EMTALA II: The Reality of Everyday Applications

Barbara Brague, RN
SC DHEC

Ann M. Pfeiffer, RN, MS
Nelson Mullins
EMTALA II: The Reality of Everyday Applications

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?

Contact information:

- Cynthia B. Hutto, Esq.
- Ann M. Pfeiffer, RN, MSN

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May 23, 2007

Ann M. Pfeiffer, RN, MSN
Compliance Consultant
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
  - A detailed summary of the meeting
  - TAG's recommendations
  - Potential practical implications for hospitals, physicians and the public
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May 23, 2007

Dan Body, Esq.
Ann M. Pfeiffer, RN, MSN
www.nelsonmullins.com
EMTALA and Behavioral Health:
Why does this population get 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
EMTALA: The Reality of Everyday Applications

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:

• 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
Questions?

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