records related to the EMC
- Qualified personnel and transportation
- Physician signs certification
- Benefits expected outweigh the risks

42 CFR 482.24 (e)(1-2)

Community Wide or State Plans

- Require particular individuals, such as psychiatric or indigent, to be treated at designated facilities
- Must conduct MSE
- Must provide stabilizing treatment
- If cannot stabilize, then conduct appropriate transfer to State/local facility

CMS Interpretive Guidelines A406, A407

2007 IPPS Final Rule- Recipient Hospital Responsibilities

- A Participating hospital that has specialized capabilities
- May not refuse to accept
- From a referring hospital within the U.S.
- An appropriate transfer of an individual who requires such specialized capabilities
- If the receiving hospital has the capacity to treat the individual
- Regardless of whether the hospital has a DED

Survey & Certification Letter 07-19

- April 26, 2007
- All hospitals are required to:
  - *appraise* medical emergencies
  - provide *initial treatment*
  - *referral* when appropriate
  - regardless of whether the hospital has an ED
- Calling 911 may not be a substitute

Further Clarification

- Medicare CoPs require to provide certain services
- Appraisal of Persons with Emergencies
- Initial Treatment
- Referral when Appropriate
- RN available and qualified
- MD available onsite or on call to provide medical direction

Current Issues

- Medical Screening
- Stabilizing Treatment
- Consent or Informed Refusal
- Appropriate Transfer

Prevention of EMTALA Allegations

- Communicate with the other facilities
- Regular Internal Audits
- Education and Training
- Monitoring System
- If an incident occurs act immediately
- If surveyed, show corrective actions

Case Studies: Patient # 1

- 33 yo male presents with agitation, talking to himself
- Long history of schizophrenia since teens reviewed in hospital records
- Basic blood chemistry negative
- Drug and alcohol screen negative
- Comprehensive physical examination is negative
- Physician orders Ativan for agitation
- Response observed and documented effective
- Mental health screening completed by behavioral health professional
- Screener recommends IVC and MD reviews record in its entirety and initiates IVC orders

Case Studies: Patient # 1 cont'd

- No beds available at hospital
- Co-ordinates with LME to find placement
- Patient is monitored for 14 hours
- Last 3 hours, patient continues to be medically stable, coherent, calm, "improved"
- Denies any thoughts of SI/HI
- Reports "feeling better"
- Wants to go home to follow up with established community supports

Questions?

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EMTALA and Statistical Analysis:

- Prevalence in the Southeast
- Most Cited Violations

What are the Numbers?

- CMS has recently implemented an EMTALA database
- National statistics can be verified
- Trends can be identified
- Prior to this point, regional offices maintained their own logs in their own manner

CMS Regional Offices

- Region 1 - Boston
- Region 2 - New York
- Region 3 - Philadelphia
- Region 4 - Atlanta
- Region 5 - Chicago
- Region 6 - Dallas
- Region 7 - Kansas City
- Region 8 - Denver
- Region 9 - San Francisco
- Region 10 - Seattle

Region 4- Atlanta

- **8 Southeastern States**
  - Alabama
  - Florida
  - Georgia
  - Kentucky
  - Mississippi
  - North Carolina
  - South Carolina
  - Tennessee

Most Frequently Cited

#1: Appropriate medical screening

#2: Stabilizing treatment/informed refusal

#3: Appropriate transfer

- increased in frequency in 2006

#4: Central Log

Violations of Appropriate Medical Screening Exam (MSE)

- No medical record
- No documented screening
- Incomplete screening
  - Not utilizing available capabilities
  - Abnormal reading not addressed
- Abdicating care to EMS or law enforcement
- Ambulance/patient is directed elsewhere

Violations of MSE related to Behavioral Health Complaints

- Screening is of psychiatric nature only
- Medically stable but has psychiatric symptoms:
  - transferred out for psychiatric care
  - no psychiatric screening
- CMS has the view that ED personnel:
  - capable to perform a minimum psychiatric screening to determine if the patient is a threat to self or others
  - even if the hospital does not have the capability to stabilize the psychiatric condition

Violations of MSE related to Pregnant Patients

- Obstetrical screening is not complete to rule out labor:
  - fetal well-being
  - cervical dilation
  - spontaneous rupture of membranes
  - contraction pattern
  - adequate observation time
- Patient "discharged" and instructed to go immediately to physician or other hospital

Violations of Stabilizing Treatment

- Discharging a patient in an unstable condition
- Transferring an unstable patient:
  - before exhausting the hospital's capability and capacity
  - even though all other steps for an appropriate transfer are followed

Violations of Informed Refusal

- Not taking all reasonable steps to ensure an informed refusal
- Not documenting all requirements of informed refusal:
  - exactly what he/she is refusing,
  - the risks of leaving
  - the benefits of staying
- Most frequent is evidence in the medical record that staff were aware patient left

Violations of Informed Refusal

- "Patient tired of waiting, will follow-up with PMD [primary physician], ambulatory"
- Interviews with staff have revealed responses including "it is your choice" without any documentation of attempts to obtain an informed refusal

Violations Related to the Central Log

- Raise a red flags for surveyors
- May lead to weaknesses in the system
- Patients that presents and choose to leave the hospital prior to triage or MSE
- When changing over software systems
- Blanks, missing fields, gaps in time
- Ensure all requirements are documented

Violations of Recipient Hospital Responsibilities

- No documentation
  - Reason
  - Individuals involved
- Not designating a recipient agent
- Refusal is appropriate but construed otherwise by discussion of payor status
- Delay in acceptance or refusal

Specific State Issues

- Investigator review of credential files, performance improvement, incident reports, or root cause analysis
- Potential Waiver under SC Peer Review Statute
- No recognition in SC Peer Review Statute that providing this information to investigative agencies is not a waiver
- Consider separate file with CV, License, DEA, delineation of privileges
- Absence of Case Law on scope of waiver

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Wrap Up:

- What You Can Do
- How to Stay Compliant

Plan of Corrections- for CMS and for Internal Improvement

- What is not acceptable as formal plan
- Some criteria for which CMS looks:
  - Root Cause Analysis
  - Corrective actions
  - Education of staff
  - Monitoring of effectiveness

Prevention of EMTALA Allegations

- Review policies and procedures on a regular basis
  - Revise accordingly
  - Are policies consistent throughout the facility
- Communicate with other facilities
- Clear and defined complaint process
- Ask staff specifically about EMTALA concerns
- If an incident occurs, act immediately
- If surveyed, show corrective actions

Prevention of EMTALA Allegations

- Regular Internal Audits
- External Validation
- Education and Training
  - Different modalities
  - Base on monitoring results
- Monitoring System

Proposed Rule 2008 IPPS

- Proposed EMTALA changes:
  - accommodate the Pandemic and All-Hazards Preparedness Act, Pub.L. 109-417.Section 302(b) of Pub.L.109-417 enacted on December 19, 2006
- CMS is soliciting comments: whether current requirements for emergency service capability in hospitals *with or without emergency departments* should be strengthened in certain area
- Public comment period will close June 12, 2007

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